# COMMONWEALTH OF VIRGINIA

# Meeting of the Board of Pharmacy

**Perimeter Center, 9960 Mayland Dr., Second Floor** **(804) 367-4456 (Tel)**
**Richmond, Virginia 23230** **(804) 527-4472(Fax)**


## Tentative Agenda of Meeting

***June 4, 2008***

**9:00AM**

| TOPIC | PAGE(S) |
|---|---|
| **Call to Order:** Bobby Ison, Chairman | |
| • Welcome and Introductions | |
| • Reading of emergency evacuation script | |
| • Approval of Agenda | |
| • Approval of previous Board meeting minutes: | 1-14 |
| ◦ March 12, 2008, Full Board meeting | |
| ◦ March 12, 2008, CQI Committee Meeting | |
| ◦ March 18, 2008 Summary Suspension Conference Call | |
| ◦ April 16, 2008, Summary Suspension Conference Call | |
| ◦ May 1, 2008, Summary Suspension Conference Call | |
| ◦ May 13, 2008 Summary Suspension Conference Call | |

**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.

**Election of Chairman and Vice Chairman for July 1, 2008-June 30, 2009**

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| **Legislation:** | |
| • Review legislative proposals for 2009 session-Scotti Russell, Elaine Yeatts | |
| ◦ Proposal on mandatory reporting of impairment or inability to safely practice | 15 |
| ◦ Scheduling change proposal | |
| **Regulations:** Elaine Yeatts, Scotti Russell | |
| • Update on regulation processes | |
| ◦ Petition for rulemaking, Health Department, non-conformity with nuclear regulations | 16-19 |
| ◦ Status of NOIRA on unprofessional conduct definitions | |
| ◦ other | |
| • Adopt exempt regulations related to volunteer practice | 20-23 |
| • Adopt emergency regulations on establishing new expiration dates for facilities | 24-31 |

**Update on Action Items**: Scotti Russell

- Meeting date for the Drug Donation Committee
- Draft for Unprofessional Conduct regulations

**Miscellaneous:**

- Request from the Department of Health concerning family planning protocols and bona fide prescriber patient relationship 32-34
- Flavoring of prescriptions
  - Does is constitute compounding?
  - Does a prescriber have to order it?
  - May a pharmacy flavor a prescription dispensed by another pharmacy?

**Reports:**

- Report by the Director, DHP, Sandra Whitley Ryals
- Report on Board of Health Professions-Jennifer H. Edwards
- Executive Director's Report-Scotti Russell
  - Report on NABP annual meeting
  - report on disciplinary program-Cathy Reiniers-Day
  - report on licensing, inspections, website-Caroline Juran
  - report on the prescription monitoring program-Ralph Orr

**New Business**

**Consideration of consent orders (if any)**

**Formal Hearing: Robert Davis**

**Adjourn**

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

**** Reminder: There will be several formal hearings in the afternoon before a panel of the Board immediately following adjournment of the full Board meeting. Unless you are otherwise notified, please expect to serve on the panel. The hearings may take the entire afternoon.**

(DRAFT/UNAPPROVED)

# VIRGINIA BOARD OF PHARMACY
# MINUTES OF BOARD MEETING

March 12, 2008
Commonwealth Conference Center
Second Floor; Board Room 4

Perimeter Center
9960 Mayland Drive
Richmond, VA 23233-1463

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

PRESIDING: Bobby Ison, Chairman

MEMBERS PRESENT:
Gill B. Abernathy
John O. Beckner
Willie Brown
Jennifer H. Edwards
David C. Kozera
Michael E. Stredler
Brandon K. Yi

MEMBERS ABSENT:
Leo H. Ross
Gerard Dabney

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

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

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

APPROVAL OF MINUTES: The Board reviewed draft minutes for December 12, 2008 and February 13, 2008. With no changes to the minutes, the minutes were approved as presented.

PUBLIC COMMENTS: There were no public comments.

FORMAL HEARING:

THOMAS J. O'ROURKE
Pharmacy Technician
Registration # 0230-000150

A formal hearing in the matter of Thomas J. O'Rourke was held to discuss his petition for reinstatement of his pharmacy technician registration that was mandatorily suspended on September 27, 2007, and allegations that he may have violated certain laws or

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regulations governing the practice of pharmacy technicians in Virginia.

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

Loretta S. Hopson-Bush, DHP Senior Investigator, testified on behalf of the Commonwealth.

Thomas J. O'Rourke testified on his own behalf.

Closed Meeting: Mr. Kozera moved, and the Board voted unanimously, to enter into closed meeting pursuant to § 2.2-3711(A)(28) of the Code of Virginia for the purpose of deliberation to reach a decision in the matter of Thomas J. O'Rourke. Additionally, he moved that Cathy Reiniers-Day, Scotti Russell and Howard Casway attend the closed meeting because their presence was deemed necessary and would aid the Board in its deliberation.

Reconvene: Mr. Kozera 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. Yi 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. Yi moved, and the Board voted unanimously that Mr. O'Rourke's petition for reinstatement be granted and that he be allowed to renew his pharmacy technician registration.

REPORTS:

- Director of DHP
  Sandra Whitley Ryals

Ms. Ryals provided the Board with an update on the budget climate that the state is currently facing including severely limited hiring authority for new or vacant positions and strict limitations on travel. She also briefly discussed progress being made toward meeting the Virginia Performs goals with respect to the 250-day case resolution time. Ms. Ryals discussed some of the actions she had taken to improve efficiencies and better allocate resources including the re-deployment of the compliance unit.

- BHP Report
  Jennifer Edwards

Ms. Edwards gave a report on the Board of Health Professions. She stated that Ms. Yeatts had already discussed some of what

BHP was tracking in the legislative update. She also stated that BHP had been working on a tool regarding culturally and linguistically appropriate healthcare-related language and that a link to this tool would soon be on the website. Lastly, Ms. Edwards informed the Board that she had been appointed to the Enforcement Committee of BHP.

- Executive Director's Report
  Scotti Russell

Ms. Russell stated that the NABP annual meeting in May would be in Baltimore, MD, this year. She has requested that the Chairman attend as the voting delegate and is waiting for approval. She stated that NABP does have a travel grant for voting delegates that would cover most of the travel costs for the Chairman.

Ms. Russell also introduced Susan Beasecker, who was previously part of the compliance unit and is now working directly for the Board of Pharmacy. She explained that Ms. Beasecker is also doing some compliance work for two other boards, and that those costs are being allocated to those boards.

- Disciplinary Update
  Cathy Reiniers-Day

Ms. Reiniers-Day presented the Board's disciplinary caseload report and stated that there were 114 cases at the enforcement level, 137 cases at the probable cause level, 5 cases at the informal conference level, 1 case at the formal hearing level and 53 cases at the APD level. She explained that enforcement had been "blitzing" with their older cases to send them to the boards, therefore, the cases at board level were higher in number, which also led to APD having a high number of cases. It was anticipated that the numbers should level out within the next few months.

- Licensing Update
  Caroline Juran

Ms. Juran reported that the Board had issued over 575 additional licenses since the last Board meeting in December. She updated the Board on its request from the December meeting to post consent orders authorizing innovative (pilot) programs on the website. She explained that, after researching the subject, this was not possible due to the current layout of the website, but that as an alternative, she posted information pertaining to pilot programs in the frequently asked questions (FAQ) section on the website. The FAQ states that persons may obtain a copy of a consent order authorizing a pilot program by directly contacting the Board office. She then informed the Board that it currently only had one active pilot program, as another pilot program had recently closed. Ms. Juran stated that the annual CE audit was underway. Additionally, she stated that the format used to display Board approved pharmacy technician training programs on the website had changed and that it was now easier for the public to search this list. Lastly, she stated that a workshop had been held recently to review new items for the Virginia Pharmacy Technician Exam. Ms. Juran explained that these workshops are periodically held to create new test items, so as to maintain the security of the exam process.

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- PMP Update
  Ralph Orr

Mr. Orr reported on 2007 statistics for the Prescription Monitoring Program stating that the program had filled over 22,000 requests in 2007, more than triple the number filled in 2006. Mr. Orr discussed the goals for 2008 to include adding 2,500 new users to the program website, filling 45,000 requests, and having 1,000 healthcare providers complete the program's sponsored online pain management course. Ms. Abernathy suggested adding additional links to the course directly on the Boards of Pharmacy and Medicine websites. Mr. Orr stated that the program is working towards upgrading the program's capabilities by procuring new servers and software which will enable the program to provide 24/7 access to users of the program. While some interagency issues still need to be worked out, it is hoped that this program enhancement will be completed by early summer.

LEGISLATION UPDATE:

Ms. Yeatts provided an update on legislation passed by the 2008 General Assembly that the Department had been tracking. HB85 requires the Board in emergency regulations to establish a drug donation program. HB1128 allows the Board to require up to two hours CE in specific content areas by notifying licensees. There was some discussion that if the Board wants to do this for the 2009 renewal cycle, it will need to make that decision at the September 2008 Board meeting in order to provide notification at renewal time. HB1129 allows the Board to establish expiration dates for licenses in regulation and has an emergency regulation clause. HB1147 and SB405 will have an effect on information that must be obtained from non-resident pharmacies and has a provision requiring a Virginia-licensed PIC. HB1222 shortens the notification requirement for volunteer pharmacists at charitable medical events and will require exempt regulation changes to current regulations.

REGULATION UPDATE:

Ms. Yeatts provided an update on current regulatory processes.

- Exempt action on reference change to Code section related to assisted living facilities

Ms. Yeatts provided an exempt change to 18 VAC 110-20-530, subsection 9, in which a reference to Title 63.1 needs to be changed to 63.2 due to a recodification.

**Motion:**

**A motion was made and passed unanimously to adopt the exempt change to 18 VAC 110-20-530. (motion by Beckner, second by Brown)**

- Exempt action related to volunteer pharmacists at charitable events

Ms. Yeatts stated that the Governor had not yet signed this bill, and as such the Board would not be able to take action on this item today.

- HB85 Drug donation program

The Board began discussions of emergency regulations related to the new statutory requirement to establish a drug donation program

in which unused medications that met certain standards and for which integrity of the product could be determined could be donated for re-dispensing to persons that are indigent. The Board reviewed regulations in Maryland which is the only state that allows any drug, other that Schedule II-V, to be returned for such purpose. The Board also reviewed regulations from several other states that had more limited programs, some only accepting from institutional settings, and some only accepting cancer drugs. This will be referred to the committee of the Board that was originally established to explore the issue of drug disposal and a meeting date will be established. John Beckner, Brandon Yi, Jennifer Edwards and Dave Kozera were the Board members assigned to the committee. Other interested entities will be asked to assist the committee to include a representative from DMAS with respect to unused drugs in nursing homes. This same committee will also look at options for establishing drug disposal mechanisms with possibly a recommendation for a pilot project in response to HB86 that was carried over until 2009. The state police and DEQ, at some point, will be asked to assist the committee with this effort.

**Action Item:** **Staff will coordinate with the committee members and set a meeting date prior to the next Board meeting in June.**

- Unprofessional Conduct Regulations

Ms. Yeatts stated that the NOIRA is still under administrative review and had not yet been published, but that the Board could begin work to determine the unprofessional conduct acts to include in the regulations. She suggested that the Board members review the information in the agenda package with respect to other boards' definitions, and e-mail Ms. Russell as to what acts they might want to include.

**Action Item:** **For the June meeting, staff will provide a draft for the Board to review.**

ADJOURN: With all business concluded, the meeting adjourned at 12:30 PM.

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Elizabeth Scott Russell
Executive Director

Bobby Ison, Board Chairman

Date

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# VIRGINIA BOARD OF PHARMACY
# MINUTES OF AD HOC COMMITTEE FOR CONTINUOUS QUALITY IMPROVEMENT

March 12, 2008
Second Floor
Board Room 4

Perimeter Center
9960 Mayland Drive, Suite 300
Richmond, Virginia 23233

**CALL TO ORDER:** A working meeting of an ad hoc committee of the Board of Pharmacy for the purpose of discussing the possible need to require continuous quality improvement programs was called to order at 1pm.

**PRESIDING:** Gill B. Abernathy, Committee Chair

**MEMBERS PRESENT:**
Michael E. Stredler
David C. Kozera
Jennifer H. Edwards
Brandon K. Yi

**STAFF PRESENT:**
Elizabeth Scott Russell, Executive Director
Cathy Reiniers-Day, Deputy Executive Director
Caroline D. Juran, Deputy Executive Director
Elaine J. Yeatts, Senior Regulatory Analyst
Vicki Garrison, Pharmacy Inspector

**DISCUSSION:** The committee discussed various ways for reducing medication errors and improving patient safety. It was determined that Board staff should draft legislative proposals for 2009, one requiring pharmacies to establish and maintain a continuous quality improvement program with the statute very general, and give the Board the authority to promulgate regulations specifying details. The second proposal would be to require mandatory reporting of pharmacists and pharmacy technicians who are considered unsafe to practice for reason of impairment, incompetence, etc. in any setting similar to current requirements for hospitals to report. The legislative proposals will be presented to the full Board in June 2008.

**ADJOURN:** The meeting was adjourned at approximately 2:30PM.

Elizabeth Scott Russell
Executive Director

Bobby Ison, Chairman

Date

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

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 8:30 a.m., on March 18, 2008, to consider the summary suspension of the licenses of Clyde T. VanHuss, Jr., and James Q. Underwood, III, to practice as pharmacists.

PRESIDING: Bobby Ison, Chairman

MEMBERS PRESENT:
Gill B. Abernathy
John O. Beckner
Dave C. Kozera
Michael E. Stredler
Brandon K. Yi

STAFF PRESENT:
Elizabeth Scott Russell, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
Elizabeth M. Revere, Administrative Assistant
Susan A. Beasecker, Compliance Case Manager
Ishneila Moore, Senior Assistant Attorney General
William C. Garrett, Assistant Attorney General
Mykl D. Egan, Adjudication Specialist
Amanda E. Mitchell, Adjudication Specialist

POLL OF MEMBERS: Each Board member was 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 two possible summary suspension cases. Each Board member polled stated that they would not have been able to attend.

With six Board members participating and four members unable to participate, it was established that a quorum could not have been convened in a regular meeting to consider these matters.

| | |
|---|---|
| CYLDE T. VANHUSS, JR.<br>License # 0202-005534 | Mr. Garrett presented a summary of the evidence in the case. |
| Decision: | Mr Beckner moved, and the Board voted 6-0 in favor of the motion, that with the evidence presented, the practice as a pharmacist by Clyde T. VanHuss, Jr., pose s a substantial danger to the public; and therefore, that the license of Clyde T. VanHuss, Jr., to practice as a pharmacist be summarily suspended; and that a Consent Order be offered to Mr. VanHuss for the indefinite suspension of his license in lieu of a hearing. |
| JAMES Q. UNDERWOOD, III<br>License # 0202-006303 | Mr. Garrett presented a summary of the evidence in the case. |
| Decision: | Mr. Yi moved, and the Board voted 6-0 in favor of the motion, that with the evidence presented, the practice as a pharmacist by James Q. Underwood, III, poses a substantial danger to the public; and therefore, that the license of James Q. Underwood, III, to practice as s pharmacist be summarily suspended; and that a Consent Order be offered to Mr. Underwood for the indefinite suspension of his license in lieu of a hearing. |
| ADJOURN: | With all business concluded, the conference call adjourned at 8:55 a.m. |

Elizabeth M. Revere
Discipline Program Specialist

Cathy M. Reiniers-Day
Deputy Executive Director

Bobby Ison, Chairman

Date

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

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 April 16, 2008, to consider the summary suspension of the license of Nader Abedinzadeh, to practice as a pharmacist.

PRESIDING: Bobby Ison, Chairman

MEMBERS PRESENT:
Willie Brown
Dave C. Kozera
Leo H. Ross
Michael E. Stredler
Brandon K. Yi

STAFF PRESENT:
Cathy M. Reiniers-Day, Deputy Executive Director
Elizabeth M. Revere, Administrative Assistant
Susan A. Beasecker, Compliance Case Manager
Howard Casway, Senior Assistant Attorney General
William C. Garrett, Assistant Attorney General
Amanda E. Mitchell, 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 six Board members participating and four members unable to participate, it was established that a quorum could not have been convened in a regular meeting to consider these matters.

NADAR ABEDINZADEH
License # 0202-011595

Mr. Garrett presented a summary of the evidence in the case.

Decision: Mr. Brown moved, and the Board voted 6-0 in favor of the motion, that with the evidence presented, the practice as a pharmacist by Nadar Abedinzadeh, poses a substantial danger to the public; and therefore, that the license of Nadar Abendinzadeh, to practice as a pharmacist be summarily suspended; and that a Consent Order be offered to Mr. Abedinzadeh for the indefinite suspension of his license in lieu of a hearing.

ADJOURN: With all business concluded, the conference call adjourned at 9:10 a.m.

Elizabeth M. Revere
Discipline Program Specialist

Cathy M. Reiniers-Day
Deputy Executive Director

Bobby Ison, Chairman

Date

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

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 11:25 a.m., on May 1, 2008, to consider the summary suspension of the registrations of Melissa Moore and Susan Vipperman to practice as pharmacy technicians.

PRESIDING: Bobby Ison, Chairman

MEMBERS PRESENT:
John Beckner
Jennifer Edwards
Dave C. Kozera
Leo H. Ross
Michael E. Stredler

STAFF PRESENT:
Elizabeth Scott Russell, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
Elizabeth M. Revere, Administrative Assistant
Howard Casway, Senior Assistant Attorney General
James Schliessmann, Assistant Attorney General
Amanda E. Mitchell, DHP Adjudication Specialist
Mykl D. 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 two possible summary suspension cases. The Board members stated that they would not have been able to attend.

With six Board members participating and four members unable to participate, it was established that a quorum could not have been convened in a regular meeting to consider these matters.

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MELISSA T. MOORE
Registration # 0230-012153

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

Decision:

Mr. Stredler moved, and the Board voted 6-0 in favor of the motion, that with the evidence presented, the practice as a pharmacy technician by Melissa T. Moore poses a substantial danger to the public; and therefore, that the registration of Melissa T. Moore, to practice as a pharmacy technician be summarily suspended; and that a Consent Order be offered to Ms. Moore for the revocation of her registration in lieu of a hearing.

SUSAN A. VIPPERMAN
Registration # 0230-003617

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

Ms. Edwards moved, and the Board voted 6-0 in favor of the motion, that with the evidence presented, the practice as a pharmacy technician by Susan A. Vipperman poses a substantial danger to the public; and therefore, that the registration of Susan A. Vipperman, to practice as a pharmacy technician be summarily suspended; and that a Consent Order be offered to Ms. Vipperman for the indefinite suspension of her registration in lieu of a hearing.

ADJOURN:

With all business concluded, the conference call adjourned at 11:40 a.m.

Elizabeth M. Revere
Discipline Program Specialist

Cathy M. Reiniers-Day
Deputy Executive Director

Bobby Ison, Chairman

Date

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

Tuesday, May 13, 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 8:38 a.m., on May 13, 2008, to consider the summary suspension of the registration of Leslie M. Robertson to practice as a pharmacy technician.

PRESIDING: Bobby Ison, Chairman

MEMBERS PRESENT:
John Beckner
Willie Brown
Dave Kozera
Leo H. Ross
Michael E. Stredler
Brandon Yi

STAFF PRESENT:
Elizabeth Scott Russell, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
Elizabeth M. Revere, Administrative Assistant
Howard Casway, Senior Assistant Attorney General
James Schliessmann, Assistant Attorney General
Mykl D. 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 these matters.

LESLIE M. ROBERTSON
Registration # 0230-003645

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

Mr. Kozera stated that he supervised Ms. Robertson and recused himself from this matter.

Decision:

Mr. Brown moved, and the Panel voted 6-0 in favor of the motion, that with the evidence presented, the practice as a pharmacy technician by Leslie M. Robertson poses a substantial danger to the public; and therefore, that the registration of Leslie M. Robertson, to practice as a pharmacy technician be summarily suspended.

Mr. Yi moved, and the Panel voted 6-0 in favor of the motion, that a Consent Order be offered to Ms. Robertson for the revocation of her registration in lieu of a hearing.

ADJOURN:

With all business concluded, the conference call adjourned at 8:44 a.m.

Elizabeth M. Revere
Discipline Program Specialist

Cathy M. Reiniers-Day
Deputy Executive Director

Bobby Ison, Chairman

Date

*Department of Health Professions*
**2009 Session of the General Assembly**

**DHP-PHA-#enter proposal number**

A bill to enact § 54.1-3316.1 of the *Code of Virginia* to require reporting of known information relating to the practice of pharmacy to the Board.

Be in enacted by the General Assembly:

1. That § 54.1-3316.1 of the *Code of Virginia* is enacted as follows:

**§ 54.1-3316.1. Mandatory reporting**

A. Every pharmacy owner, pharmacist, pharmacy intern, and pharmacy technician shall report to the Board of Pharmacy within 30 days the following information of which he may become aware in his professional capacity:

1. That a pharmacist, pharmacy intern, or pharmacy technician employed by the pharmacy is in need of treatment or has been committed or admitted as a patient at a health care institution, for treatment of substance abuse or a psychiatric illness that may render that person a danger to himself or the public.

2. Any evidence that indicates a reasonable probability that a pharmacist, pharmacy intern, or pharmacy technician (i) is or may be professionally incompetent; (ii) has or may have engaged in intentional or negligent conduct that causes or is likely to cause injury to a patient or patients; (iii) is or may be mentally or physically unable to engage safely in the practice of his profession; (iv) has or may have engaged in unethical, fraudulent or unprofessional conduct as defined in §54.1-3316 and Board regulations; or (v) has or may have engaged in substance abuse or diversion of prescription drugs. Such evidence shall include, but is not limited to, denial or termination of employment, restrictions imposed on employment, or voluntary resignation in order to avoid investigation or termination.

B. No person shall be obligated to report any matter to the Board if the person has actual notice that the matter has already been reported to the Board.

C. Any person making a report required by this section, providing information pursuant to an investigation, or testifying in a judicial or administrative proceeding as a result of such report shall be immune from any civil liability resulting therefrom unless such person acted in bad faith or with malicious intent.

| Date/Time Filed with Registrar of Regulations | VA.R. Document Number: R_____ - _____<br>Date of Publication in Virginia Register: |
|---|---|

**Commonwealth of Virginia**

# RESPONSE TO PETITION FOR RULEMAKING

**Check one:** ☒ **Initial Agency Notice** ☐ **Agency Decision**

**Regulatory Coordinator:** Elaine J. Yeatts
**Telephone:** (804) 662-9918 **E-mail:** elaine.yeatts@dhp.virginia.gov

**Agency Name:** Board of Pharmacy, Department of Health Professions

**Chapters affected:**

| **VAC No.** *(e.g., 4 VAC 20-490):* | **Chapter Name** *(e.g., Regulations Pertaining to Sharks):* |
|---|---|
| 18 VAC 110-20 | Regulations Governing the Practice of Pharmacy |

**Statutory Authority:** 54.1-2400 and Chapters 33 and 34 of Title 54.1

**Name of petitioner:** Dr. Carl Armstrong, Virginia Dept. of Health, Division of Radiological Health

**Nature of petitioner's request: Amend regulations for consistency with 12VAC5-481-10 et seq. and 10 CFR Parts 30 and 35**

## INITIAL AGENCY NOTICE

**Agency's plan for disposition of the request: Board staff will review other state and federal regulations to determine points of inconsistency and recommend amendments or the possible repeal of Board regulations relating to nuclear pharmacies.**

**Comments may be submitted until** June 25, 2008

## AGENCY DECISION

☐ **Request Granted**

☐ **Request Denied**

**Statement of reasons for decision:**

**Agency Contact for Further Information:**
**Name:** Elizabeth Scott Russell
**Title:** Executive Director, Board of Pharmacy
**Address:** 9960 Mayland Drive, Richmond, VA 23233
**Telephone:** (804) 367-4456 **Fax:** (804) 527-4472 **Toll Free:** 1- -
**E-mail:** scotti.russell@dhp.virginia.gov

**Date Submitted:** 5/5/08

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# COMMONWEALTH of VIRGINIA

## FAX COVER SHEET
## Virginia Department of Health
### Radiological Health Program

DATE: 4/25/08

FROM: Mike Welling

TO: Board of Pharmacy

ATTN:

PAGES: 2 + Header

Comments:

I am submitting a petition for rulemaking on behalf of the Department of Health, Radioactive Materials Program. If you have any questions I can be reached at 864-8168.

Mike Welling

PHONE NUMBERS

| | | |
|---|---|---|
| Mike Welling | (804) 864-8168 | Director, Agreement State Program |
| Dante Laciste | (804) 864-7943 | Radiation Safety Specialist |
| Ron Tanner | (804) 864-8211 | Fiscal Tech, Sr. |
| FAX: | (804) 864-7238 | |

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# COMMONWEALTH OF VIRGINIA
# Board of Pharmacy

9960 Mayland Drive, Suite 300
Richmond, Virginia 23233-1463

(804) 367-4456 (Tel)
(804) 527-4472 (Fax)

## Petition for Rule-making

*The Code of Virginia (§ 2.2-4007) and the Public Participation Guidelines of this board require a person who wishes to petition the board to develop a new regulation or amend an existing regulation to provide certain information. Within 14 days of receiving a valid petition, the board will notify the petitioner and send a notice to the Register of Regulations identifying the petitioner, the nature of the request and the plan for responding to the petition. Following publication of the petition in the Register, a 21-day comment period will begin to allow written comment on the petition. Within 90 days after the comment period, the board will issue a written decision on the petition.*

**Please provide the information requested below. (Print or Type)**

| | | |
|---|---|---|
| Petitioner's full name (Last, First, Middle Initial, Suffix,)<br>Virginia Department of Health, Division of Radiological Health | | |
| Street Address<br>109 Governor Street, Room 730 | Area Code and Telephone Number<br>804-864-8150 | |
| City<br>Richmond | State<br>VA | Zip Code<br>23219 |
| Email Address (optional) | Fax (optional) | |

**Respond to the following questions:**

1. What regulation are you petitioning the board to amend? Please state the title of the regulation and the section/sections you want the board to consider amending.

18VAC110-20-220 General requirements for pharmacies providing radiopharmaceutical services.
18VAC110-20-230 Qualifications as a nuclear pharmacist.

2. Please summarize the substance of the change you are requesting and state the rationale or purpose for the new or amended rule.

A review of the Board of Pharmacy's regulations listed in Item 1 has brought to our attention that these regulations are not consistent with 12VAC5-481 and 10 CFR Part 30 and 35. These differences create a conflict with the licensing and inspection of radiopharmaceuticals. Specifically they are:

a. 18VAC110-20-220 A states: "In emergency situations, in the absence of the nuclear pharmacist, he may designate one or more other qualified pharmacists to have access to the licensed areas." According to our licenses only authorized nuclear pharmacists or people working under their direct supervision may handle radioactive material to be dispensed as radiopharmaceuticals.
b. 18VAC110-20-220 E and F states labeling requirements which are inconsistent with 12VAC5-481-480 I.
c. 18VAC110-20-220 G uses the term "radiometric methods" for determining doses. 12VAC5-481-480 I states that licensees shall measure by direct measurement or by combination of measurements and calculations.
d. 18VAC110-20-230 lists the qualifications for a nuclear pharmacist which are not equivalent to the requirements in 12VAC5-481 or 10 CFR 35.55.
e. 18 VAC110-20-230 4 states "documentation of NRC approvals as an authorized nuclear pharmacist". The Department of Health accepts other agreement state approvals as well as NRC when licensing authorized nuclear pharmacists. Also licensees are allowed to have authorized nuclear pharmacists work for 30 days before notifying the Department of Health if they are licensed by another agreement state or NRC.

On December 14, 2005 then Governor Warner submitted a letter to the Nuclear Regulatory Commission (NRC) expressing Virginia's intent to pursue an agreement with the NRC for regulating radioactive materials in Virginia. In January 2006 Secretary of Health and Human

Services expressed Governor Kaine's support to the NRC for Virginia to enter into the agreement. On September 20, 2006 12VAC5-481, Virginias Radiation Protection Regulations, became effective. These regulations are based upon the NRC's regulations in 10 CFR. The Division of Radiological Health in the Department of Health is in the process of applying to the NRC for agreement state status.

We recommend the Board of Pharmacy amend these regulations to either be identical to the regulations of 12VAC5-481 or incorporate by reference 12VAC5-481 in 18VAC110-20-220 and 18VAC110-20-230.

3. State the legal authority of the board to take the action requested. In general, the legal authority for the adoption of regulations by the board is found in § 54.1-2400 of the Code of Virginia. If there is other legal authority for promulgation of a regulation, please provide that Code reference.

**Signature:** Carl W. Armstrong MD. **Date:** 4/25/08

# Exempt Regulation
# House Bill 1222

## BOARD OF PHARMACY
### Restricted volunteer license

**18VAC110-20-75. Registration for voluntary practice by out-of-state licensees.**

Any pharmacist who seeks registration to practice on a voluntary basis pursuant to subdivision 12 of §54.1-3301 of the Code of Virginia under the auspices of a publicly supported, all volunteer, nonprofit organization ~~with no paid employees~~ that sponsors the provision of health care to populations of underserved people ~~throughout the world~~ shall:

1. File a complete application for registration on a form provided by the board at least ~~15~~ five business days prior to engaging in such practice;

2. Provide a complete list of each state in which he has held a pharmacist license and a copy of any current license;

3. Provide the name of the nonprofit organization and the dates and location of the voluntary provision of services;

4. Pay a registration fee of $10; and

5. Provide a notarized statement from a representative of the nonprofit organization attesting to its compliance with the provisions of subdivision 12 of §54.1-3301 of the Code of Virginia.

Excerpt



## VIRGINIA ACTS OF ASSEMBLY — CHAPTER

*An Act to amend and reenact §§ 54.1-2901, 54.1-3001, 54.1-3202, 54.1-3301, and 54.1-3801 of the Code of Virginia, relating to charitable medical events.*

[H 1222]

Approved

**Be it enacted by the General Assembly of Virginia:**

**1. That §§ 54.1-2901, 54.1-3001, 54.1-3202, 54.1-3301, and 54.1-3801 of the Code of Virginia are amended and reenacted as follows:**

§ 54.1-2901. Exceptions and exemptions generally.

A. The provisions of this chapter shall not prevent or prohibit:

1. Any person entitled to practice his profession under any prior law on June 24, 1944, from continuing such practice within the scope of the definition of his particular school of practice;

2. Any person licensed to practice naturopathy prior to June 30, 1980, from continuing such practice in accordance with regulations promulgated by the Board;

3. Any licensed nurse practitioner from rendering care under the supervision of a duly licensed physician when such services are authorized by regulations promulgated jointly by the Board of Medicine and the Board of Nursing;

4. Any registered professional nurse, licensed nurse practitioner, graduate laboratory technician or other technical personnel who have been properly trained from rendering care or services within the scope of their usual professional activities which shall include the taking of blood, the giving of intravenous infusions and intravenous injections, and the insertion of tubes when performed under the orders of a person licensed to practice medicine;

5. Any dentist, pharmacist or optometrist from rendering care or services within the scope of his usual professional activities;

6. Any practitioner licensed or certified by the Board from delegating to personnel supervised by him, such activities or functions as are nondiscretionary and do not require the exercise of professional judgment for their performance and which are usually or customarily delegated to such persons by practitioners of the healing arts, if such activities or functions are authorized by and performed for such practitioners of the healing arts and responsibility for such activities or functions is assumed by such practitioners of the healing arts;

7. The rendering of medical advice or information through telecommunications from a physician licensed to practice medicine in Virginia or an adjoining state to emergency medical personnel acting in an emergency situation;

8. The domestic administration of family remedies;

9. The giving or use of massages, steam baths, dry heat rooms, infrared heat or ultraviolet lamps in public or private health clubs and spas;

10. The manufacture or sale of proprietary medicines in this Commonwealth by licensed pharmacists or druggists;

11. The advertising or sale of commercial appliances or remedies;

12. The fitting by nonitinerant persons or manufacturers of artificial eyes, limbs or other apparatus or appliances or the fitting of plaster cast counterparts of deformed portions of the body by a nonitinerant bracemaker or prosthetist for the purpose of having a three-dimensional record of the deformity, when such bracemaker or prosthetist has received a prescription from a licensed physician directing the fitting of such casts and such activities are conducted in conformity with the laws of Virginia;

13. Any person from the rendering of first aid or medical assistance in an emergency in the absence of a person licensed to practice medicine or osteopathy under the provisions of this chapter;

14. The practice of the religious tenets of any church in the ministration to the sick and suffering by mental or spiritual means without the use of any drug or material remedy, whether gratuitously or for compensation;

15. Any legally qualified out-of-state or foreign practitioner from meeting in consultation with legally licensed practitioners in this Commonwealth;

16. Any practitioner of the healing arts licensed or certified and in good standing with the applicable regulatory agency in another state or Canada when that practitioner of the healing arts is in Virginia temporarily and such practitioner has been issued a temporary license or certification by the Board from practicing medicine or the duties of the profession for which he is licensed or certified (i) in a summer camp or in conjunction with patients who are participating in recreational activities, (ii) while

179 Virginia who (i) does not regularly practice nursing in Virginia, (ii) holds a current valid license or
180 certification to practice nursing in another state, territory, district or possession of the United States, (iii)
181 volunteers to provide free health care to an underserved area of this Commonwealth under the auspices
182 of a publicly supported all volunteer, nonprofit organization ~~with no paid employees~~ that sponsors the
183 provision of health care to populations of underserved people ~~throughout the world~~, (iv) files a copy of
184 the license or certification issued in such other jurisdiction with the Board, (v) notifies the Board at least
185 ~~fifteen~~ *five business* days prior to the voluntary provision of services of the dates and location of such
186 service, and (vi) acknowledges, in writing, that such licensure exemption shall only be valid, in
187 compliance with the Board's regulations, during the limited period that such free health care is made
188 available through the volunteer, nonprofit organization on the dates and at the location filed with the
189 Board. The Board may deny the right to practice in Virginia to any nurse whose license or certificate
190 has been previously suspended or revoked, who has been convicted of a felony or who is otherwise
191 found to be in violation of applicable laws or regulations. *However, the board shall allow a nurse who*
192 *meets the above criteria to provide volunteer services without prior notice for a period of up to three*
193 *days, provided the nonprofit organization verifies that the practitioner has a valid, unrestricted license*
194 *in another state.*
195 § 54.1-3202. Exemptions.
196 This chapter shall not apply to:
197 1. Physicians licensed to practice medicine by the Board of Medicine or to prohibit the sale of
198 nonprescription eyeglasses and sunglasses. Contact lenses shall not be sold as merchandise from a retail
199 business other than one operated by a physician, an optometrist or an optician; or
200 2. Any optometrist rendering free health care to an underserved population in Virginia who (i) does
201 not regularly practice optometry in Virginia, (ii) holds a current valid license or certificate to practice
202 optometry in another state, territory, district or possession of the United States, (iii) volunteers to
203 provide free health care in an underserved area of this Commonwealth under the auspices of a publicly
204 supported all volunteer, nonprofit organization ~~with no paid employees~~ that sponsors the provision of
205 health care to populations of underserved people ~~throughout the world~~, (iv) files a copy of his license or
206 certification in such other jurisdiction with the Board, (v) notifies the Board at least ~~fifteen~~ *five business*
207 days prior to the voluntary provision of services of the dates and location of such service, and (vi)
208 acknowledges, in writing, that such licensure exemption shall only be valid, in compliance with the
209 Board's regulations, during the limited period that such free health care is made available through the
210 volunteer, nonprofit organization on the dates and at the location filed with the Board. The Board may
211 deny the right to practice in Virginia to any optometrist whose license or certificate has been previously
212 suspended or revoked, who has been convicted of a felony or who is otherwise found to be in violation
213 of applicable laws or regulations. *However, the board shall allow an optometrist who meets the above*
214 *criteria to provide volunteer services without prior notice for a period of up to three days, provided the*
215 *nonprofit organization verifies that the practitioner has a valid, unrestricted license in another state.*
216 § 54.1-3301. Exceptions.
217 This chapter shall not be construed to:
218 1. Interfere with any legally qualified practitioner of dentistry, or veterinary medicine or any
219 physician acting on behalf of the Virginia Department of Health or local health departments, in the
220 compounding of his prescriptions or the purchase and possession of drugs as he may require;
221 2. Prevent any legally qualified practitioner of dentistry, or veterinary medicine or any prescriber, as
222 defined in § 54.1-3401, acting on behalf of the Virginia Department of Health or local health
223 departments, from administering or supplying to his patients the medicines that he deems proper under
224 the conditions of § 54.1-3303 or from causing drugs to be administered or dispensed pursuant to
225 §§ 32.1-42.1 and 54.1-3408;
226 3. Prohibit the sale by merchants and retail dealers of proprietary medicines as defined in Chapter 34
227 (§ 54.1-3400 et seq.) of this title;
228 4. Prevent the operation of automated drug dispensing systems in hospitals pursuant to Chapter 34
229 (§ 54.1-3400 et seq.) of this title;
230 5. Prohibit the employment of ancillary personnel to assist a pharmacist as provided in the
231 regulations of the Board;
232 6. Interfere with any legally qualified practitioner of medicine, osteopathy, or podiatry from
233 purchasing, possessing or administering controlled substances to his own patients or providing controlled
234 substances to his own patients in a bona fide medical emergency or providing manufacturers'
235 professional samples to his own patients;
236 7. Interfere with any legally qualified practitioner of optometry, certified or licensed to use diagnostic
237 pharmaceutical agents, from purchasing, possessing or administering those controlled substances as
238 specified in § 54.1-3221 or interfere with any legally qualified practitioner of optometry certified to
239 prescribe therapeutic pharmaceutical agents from purchasing, possessing, or administering to his own

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patients those controlled substances as specified in § 54.1-3222 and the TPA formulary or providing manufacturers' samples of these drugs to his own patients;

8. Interfere with any physician assistant with prescriptive authority receiving and dispensing to his own patients manufacturers' professional samples of controlled substances and devices that he is authorized, in compliance with the provisions of § 54.1-2952.1, to prescribe according to his practice setting and a written agreement with a physician or podiatrist;

9. Interfere with any licensed nurse practitioner with prescriptive authority receiving and dispensing to his own patients manufacturers' professional samples of controlled substances and devices that he is authorized, in compliance with the provisions of § 54.1-2957.01, to prescribe according to his practice setting and a written agreement with a physician;

10. Interfere with any legally qualified practitioner of medicine or osteopathy participating in an indigent patient program offered by a pharmaceutical manufacturer in which the practitioner sends a prescription for one of his own patients to the manufacturer, and the manufacturer donates a stock bottle of the prescription drug ordered at no cost to the practitioner or patient. The practitioner may dispense such medication at no cost to the patient without holding a license to dispense from the Board of Pharmacy. However, the container in which the drug is dispensed shall be labeled in accordance with the requirements of § 54.1-3410, and, unless directed otherwise by the practitioner or the patient, shall meet standards for special packaging as set forth in § 54.1-3426 and Board of Pharmacy regulations. In lieu of dispensing directly to the patient, a practitioner may transfer the donated drug with a valid prescription to a pharmacy for dispensing to the patient. The practitioner or pharmacy participating in the program shall not use the donated drug for any purpose other than dispensing to the patient for whom it was originally donated, except as authorized by the donating manufacturer for another patient meeting that manufacturer's requirements for the indigent patient program. Neither the practitioner nor the pharmacy shall charge the patient for any medication provided through a manufacturer's indigent patient program pursuant to this subdivision. A participating pharmacy may charge a reasonable dispensing or administrative fee to offset the cost of dispensing, not to exceed the comparable allowable fee reimbursed by the Virginia Medicaid program. However, if the patient is unable to pay such fee, the dispensing or administrative fee shall be waived;

11. Interfere with any legally qualified practitioner of medicine or osteopathy from providing controlled substances to his own patients in a free clinic without charge when such controlled substances are donated by an entity other than a pharmaceutical manufacturer as authorized by subdivision 10. The practitioner shall first obtain a controlled substances registration from the Board and shall comply with the labeling and packaging requirements of this chapter and the Board's regulations; or

12. Prevent any pharmacist from providing free health care to an underserved population in Virginia who (i) does not regularly practice pharmacy in Virginia, (ii) holds a current valid license or certificate to practice pharmacy in another state, territory, district or possession of the United States, (iii) volunteers to provide free health care to an underserved area of this Commonwealth under the auspices of a publicly supported all volunteer, nonprofit organization ~~with no paid employees~~ that sponsors the provision of health care to populations of underserved people ~~throughout the world~~, (iv) files a copy of the license or certificate issued in such other jurisdiction with the Board, (v) notifies the Board at least ~~15~~ *five business* days prior to the voluntary provision of services of the dates and location of such service, and (vi) acknowledges, in writing, that such licensure exemption shall only be valid, in compliance with the Board's regulations, during the limited period that such free health care is made available through the volunteer, nonprofit organization on the dates and at the location filed with the Board. The Board may deny the right to practice in Virginia to any pharmacist whose license has been previously suspended or revoked, who has been convicted of a felony or who is otherwise found to be in violation of applicable laws or regulations. *However, the board shall allow a pharmacist who meets the above criteria to provide volunteer services without prior notice for a period of up to three days, provided the nonprofit organization verifies that the practitioner has a valid, unrestricted license in another state.*

This section shall not be construed as exempting any person from the licensure, registration, permitting and record keeping requirements of this chapter or Chapter 34 of this title.

§ 54.1-3801. Exceptions.

This chapter shall not apply to:

1. The owner of an animal and the owner's full-time, regular employee caring for and treating the animal belonging to such owner, except where the ownership of the animal was transferred for the purpose of circumventing the requirements of this chapter;

2. Veterinarians licensed in other states called in actual consultation or to attend a case in this Commonwealth who do not open an office or appoint a place to practice within this Commonwealth;

3. Veterinarians employed by the United States or by this Commonwealth while actually engaged in the performance of their official duties; or

ENROLLED

HB1222ER

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# Emergency Regulation
# House Bill 1129

## BOARD OF PHARMACY
### Renewal dates

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

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

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

C. Initial application fees.

| | |
|---|---|
| 1. Pharmacist license | $180 |
| 2. Pharmacy intern registration | $15 |
| 3. Pharmacy technician registration | $25 |
| 4. Pharmacy permit | $270 |
| 5. Permitted physician licensed to dispense drugs | $270 |
| 6. 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. Approval of a pharmacy technician training program | $150 |
| 13. Approval of a continuing education program | $100 |

D. Annual renewal fees.

| | |
|---|---|
| 1. Pharmacist active license – due December 31 | $90 |
| 2. Pharmacist inactive license – due December 31 | $45 |
| 3. Pharmacy technician registration – due December 31 | $25 |
| 4. Pharmacy permit – due April 30 | $270 |
| 5. Physician permit to practice pharmacy – due February 28 | $270 |
| 6. Medical equipment supplier permit – due February 28 | $180 |

7. Humane society permit – due February 28 $20

8. Nonresident pharmacy – due April 30 $270

9. Controlled substances registrations – due February 28 $90

10. Innovative program continued approval based on board order not to exceed $200 per approval period.

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

1. Pharmacist license $30

2. Pharmacist inactive license $15

3. Pharmacy technician registration $10

4. Pharmacy permit $90

5. Physician permit to practice pharmacy $90

6. Medical equipment supplier permit $60

7. Humane society permit $5

8. Nonresident pharmacy $90

9. Controlled substances registrations $30

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

1. Pharmacist license $210

2. Pharmacist license after revocation or suspension $500

3. Pharmacy technician registration $35

4. Pharmacy technician registration after revocation or suspension $125

5. Facilities or entities that cease operation and wish to resume shall not be eligible for reinstatement but shall apply for a new permit or registration. Facilities or entities that failed to renew and continued to operate for more than one renewal cycle shall pay the current and all back renewal fees for the years in which they were operating plus the following reinstatement fees:

a. Pharmacy permit $240

b. Physician permit to practice pharmacy $240

c. Medical equipment supplier permit $210

d. Humane society permit $30

e. Nonresident pharmacy $115

f. Controlled substances registration $180

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

1. Change of pharmacist-in-charge $50

2. Change of ownership for any facility $50

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

4. Reinspection of any facility $150

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

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

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

H. Miscellaneous fees.

1. Duplicate wall certificate $25

2. Returned check $35

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

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

**18VAC110-50-20. Fees.**

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

B. Initial application fees.

1. Nonrestricted manufacturer permit $270

2. Restricted manufacturer permit $180

3. Wholesale distributor license $270

4. Warehouser permit $270

5. Nonresident wholesale distributor $270

6. Controlled substances registration $90

C. Annual renewal fees shall be due on February 28 of each year.

| | |
|---|---|
| 1. Nonrestricted manufacturer permit | $270 |
| 2. Restricted manufacturer permit | $180 |
| 3. Wholesale distributor license | $270 |
| 4. Warehouser permit | $270 |
| 5. Nonresident wholesale distributor | $270 |
| 6. Controlled substances registration | $90 |

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

| | |
|---|---|
| 1. Nonrestricted manufacturer permit | $90 |
| 2. Restricted manufacturer permit | $60 |
| 3. Wholesale distributor license | $90 |
| 4. Warehouser permit | $90 |
| 5. Nonresident wholesale distributor | $90 |
| 6. Controlled substances registration | $30 |

E. Reinstatement fees.

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

2. Engaging in activities requiring a license, permit, or registration after the expiration date of such license, permit, or registration shall be grounds for disciplinary action by the board. 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.

3. 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. Nonrestricted manufacturer permit | $240 |
| b. Restricted manufacturer permit | $210 |
| c. Wholesale distributor license | $240 |
| d. Warehouser permit | $240 |
| e. Nonresident wholesale distributor | $240 |
| f. Controlled substances registration | $180 |

F. Application for change or inspection fees.

| | |
|---|---|
| 1. Reinspection fee | $150 |
| 2. Inspection fee for change of location, structural changes, or security system changes | $150 |
| 3. Change of ownership fee | $50 |
| 4. Change of responsible party | $50 |

G. The fee for a returned check shall be $35.

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

| | |
|---|---|
| 1. Nonrestricted manufacturer permit | $210 |
| 2. Restricted manufacturer permit | $140 |
| 3. Wholesale distributor license | $210 |
| 4. Warehouser permit | $210 |
| 5. Nonresident wholesale distributor | $210 |

# VIRGINIA ACTS OF ASSEMBLY -- 2008 SESSION

## CHAPTER 320

*An Act to amend and reenact §§ 54.1-3434, 54.1-3434.2, 54.1-3435, 54.1-3435.01, 54.1-3435.2, 54.1-3435.4, and 54.1-3439 of the Code of Virginia, relating to the expiration of various pharmacy licenses.*

[H 1129]

Approved March 4, 2008

**Be it enacted by the General Assembly of Virginia:**

**1. That §§ 54.1-3434, 54.1-3434.2, 54.1-3435, 54.1-3435.01, 54.1-3435.2, 54.1-3435.4, and 54.1-3439 of the Code of Virginia are amended and reenacted as follows:**

§ 54.1-3434. Permit to conduct pharmacy.

No person shall conduct a pharmacy without first obtaining a permit from the Board.

The application for such permit shall be made on a form provided by the Board and signed by a pharmacist who will be in full and actual charge of the pharmacy and who will be fully engaged in the practice of pharmacy at the location designated on the application.

The application shall (i) show the corporate name and trade name, (ii) list any pharmacist in addition to the pharmacist-in-charge practicing at the location indicated on the application, and (iii) list the hours during which the pharmacy will be open to provide pharmacy services. Any change in the hours of operation, which is expected to last more than one week, shall be reported to the Board in writing and posted, at least fourteen days prior to the anticipated change, in a conspicuous place to provide notice to the public. The Board shall promulgate regulations to provide exceptions to this prior notification.

If the owner is other than the pharmacist making the application, the type of ownership shall be indicated and shall list any partner or partners, and, if a corporation, then the corporate officers and directors. Further, if the owner is not a pharmacist, he shall not abridge the authority of the pharmacist-in-charge to exercise professional judgment relating to the dispensing of drugs in accordance with this act and Board regulations.

The permit shall be issued only to the pharmacist who signs the application as the pharmacist-in-charge and as such assumes the full responsibilities for the legal operation of the pharmacy. This permit and responsibilities shall not be construed to negate any responsibility of any pharmacist or other person.

Upon termination of practice by the pharmacist-in-charge, or upon any change in partnership composition, or upon the acquisition, as defined in Board regulations, of the existing corporation by another person or the closing of a pharmacy, the permit previously issued shall be immediately surrendered to the Board by the pharmacist-in-charge to whom it was issued, or by his legal representative, and an application for a new permit may be made in accordance with the requirements of this chapter.

The Board shall promulgate regulations (i) defining acquisition of an existing permitted, registered or licensed facility or of any corporation under which the facility is directly or indirectly organized; (ii) providing for the transfer, confidentiality, integrity, and security of the pharmacy's prescription dispensing records and other patient records, regardless of where located; and (iii) establishing a reasonable time period for designation of a new pharmacist-in-charge. At the conclusion of the time period for designation of a new pharmacist-in-charge, a pharmacy which has failed to designate a new pharmacist-in-charge shall not operate as a pharmacy nor maintain a stock of prescription drugs on the premises. The Director shall immediately notify the owner of record that the pharmacy no longer holds a valid permit and that the owner shall make provision for the proper disposition of all Schedule II through VI drugs and devices on the premises within fifteen days of receipt of this notice. At the conclusion of the fifteen-day period, the Director or his authorized agent shall seize and indefinitely secure all Schedule II through VI drugs and devices still on the premises, and notify the owner of such seizure. The Director may properly dispose of the seized drugs and devices after six months from the date of the notice of seizure if the owner has not claimed and provided for the proper disposition of the property. The Board shall assess a fee of not less than the cost of storage of said drugs upon the owner for reclaiming seized property.

The succeeding pharmacist-in-charge shall cause an inventory to be made of all Schedule I, II, III, IV and V drugs on hand. Such inventory shall be completed as of the date he becomes pharmacist-in-charge and prior to opening for business on that date.

The pharmacist to whom such permit is issued shall provide safeguards against diversion of all controlled substances.

An application for a pharmacy permit shall be accompanied by a fee determined by the Board. All permits shall expire ~~on December 31 of each year~~ *annually on a date determined by the Board in*

*regulation.*

Every pharmacy must be equipped so that prescriptions can be properly filled. The Board of Pharmacy shall prescribe the minimum of such professional and technical equipment and reference material which a pharmacy shall at all times possess. No permit shall be issued or continued for the conduct of a pharmacy until or unless there is compliance with the provisions of this chapter and regulations promulgated by the Board.

Each day during which a person is in violation of this section shall constitute a separate offense.

§ 54.1-3434.2. Permit to be issued.

The Board shall only register nonresident pharmacies that maintain a current unrestricted license, certificate, permit, or registration as a pharmacy in a jurisdiction within the United States, or within another jurisdiction that may lawfully deliver prescription drugs directly or indirectly to consumers within the United States.

Applications for a nonresident pharmacy registration, under this section, shall be made on a form furnished by the Board. The Board may require such information as it deems is necessary to carry out the purpose of the section.

The permit or nonresident pharmacy registration shall be renewed annually on ~~or before January 1 of each year~~ *a date determined by the Board in regulation.*

§ 54.1-3435. License to act as wholesale distributor; renewal; fee.

It shall be unlawful for any person to engage in the wholesale distribution of prescription drugs in this Commonwealth without a valid unrevoked license issued by the Board. The applicant for licensure as a wholesale distributor, as defined in § 54.1-3401, in this Commonwealth shall apply to the Board for a license, using such forms as the Board may furnish; renew such license using such forms as the Board may furnish, if granted, annually on ~~or before January 1 of each year~~ *a date determined by the Board in regulation*; notify the Board within thirty days of any substantive change in the information reported on the application form previously submitted to the Board; and remit a fee as determined by the Board.

The Board may promulgate such regulations relating to the storage, handling, and distribution of prescription drugs by wholesale distributors as it deems necessary to implement this section, to prevent diversion of prescription drugs, and to protect the public.

§ 54.1-3435.01. Registration of nonresident wholesale distributors; renewal; fee.

A. Any person located outside this Commonwealth who engages in the wholesale distribution of prescription drugs into this Commonwealth shall be registered with the Board. The applicant for registration as a nonresident wholesale distributor shall apply to the Board using such forms as the Board may furnish; renew such registration, if granted, using such forms as the Board may furnish, annually on ~~or before January 1 of each year~~ *a date determined by the Board in regulation*; notify the Board within thirty days of any substantive change in the information previously submitted to the Board; and remit a fee, which shall be the fee specified for wholesale distributors located within the Commonwealth.

B. The nonresident wholesale distributor shall at all times maintain a valid, unexpired license, permit, or registration in the state in which it is located and shall furnish proof of such upon application and at each renewal.

C. Records of prescription drugs distributed into this Commonwealth shall be maintained in such a manner that they are readily retrievable from records of distributions into other jurisdictions and shall be provided to the Board, its authorized agent, or any agent designated by the Superintendent of the Department of State Police upon request within seven days of receipt of such request.

D. This section shall not apply to persons who distribute prescription drugs directly to a licensed wholesale distributor located within this Commonwealth.

§ 54.1-3435.2. Permit to act as medical equipment supplier; storage; limitation; regulations.

A. Unless otherwise authorized by this chapter or Chapter 33 (§ 54.1-3300 et seq.) of this title, it shall be unlawful for any person to act as a medical equipment supplier, as defined in § 54.1-3401, in this Commonwealth without a valid unrevoked permit issued by the Board. The applicant for a permit to act as a medical equipment supplier in this Commonwealth shall apply to the Board for a permit, using such form as the Board may furnish; renew such permit, if granted, annually on ~~or before January 1 of each year~~ *a date determined by the Board in regulation*; and remit a fee as determined by the Board.

B. Prescription drugs received, stored, and distributed by authority of this section shall be limited to those Schedule VI controlled substances with no medicinal properties which are used for the operation and cleaning of medical equipment and solutions for peritoneal dialysis.

C. Distribution of any Schedule VI drug or device or of any hypodermic needle or syringe, or medicinal oxygen by authority of this section is limited to delivery to the ultimate user upon lawful order by a prescriber authorized to prescribe such drugs and devices.

D. The Board may promulgate such regulations relating to the storage, handling, and distribution of prescription drugs, devices and controlled paraphernalia by medical equipment suppliers as it deems necessary to implement this section, to prevent diversion of prescription drugs and devices and controlled paraphernalia, and to protect the public.

§ 54.1-3435.4. Permit to act as warehouser; regulations.

A. Unless otherwise authorized by this chapter or Chapter 33 (§ 54.1-3300 et seq.) of this title, it shall be unlawful for any person to act as a warehouser, as defined in § 54.1-3401, in this Commonwealth without a valid unrevoked permit issued by the Board. The applicant for a permit to act as a warehouser in this Commonwealth shall apply to the Board for a permit, using such form as the Board may furnish; renew such permit, if granted, annually on ~~or before January 1 of each year~~ *a date determined by the Board in regulation*; and remit a fee as determined by the Board.

B. The Board may promulgate such regulations relating to the storage, handling, and distribution of prescription drugs and devices by warehousers as it deems necessary to implement this section, to prevent diversion of prescription drugs and devices, and to protect the public.

C. Warehousers shall allow the Board or its authorized agents to enter and inspect, at reasonable times and in a reasonable manner, their premises and delivery vehicles, and to audit their records and written operating procedures. Such agents shall be required to show appropriate identification prior to being permitted access to warehousers' premises and delivery vehicles.

§ 54.1-3439. Application for nonrestricted manufacturing permit; fee.

Every person desiring to manufacture any drug or proprietary medicines shall annually apply to the Board for a nonrestricted manufacturing permit. The application shall be accompanied by the required fee. Separate applications shall be made and separate permits issued for each specific place of manufacturing. Each such permit shall expire ~~on December 31~~ *annually on a date determined by the Board in regulation.*

**2. That the Board of Pharmacy shall promulgate regulations to implement the provisions of this act to be effective within 280 days of its enactment.**

**DRAFT**
**5/2/08**
**Family Planning Expedited Visit Instructions**

Purpose: The goal of the family planning expedited visit is to improve pregnancy planning and prevent unintentional and unplanned pregnancy. The family planning expedited visit is an abbreviated family planning visit designed to remove client barriers for accessing contraceptive methods. The expedited visit process is designed for implementation in the clinical and non-traditional settings. These clinical settings may include but are not limited to: STI, Pregnancy Test, Immunization, Pediatric, Teen, WIC, Walk In, and mobile clinical settings. The expedited visit form will serve as the family planning encounter and should be entered as a visit into WebVISION.

Criteria for using the family planning expedited visit form

- A clinician (MD or NP) must be present at the site.
- Contraceptive methods must be available for dispensing.
- The expedited visit form must be completed.
- The client must receive a scheduled appointment for a comprehensive family planning visit within 90 days of the expedited visit. The return visit will include a comprehensive history, physical assessment, evaluation of the birth control method, client centered counseling and the required educational components of family planning.
- Only three cycles may be dispensed.
- Only one expedited visit will be permitted..

Steps for completing the VDH Family Planning Expedited Visit

- Have the client complete as much of the form as possible.
- The nurse must review the form with the client and obtain clarifying information.
- The nurse will sign and date the form.
- The clinician on site will be given the completed form for review.
- The clinician is not required to actually see or examine the client on site, but may elect to.
- Clinician will elect to prescribe or decline to prescribe a birth control method based on client information, clinical judgment and protocol(s). The quick start process should be utilized whenever possible. Signature of the clinician is required on the form.
- If a method is ordered the nurse will provide: 1) method specific counseling and education, 2) provide a back up contraceptive method to be used if appropriate, 3) provide information on emergency contraception.
- Initiate referrals as identified.

- Schedule the client for a return comprehensive family planning visit within 90 days of the expedited visit..
- Nurse will enter: "follow up required," the return appointment date, and sign and date the form.
- The completed form will be added to the patient's medical record.

**Family Planning Expedited Visit** **DATE:** _____

**Name:** _____

**Address:** _____

**DOB:**_____ **Age:**_____

**Race/Ethnicity (circle):** W B Asian American Indian Alaska Native Pacific Islander Multiracial Hispanic Non-Hispanic Other

**LMP:** _____/_____/_____ **ALLERGIES:** _____

**Using any kind of birth control**? Yes No
If yes, what? _____

**Smoke**? Yes No **Drink alcohol**? Yes No
**List Current Medications/dosage/start date** (include OTC & Street Drugs)
_____
_____

**Urine Pregnancy Test today:** POSITIVE NEGATIVE N/A

**Problems since LMP**?

| | | | |
|---|---|---|---|
| Nausea | Y | N | _____ |
| Vomiting | Y | N | _____ |
| Bleeding | Y | N | _____ |
| Cramping | Y | N | _____ |
| Other | Y | N | _____ |

**Have you been to a medical provider since LMP**? Yes No
If yes, why? _____
_____

**OB History**: G _____ P _____
Date of last pregnancy: _____
Pregnancy complications:_____
Future pregnancy plans:_____

**Contraceptive History:**

| | | | |
|---|---|---|---|
| OCs | Y | N | _____ |
| DEPO | Y | N | _____ |
| OrthoEvra | Y | N | _____ |
| IMPLANTS | Y | N | _____ |
| IUDs | Y | N | _____ |
| Condoms/foam | Y | N | _____ |
| Other | Y | N | _____ |

**Comments:**

**Referral** (circle)? WIC DSS BabyCare FP Plan First
Other: _____

**Interviewer Signature:** _____ **Date:** _____

**QUICK START**

**BP**: _____

**WT**: _____

**Last Intercourse** (date)?
_____
If unprotected & 5 days or less, offer EC

**Medical History**:

| | |
|---|---|
| Hypertension? | Y N |
| Heart disaese? | Y N |
| Diabetes? | Y N |
| Blood clots? | Y N |
| Chest pain? | Y N |
| Breast CA? | Y N |
| Cervical CA? | Y N |
| Abnormal Pap | Y N |
| Migraine HA? | Y N |
| Seizures? | Y N |
| Liver disease? | Y N |
| Vag Bleeding? | Y N |
| Breast feeding? | Y N |

Other:_____

**Dispense:**
_____ X 1 pack

NuvaRing X 1 month

DMPA 104 SQ X 1

EC_____
Other_____ X 1 month

Clinician: _____
MD, NP, CNM, PA

**RN follow-up**: _____
_____

**F/U appt:** _____

**Nurse** : _____
**Date:**