COMMONWEALTH OF VIRGINIA

Meeting of the Board of Pharmacy

Perimeter Center, 9960 Mayland Drive, Second Floor (804) 367-4456 (Tel)
Henrico, Virginia 23233 (804) 527-4472(Fax)

Tentative Agenda of Meeting

June 8, 2011

9:00AM

TOPIC	PAGE(S)
Call to Order: Brandon Yi, Chairman	
• Welcome and Introductions	
• Reading of emergency evacuation script	
• Approval of Agenda	
• Approval of previous Board meeting minutes:	
◦ March 9, 2011, Full Board Meeting	1-10
◦ May 17, 2011, Ad Hoc Committee, On-Hold Prescriptions	11-19
◦ May 18, 2011, Ad Hoc Committee, Pharmacy Inspections	20-29
◦ May 18, 2011, Ad Hoc Committee, CQI Program	30-32

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.

Legislation: - Elaine Yeatts	
• 2012 Legislative Proposal	33-38
◦ Rescheduling bill – Ultram and carisoprodol	
Regulations: - Elaine Yeatts	
• Update	39
• Fast-track for CE requirements	40-43 + handout
• Adoption of proposed regulations of new administrative fees	44-51
• Petitions for rulemaking regarding automated dispensing devices	51-57
Update on Action Items:	
• Continuous quality improvement program-Caroline Juran/Elaine Yeatts	58-60
◦ Provide update from ad hoc committee meeting	
◦ Adopt NOIRA	
• On-hold prescriptions - Caroline Juran	61
◦ Provide update from ad hoc committee meeting	
◦ Review draft proposed regulations in minutes	
• Pharmacy routine inspection program – Sammy Johnson	62
◦ Provide update from ad hoc committee meeting	
◦ Review proposed changes to guidance document 110-9	

Miscellaneous: Caroline Juran

- Methods for handling disciplinary matters
  - Review statistics for key performance measures and need to improve clearance rate — 63-70
  - Review other boards' methods for delegating authority to professional staff — 71-74
  - Discuss delegating authority to Board of Pharmacy professional staff to issue confidential consent agreements, pre-hearing consent orders, and perform probable cause review and case closure
  - Update guidance document for use of agency subordinate — 75-79
- Request to amend regulation to allow acceptance of score transfer without obtaining additional hours of practical experience after failing NAPLEX 3 or more times and resident state has issued pharmacist license — 80-85
- Board budget — Handout
- Request for examination accommodation — Handout

Reports:

- Update on Workforce Surveys – Elizabeth Carter, Ph.D, Director, DHP Healthcare Workforce Data Center — 86-112
- Report on Board of Health Professions – David C. Kozera
- Report on disciplinary matters – Cathy Reiniers-Day
- Executive Director's Report - Caroline D. Juran

Recognition of Board members whose terms are expiring June 30, 2011:

- John Beckner, 2nd term
- Gerard Dabney, 1st term

Election of Officers - Chairman and Vice Chairman

New Business

Consideration of consent orders (if any)

Adjourn

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

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF BOARD MEETING

March 9, 2011
Second Floor
Board Room 4

Perimeter Center
9960 Mayland Drive, Suite 300
Henrico, Virginia 23233-1463

CALL TO ORDER: The meeting was called to order at 9:13 AM.

PRESIDING: Brandon Yi, Chairman

MEMBERS PRESENT:
Gill B. Abernathy
John O. Beckner
Gerard Dabney
David C. Kozera
Leo H. Ross
Ellen B. Shinaberry

MEMBERS ABSENT:
Pratt P. Stelly
Jody H. Allen
Robert M. Rhodes

STAFF PRESENT:
Caroline D. Juran, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
Sammy Johnson, Deputy Executive Director
Howard M. Casway, Senior Assistant Attorney General
Elaine J. Yeatts, Senior Regulatory Analyst, DHP
Sharon Davenport, Administrative Assistant

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

ANNOUNCEMENTS: Prior to introductions, Mr. Yi announced that Caroline D. Juran had been recently selected as the new Executive Director for the Board. Additionally, he announced that Sammy Johnson had assumed the position of Deputy Executive Director for the Board overseeing the licensure program.

APPROVAL OF AGENDA: An amended agenda was presented and approved by the Board which added discussions to review amended language in guidance document 110-30 regarding drugs within an animal shelter or pound and amended language in guidance document 110-9 regarding automated dispensing devices, USP 797 physical standards, and perpetual inventories.

APPROVAL OF MINUTES: The Board reviewed draft minutes for December 15, 2010; December 22, 2010; February 2, 2011; February 8, 2011; February 9, 2011; and February 23, 2011. With no changes to the minutes, the minutes were approved as presented.

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PUBLIC COMMENTS: There were no public comments made at this time.

DHP DIRECTOR'S REPORT: Mr. Yi stated that Dr. Cane could not attend the meeting due to a last-minute conflict which required her attention. Ms. Juran explained that Dr. Cane requested her to apologize to the board for her absence and share that her report was primarily to summarize activities related to the General Assembly which she believed Ms. Yeatts could cover in her report.

LEGISLATION: Ms. Yeatts provided a summary of legislation from the 2011 General Assembly session that might be of possible interest to the Board. Additionally, she suggested the Board form a taskforce for promulgating emergency regulations for implementing provisions regarding continuous quality improvement programs as required in HB2220. There was agreement that at least three board members should participate on the taskforce, however, Mr. Yi did not make appointments at that time since three board members were absent.

Action Item: **The Board determined that Ms. Juran should send an email to all board members and key stakeholders soliciting participation on the taskforce for promulgating emergency regulations for implementing provisions regarding continuous quality improvement programs as required in HB2220 and that Mr. Yi would appoint interested persons to such taskforce.**

REGULATIONS:

- Regulation update

Ms. Yeatts reported that the emergency regulations for repackaging in community service boards and behavioral health authorities will expire on December 19, 2011, and therefore, the Board should consider adopting proposed regulations to continue this authority. Additionally, she reported that the effective date for the fast-track regulation regarding the signing of delivery records for automated dispensing devices in hospitals was listed incorrectly in the agenda packet. The effective date should be March 17, 2011. She also stated the elimination of an alarm system for certain EMS agencies is being handled as a fast-track regulation and that it is at the Governor's office for review. However, she was recently informed that regulation regarding administrative fees cannot be handled as a fast-track regulation and must adhere to the regular APA process.

Motion: **The Board voted unanimously to adopt proposed regulations for repackaging in community service boards and behavioral health authorities. (motion by Beckner, second by Ross)**

UPDATE ON ACTION ITEMS:

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- Update on "on-hold" prescriptions

Ms. Juran reported that the ad hoc committee formed at the December board meeting for reviewing the possible need for regulations regarding on-hold prescriptions did not meet due to staff's workload resulting from staffing shortages and commitments associated with the General Assembly. Therefore, she recommended that the full Board discuss the possible need for regulations and if needed, consider adopting the NOIRA as drafted by staff. The Board agreed the following concerns exist regarding on-hold prescriptions: prescriptions can be lost or stolen if data-entry and filing of prescription is not performed in a timely manner; verification of data-entry may not be performed by a pharmacist at the time it is entered into the computer; and many pharmacists believe the current requirement to file prescriptions by date of initial dispensing is burdensome since this requires the pharmacist to move the on-hold prescription from an original file to the file containing prescriptions initially dispensed that day. Therefore, the Board determined regulations are needed and the NOIRA was adopted as presented.

Motion:

The Board determined that regulatory action is needed to address concerns regarding on-hold prescriptions and voted unanimously to adopt the NOIRA as presented by staff. (motion by Kozera, second by Beckner)

MISCELLANEOUS:

- Guidance Document 110-34, submission of social security numbers or control numbers for wholesale distributors

Ms. Juran explained that current regulations governing wholesale distributors require the submission of social security numbers or control numbers issued by the Virginia DMV for each corporate officer and director. However, recently the Board has received requests from non-resident wholesale distributor applicants representing large corporations with many corporate officers to not provide the social security number of individuals who are not directly responsible for supervising the facility listed on the application and who do not have a control number issued by the DMV. At the time the regulation was enacted, concerns for identity theft were not as prevalent and significant concerns existed for some wholesale distributors operating illegally. The Board discussed the allowance to collect social security numbers or control numbers from individuals who are specifically responsible for the operations of the facility and not every officer and director. Staff presented the board with draft language to amend Guidance Document 110-34 which states the following individuals shall submit a social security number or control number: person serving as responsible party, and; individual owner or sole proprietor, or; each partner or corporate officer and director, who is specifically responsible for the operations of the facility listed on the

application.

Motion:

The Board voted unanimously to amend Guidance Document 110-34, as presented by staff, to limit the individuals who shall submit a social security number or control number when applying for a wholesale distributor permit. (motion by Ross, second by Dabney)

- Guidance Document 110-30, drugs within animal shelters or pounds

Ms. Juran explained that staff had been contacted recently by Dr. Dan Kovich, Staff Veterinarian for Animal Care and Health Policy, Virginia Department of Agriculture and Consumer Services. Dr. Kovich reported that confusion appears to exist within the animal shelters and pounds as to what drugs may be stored within the facility, when the drugs may be administered, and the role of the supervising veterinarian. Of particular concern was the allowance for certain Schedule VI drugs to prevent and treat certain communicable diseases as authorized in § 54.1-3423 E. Ms. Juran and Mr. Casway participated in a meeting to further discuss this matter. Because the Code does not define the required elements of a written protocol or training record when using certain Schedule VI drugs to prevent and treat certain communicable diseases and confusion appears to exist regarding requirements for stocking drugs for euthanasia compared to drugs for communicable diseases, the meeting participants determined that the Boards of Pharmacy and Veterinary Medicine should consider adopting a guidance document to clarify the allowances to purchase, possess, and administer drugs within an animal shelter or pound. Ms. Juran presented draft language resulting from this meeting which amends Guidance Document 110-30.

Motion:

The Board voted unanimously to amend Guidance Document 110-34, as presented by staff, to clarify the allowances to purchase, possess, and administer drugs within an animal shelter or pound. (motion by Kozera, second by Ross)

- Inventory requirements of drugs in Schedules II-V

The Board has received inquiries regarding whether the inventory of drugs in Schedules II-V must involve a physical count of the drugs or whether an estimation is permitted. The Board reviewed the inventory requirements listed in § 54.1-3404 and § 54.1-3434 of the Code, 18 VAC 110-20-240 of the Regulations, and 21 CFR 1304.11 and concluded that clarification should be provided. Ms. Juran reported that she is aware that North Carolina and Kentucky expect compliance with the federal allowance of physically counting all Schedule II drugs, but allowing for an estimation of drugs in Schedules III-V, unless the container holds more than 1,000 tablets/capsules. Concern was expressed for allowing an estimation of inventory when a theft or loss of drug had occurred. The Board concluded that those persons required in law to perform

an inventory of drugs shall physically count all drugs in Schedules II-V when a theft or loss of drug has occurred, but may otherwise perform the inventory in a manner consistent with federal allowances which require a physical count of drugs in Schedule II, but allow for an estimation of drugs in Schedules III-V unless the container contains greater than 1,000 tablets/capsules. It was acknowledged. that nothing would prevent a person when performing an inventory from choosing to physically count all drugs in Schedules II-V.

Motion:

The Board voted unanimously that:

- **staff shall prepare a Guidance Document clarifying that those persons required in law to perform an inventory of drugs shall physically count all drugs in Schedules II-V when a theft or loss of drug has occurred, but may otherwise perform the inventory in a manner consistent with federal allowances which require a physical count of drugs in Schedule II, but allow for an estimation of drugs in Schedules III-V unless the container contains greater than 1,000 tablets/capsules;**
- **reference to performing a physical count in Major Deficiencies #13 and #14 of Guidance Document 110-9 shall be stricken; and,**
- **staff shall apply this guidance toward any open disciplinary cases involving the citing of Major Deficiency #13 or #14 related to inventory, wherein a physical count was not performed. (motion by Beckner, second by Dabney)**

- Status of pharmacy routine inspection program

Mr. Johnson provided statistics indicating the percentage of community pharmacies cited no deficiencies, deficiencies, and deficiencies that resulted in a monetary penalty covering a period of time from July 1, 2010 to February 28, 2011. Between July 1, 2010 and November 30, 2010, 42% of the inspected pharmacies were cited deficiencies that resulted in a monetary penalty. Between December 1, 2010 and February 28, 2011, 58% or 66 pharmacies were cited deficiencies that resulted in a monetary penalty. Of the 66 pharmacies, 46 were cited with Major Deficiency #15 regarding requirements for a perpetual inventory of drugs in Schedule II. Additionally, Mr. Johnson provided statistics for the hospital pharmacies where a pilot inspection had been recently performed. Between December 1, 2010 and February 28, 2011, 80% or 8 hospital pharmacies were cited a deficiency resulting in a monetary penalty. Of the 16 hospital pharmacies inspected between July 1, 2010 and February 28, 2011, 12 were cited for a Minor Deficiency #38 regarding automated dispensing devices.

- Guidance Document 110-9, perpetual inventories

There was discussion concerning the frequent citing of Major Deficiency #15 regarding perpetual inventories and recent examples

of pharmacists cited with the deficiency for performing the monthly perpetual inventory either one day before or after the applicable calendar month. After further discussion, the Board determined that Major Deficiency #15 should be amended to allow the monthly perpetual inventory to be performed as early as seven days prior to the applicable calendar month and as late as seven days after the applicable calendar month.

Motion:

The Board voted unanimously to amend Major Deficiency #15 in Guidance Document 110-9 to read "Perpetual inventory not being maintained as required; perpetual inventory performed more than seven days prior or more than seven days after designated calendar month for which an inventory is required" and to not apply this change to any disciplinary cases opened prior to March 9, 2011. (motion by Kozera, second by Beckner)

- Guidance Document 110-9, USP 797 physical standards

Mr. Johnson noted that during a recent pilot inspection of a hospital pharmacy, the pharmacy had a clean room but that not all physical requirements were compliant, e.g., ceiling, flooring. Ms. Juran stated that a monetary penalty of $5,000 is imposed for Major Deficiency #21 when a pharmacy performing sterile compounding has no clean room, but there is no deficiency listed in the guidance document when the clean room does not comply with all physical standards of USP Chapter 797.

Motion:

The Board voted unanimously to add Major Deficiency #32 to Guidance Document 110-9 which would read "Have clean room, but not all physical standards in compliance, e.g., flooring, ceiling" and to impose a $2,000 monetary penalty when citing this deficiency. (motion by Shinaberry, second by Ross)

- Guidance Document 110-9, automated dispensing devices

There was discussion regarding the frequency in citing Minor Deficiency #38 regarding automated dispensing devices in hospitals. Ms. Juran informed the Board that she had been made aware that a petition for rulemaking to amend the applicable regulation would be received by the Board prior to the June 2011 board meeting. Therefore, it was suggested that the Board not take any action on this deficiency until it reviews the petition for rulemaking. Additionally, Ms. Juran noted that the inspection process will have been active for one year in June 2011 and that overall it has been a successful initiative, however, the Board may want a committee to review the deficiencies listed in Guidance Document 110-9 and make any necessary revisions prior to inspections going "live" in hospital pharmacies.

Action Item:

The Board determined that Ms. Juran should send an email to all board members soliciting participation on an ad hoc

committee to review the inspection process and the deficiencies identified in Guidance Document 110-9, and that Mr. Yi would appoint at least three board members to this committee.

- Agency Operating Efficiency Measures, sending agenda packets

Ms. Juran reported that the agency is attempting to increase electronic communication to reduce mailing costs and wanted to know if agenda packets for business matters could be scanned and sent via email, in lieu of mailing hard copies. The concept was generally accepted, although some may prefer a hard copy to be provided at the time of the meeting.

Action Item:

The Board determined that Ms. Juran should send an email to all board members to determine individual preferences for receiving agenda packets for business matters.

REPORTS:

- Report on DEA public meetings for surrender of unwanted controlled substances, National Take Back Day, PMP regulatory action

Ralph Orr, Program Director for Virginia's Prescription Monitoring Program (PMP) reported that he attended a public meeting conducted by the DEA on January 19-20, 2011 in Washington, D.C. The purpose of the meeting was to hear comments to assist DEA in developing regulations to implement the Secure and Responsible Drug Disposal Act of 2010 regarding procedures for the surrender of unwanted controlled substances by the ultimate user. Mr. Orr stated that there seemed to be a great deal of consensus on many facets of the issues to include the following:

- The need for a range of options for secure disposal of controlled substances and other pharmaceutical drugs-convenience and accessibility is essential;
- Take-back programs should be able to include both controlled and non-controlled substances without sorting them;
- Security of the medications to be disposed of is critical, including tracking of containers, tamper evident seals, locked containers, and other such measures;
- Regulations should not require that individual pills/vials/etc. be counted and logged. Many presenters suggested logging by weight;
- Allow different means of destruction of collected meds while contemplating hazard requirements; and
- Cost to consumers and states must be considered.

Mr. Orr reminded the members that the Board of Pharmacy had responded to a request for comment on several questions related to drug take back, disposal, and destruction from DEA in 2009, these comments along with others from that solicitation and the comments received at the public meeting will form the basis of regulations.

National Drug Take Back Day:
Mr. Orr announced that the DEA has declared April 30, 2011 to be the second National Drug Take Back Day. The first event held in September 2010 resulted in over 2.5 tons of unused/unwanted medications being turned in at over 82 sites across Virginia. There are already over 15 sites signed up for collection in the areas surrounding Richmond. Mr. Orr stated that the DEA is carrying the bulk of the financial burden for this project at this time with some hazardous waste incineration companies providing destruction services at no cost for this specific project. More information about the take back day and listings of collections sites may be found at: www.deadiversion.usdoj.gov.

PMP Interoperability Announcement:
Mr. Orr announced that Virginia and Ohio are the first states to sign a Memorandum of Understanding with the National Association of Boards of Pharmacy (NABP) to participate in NABP's new Interconnect Hub for PMP Interoperability. This new project from NABP is scheduled to begin a pilot phase in May and be fully operational in September 2011. The hub will be the conduit or switch that enables a user in one state to receive data from their home state PMP as well as other state PMPs that are participating in the hub without having to be registered in each state. However, each state PMP maintains control over the type of user who may receive PMP data from their program.

Regulatory Action Regarding PMP Reporting Requirements:
Mr. Orr explained that information has been posted on Virginia Town Hall for exempt regulations to be published March 14, 2011 in the Virginia Register. The regulations are exempt from the APA because the changes are directly related to minimum eligibility requirements necessary for federal grant funding. The changes in the regulation include a change from twice monthly reporting of data to once weekly, changing from ASAP Standard 95 to ASAP Standard Version 4.1. Additionally, specific data elements have been changed or added: 1. The Drug Enforcement Administration (DEA) registration number of the dispenser; 2. The total number of refills ordered; 3. Whether the prescription is a new prescription or a refill; and, 4. The date the prescription was written by the prescriber. These changes will become effective October 1, 2011. A new reporting manual detailing the updated reporting requirements is being developed and will be made available to dispensers within the next 60-70 days. Mr. Orr explained that these changes will keep the program eligible for funding to make enhancements to the program in the future, such as taking advantage of new technology and improving the use of the program for users.

- Report on Board of Health Professions

Mr. Kozera reported that the Board of Health Professions met on February 15, 2011. Discussions involved health care reform and a need for all boards to work toward meeting the needs of approximately 400,000 more patients who will be enrolled in Medicaid in 2014. Current scopes of practice should be evaluated in an effort to become more efficient at meeting the patients' needs. Additionally, Mr. Kozera reported that Dr. Cane discussed agency operating efficiency measures at the February meeting and the development of staff committees to review and possibly implement these recommended efficiencies. Mr. Kozera also stated that he has agreed to participate on the Regulatory Research Committee which is currently reviewing the possible need to license genetic counselors.

- Report on disciplinary matters

Ms. Reiniers-Day presented the Board's disciplinary caseload report as of March 8, 2011, and stated that there were 274 cases docketed for the Board of Pharmacy. Three cases were at the entry level as just received; 59 cases at the enforcement level; 82 cases were at the board level (probable cause); 15 cases were with APD for the drafting of documents; one case was at the informal conference level; one case was at the formal hearing level and it was expected that the respondent would withdraw the appeal; and 113 cases were at the pending closure level wherein staff was expecting signed consent orders or confidential consent agreements.

- Executive Director's report

Ms. Juran stated that the contract for the administrator of the Virginia Federal and State Drug Law Exam had been awarded; the new contractor will begin administering the examination on July 1, 2011. The candidates' cost for taking the exam will increase slightly from $100 to $112, but she noted that it had been several years since this price was last adjusted.

Additionally, she reported that a Pharmacy Workforce Advisory Committee met on February 25, 2011, to begin drafting an online survey to assess workforce issues regarding pharmacists and, possibly, pharmacy technicians. Licensees will have the opportunity to complete the survey when renewing their licenses online this December. The committee will meet again in the next few months via teleconference.

It was also reported that the NABP Annual Meeting will be held May 21-24, 2011, in San Antonio, TX and that Ms. Juran plans to attend using travel reimbursement funds provided by NABP. She encouraged other board members to attend, but stated that the agency could not offer any travel money for their expenses.

Lastly, Ms. Juran stated that Mr. Kozera and Mr. Yi have informed her of a scheduling conflict with the September 7, 2011 board

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meeting date; alternate dates were discussed. A tentative date of September 22, 2011 was set.

NEW BUSINESS

There was no new business discussed.

ADJOURN:

With all business concluded, the meeting adjourned at 1:05 p.m.

Caroline D. Juran
Executive Director

Date

Brandon Yi, Chairman

Date

DRAFT UNAPPROVED

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF AD HOC COMMITTEE REGARDING ON-HOLD PRESCRIPTIONS

May 17, 2011
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 12:35AM.
PRESIDING:	Brandon Yi, Chairman
MEMBERS PRESENT:	John O. Beckner David C. Kozera Robert M. Rhodes
STAFF PRESENT:	Caroline D. Juran, Executive Director J. Samuel Johnson, Jr., Deputy Executive Director
PUBLIC COMMENTS:	No public comments were given at this time.
DRAFT REGULATIONS REGARDING ON-HOLD PRESCRIPTIONS:	The committee reviewed a draft of regulations that had been prepared by staff regarding the filing of prescriptions, the defining of the term "on-hold prescription" and the data entry requirements associated with on-hold prescriptions. While reviewing the entire draft several edits were made. The final document will be presented to the full Board on June 8, 2011 with the opportunity to adopt the proposed regulations on September 22, 2011. (Attachment 1)
ADJOURN:	With all business concluded, the meeting adjourned at 2:35PM.

Caroline D. Juran
Executive Director

Brandon Yi, Chairman

Date

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BOARD OF PHARMACY

18VAC110-20-10. Definitions.

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

"ACPE" means the Accreditation Council for Pharmacy Education.

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

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

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

"Board" means the Virginia Board of Pharmacy.

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

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

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

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

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

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

"DEA" means the United States Drug Enforcement Administration.

"Drug donation site" means a permitted pharmacy that specifically registers with the board for the purpose of receiving or redispensing eligible donated prescription drugs pursuant to § 54.1-3411.1 of the Code of Virginia.

"Electronic prescription" means a written prescription that is generated on an electronic application in accordance with 21 CFR Part 1300 and is transmitted to a pharmacy as an electronic data file.

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

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

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

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

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

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

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

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

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

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

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

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

"Nuclear pharmacy" means a pharmacy providing radiopharmaceutical services.

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

<u>"On-hold prescription" means a valid prescription that is received and maintained at the pharmacy for initial dispensing on a future date.</u>

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

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

"Personal supervision" means the pharmacist must be physically present and render direct, personal control over the entire service being rendered or act being performed. Neither prior nor future

instructions shall be sufficient nor, shall supervision rendered by telephone, written instructions, or by any mechanical or electronic methods be sufficient.

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

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

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

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

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

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

"Quality assurance plan" means a plan approved by the board for on-going monitoring, measuring, evaluating, and, if necessary, improving the performance of a pharmacy function or system.

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

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

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

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

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

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

packaging which all such children cannot open or obtain a toxic or harmful amount within a reasonable time.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1. Inventories and records of all drugs listed in Schedules I and II shall be maintained separately from all other records of the pharmacy. Each pharmacy shall maintain a perpetual inventory of all Schedule II drugs received and dispensed, with reconciliation at least monthly. Electronic monitoring at the pharmacy or by another entity that provides alerts for discrepancies between drugs received and drugs dispensed is acceptable provided such alerts are reviewed at least monthly.

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

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

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

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

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

B. Prescriptions.

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

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

3. Schedule III through V drugs. Prescriptions for Schedule III through V drugs shall be maintained either in a separate prescription file for drugs listed in Schedules III, IV, and V only or in such form that they are readily retrievable from the other prescriptions of the pharmacy. Prescriptions will be deemed readily retrievable if, at the time they are initially filed, the face of the prescription is stamped in red ink in the lower right corner with the letter "C" no less than one inch high and filed in the prescription file for drugs listed in the usual consecutively numbered prescription file for Schedule VI drugs. However, if a pharmacy employs an automated data processing system or other electronic recordkeeping system for

prescriptions which permits identification by prescription number and retrieval of original documents by prescriber's name, patient's name, drug dispensed, and date filled, then the requirement to mark the hard copy prescription with a red "C" is waived.

C. Chart orders.

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

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

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

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

3. Requirements for filing of chart orders.

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

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

18VAC110-20-250. Automated data processing records of prescriptions.

A. An automated data processing system may be used for the storage and retrieval of original and refill dispensing information for prescriptions instead of manual record keeping requirements, subject to the following conditions:

1. A prescription shall be placed on file as set forth in 18VAC110-20-240 B with the following provisions:

a. In lieu of a hard copy file for Schedule VI prescriptions, an electronic image of a prescription may be maintained in an electronic database provided it preserves and provides an exact image of the prescription that is clearly legible and made available within 48 hours of a request by a person authorized by law to have access to prescription information. Storing electronic images of prescriptions for Schedule II-V controlled substances instead of the hard copy shall only be authorized if such storage is allowed by federal law.

b. If the pharmacy system's automated data processing system fields are automatically populated by an electronic prescription, the automated record shall constitute the prescription and a hard copy or electronic image is not required.

c. For Schedule II-V controlled substances, electronic prescriptions shall be maintained in accordance with federal law and regulation.

2. Any computerized system shall provide retrieval (via computer monitor display or printout) of original prescription information for those prescriptions which are currently authorized for dispensing.

3. Any computerized system shall also provide retrieval via computer monitor display or printout of the dispensing history for prescriptions dispensed during the past two years.

4. ~~Documentation of the fact that the information entered into the computer each time a pharmacist fills a prescription for a drug is correct shall be provided by the individual pharmacist who makes use of such system.~~ Documentation indicating that the information entered into the computer system is correct for each on-hold prescription or each prescription that is dispensed shall be provided by the individual pharmacist who makes use of such system. If a printout is maintained of each day's prescription dispensing data or data entry of an on-hold prescription, the printout shall be verified, dated and signed by the individual pharmacist who dispensed the prescription or verified the accuracy of the data entry. The individual pharmacist shall verify that the data indicated is correct and then sign the document in the same manner as his name appears on his pharmacist license (e.g., J. H. Smith or John H. Smith).

If a bound log book~~,~~ or separate file is maintained rather than a printout, each individual pharmacist involved in dispensing shall sign a statement each day in the log, in the manner previously described, attesting to the fact that the dispensing information and data entry of on-hold prescriptions entered into the computer that day has been reviewed by him and is correct as shown.

B. Printout of dispensing data requirements. Any computerized system shall have the capability of producing a printout of any dispensing data which the user pharmacy is responsible for maintaining under the Drug Control Act (§54.1-3400 et seq. of the Code of Virginia) and any data entry of on-hold prescriptions. s~~S~~uch printout shall be provided within 48 hours of a request of an authorized agent.

18VAC110-20-270. Dispensing of prescriptions; certification of completed prescriptions; supervision of pharmacy technicians.

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

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

C. After the prescription has been prepared and prior to the delivery of the order, the pharmacist shall inspect the prescription product to verify its accuracy in all respects, and place his initials on the record of dispensing as a certification of the accuracy of, and the responsibility for, the entire transaction. Such record showing verification of accuracy shall be maintained on a pharmacy record for the required time period of two years, unless otherwise specified in regulation

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

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

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

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF AD HOC COMMITTEE ON PHARMACY INSPECTIONS

May 18, 2011
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 9:00AM.
PRESIDING:	Brandon Yi, Chairman
MEMBERS PRESENT:	Gill Abernathy John Beckner David C. Kozera Ellen Shinaberry Pratt Stelly
STAFF PRESENT:	Caroline D. Juran, Executive Director J. Samuel Johnson, Jr., Deputy Executive Director Vicki Gwaltney Garrison, Pharmacy Inspector
PUBLIC COMMENTS:	No public comments were given at this time.
DRAFT REGULATIONS DEFINING UNPROFESSIONAL CONDUCT:	The committee reviewed Guidance Document 110-9 Pharmacy Inspection Deficiency Monetary Penalty Guide that had been prepared by staff regarding major and minor inspection deficiencies. While reviewing the entire draft several edits were made. The final document will be presented to the full Board on June 8, 2011 for adoption. (Attachment 1)
ADJOURN:	With all business concluded, the meeting adjourned at 11:30AM.

Caroline D. Juran
Executive Director

Brandon Yi, Chairman

Date

Guidance Document: 110-9

Revised: ~~3/9/11~~ 6/8/11

Virginia Board of Pharmacy
Pharmacy Inspection Deficiency Monetary Penalty Guide

Major Deficiency	Law/Reg Cite	Conditions	$ Penalty
1. No PIC or PIC not fully engaged in practice at pharmacy location	54.1-3434 and 18VAC110-20-110	must have documentation	1000
2. PIC in place, inventory taken, but application not filed with Board	54.1-3434 and 18VAC110-20-110		100
3. Unregistered persons performing duties restricted to pharmacy technician when not enrolled in a Board-approved pharmacy technician training program or beyond 9 months	54.1-3321 and 18VAC110-20-111	per individual	250
4. Pharmacists/pharmacy technicians/pharmacy interns performing duties on an expired license/registration	18VAC110-20-80, 18VAC110-20-40, and 18VAC110-20-105	per individual	100
5. Pharmacy technicians, pharmacy interns without monitoring, or unlicensed persons engaging in acts restricted to pharmacists	54.1-3320		500
6. Exceeds pharmacist to pharmacy technician ratio	54.1-3320	per each technician over the ratio	100
7. COL or remodel without application or Board approval	18VAC110-20-140	must submit an application and fee	250
8. Refrigerator/freezer temperature out of range greater than +/- 4 degrees	18VAC110-20-150 and 18VAC110-20-10	determined using inspector's or pharmacy's calibrated thermometer	100 Drugs may be embargoed

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Guidance Document: 110-9

Revised: ~~3/9/11~~ 6/8/11

Major Deficiency	Law/Reg Cite	Conditions	$ Penalty
9. Alarm not operational or not being set	18VAC110-20-180 and 18VAC110-20-190		1000
9a. Alarm incapable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational. Alarm is operational but does not fully protect the prescription department and/or is not capable of detecting breaking by any means when activated.	18VAC110-20-180		250
10. Unauthorized access to alarm or locking device for Rx department	18VAC110-20-180 and 18VAC110-20-190		1000
11. Insufficient enclosures or locking devices	18VAC110-20-190		500
12. Storage of Rx drugs not in prescription department	18VAC110-20-190		500
12a. Schedule II drugs are not dispersed with other schedules of drugs or maintained in a securely locked cabinet, drawer, or safe.	18VAC110-20-200		250
13. No biennial inventory, or over 30 days late, or substantially incomplete, i.e., did not include all drugs in Schedules II-V	54.1-3404 and 18VAC110-20-240		500
14. No incoming change of PIC inventory taken within 5 days or substantially incomplete, i.e., did not include all drugs in Schedules II-V	54.1-3434 and 18VAC110-20-240		500
15. Perpetual inventory not being maintained as required; perpetual inventory performed more than 7 days prior or more than 7 days after designated calendar month for which an inventory is required	18VAC110-20-240		250
16. Theft/unusual loss of drugs not reported to the Board as required or report not maintained	54.1-3404 and 18VAC110-20-240	per report/theft-loss	250

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Guidance Document: 110-9

Revised: ~~3/9/11~~ 6/8/11

Major Deficiency	Law/Reg Cite	Conditions	$ Penalty
17. Hard copy prescriptions not maintained or retrievable as required (i.e. hard copy of fax and refill authorizations for Schedule II, II, IV & V drugs)	54.1-3404 and 18VAC110-20-240		250
18. Records of dispensing not maintained as required	54.1-3404, 18VAC110-20-240, 18VAC110-20-250, 18VAC110-20-420, and 18VAC110-20-425		250
19. Pharmacists not verifying or failing to document verification of accuracy of dispensed prescriptions	18VAC110-20-270, 18VAC110-20-420 and 18VAC110-20-425	10% threshold for documentation	500
20. Pharmacist not checking and documenting repackaging, compounding, or bulk packaging	54.1-3410.2, 18VAC110-20-355 and 18VAC110-20-425	10% threshold	250
21. No clean room	54.1-3410.2		5000
22. Certification of the direct compounding area (DCA) for CSPs indicating ISO Class 5 over 60 days late (6mo + 60 days)	54.1-3410.2		~~3000 per DCA~~ 3000
23. Certification of the buffer or clean room and ante room indicating ISO Class 7 / ISO Class 8 or better over 60 days late (6mo+60 days). Corrective action not taken within one month of certification report.	54.1-3410.2	Review 2 most recent reports	~~1000 per area~~ 1000
24. Sterile compounding of hazardous drugs performed in an area not physically separated from other preparation areas.	54.1-3410.2	Low volume defined as 15 or less hazardous drug CSP/week. Review 2 months records.	2000

Guidance Document: 110-9

Revised: ~~3/9/11~~ 6/8/11

Major Deficiency	Law/Reg Cite	Conditions	$ Penalty
25. No documentation of sterilization methods or endotoxin pyrogen testing for high-risk level CSPs; or, no documentation of initial and semi-annual media-fill testing for persons performing high-risk level CSPs; or, documentation that a person who failed a media-fill test has performed high-risk level CSPs after receipt of the negative test result and prior to retraining and receipt of passing media-fill test; or, high-risk drugs intended for use are improperly stored.	54.1-3410.2		5000 per incident within previous 30 days
26. Training documentation involving media-fill tests for low and medium-risk levels not maintained for > 30% of individuals preparing CSPs, or no documentation maintained of a passing media-fill test for any individual preparing low and medium-risk CSPs >45 days after receipt of a failed media-fill test	54.1-3410.2		500
27. Compounding using ingredients in violation	54.1-3410.2		1000
28. Compounding copies of commercially available products	54.1-3410.2	per Rx dispensed up to maximum of 100 RX or $5000	50
29. Unlawful compounding for further distribution by other entities	54.1-3410.2		500
30. Security of after-hours stock not in compliance	18VAC110-20-450		500
31. For LTC, ADD being accessed for orders prior to pharmacist review and release	18VAC110-20-555		250
32. Have clean room, but not all physical standards in compliance, e.g., flooring, ceiling	54.1-3410.2		2000

Guidance Document: 110-9

Revised: ~~3/9/11~~ 6/8/11

Minor Deficiencies

If three (3) or more minor deficiencies are cited, a $250 monetary penalty shall be imposed. Another $100 monetary penalty will be added for each additional minor deficiency over the initial three.

Minor Deficiency	Law/Regulation Cite	Conditions
General Requirements:		
1. Repealed ~~Site specific training documentation not maintained as required~~	~~18VAC110-20-111~~	
2. Special/limited-use scope being exceeded without approval	18VAC110-20-120	
3. Decreased hours of operation without public/Board notice	18VAC110-20-135	
4. No hot/cold running water	18VAC110-20-150	
5. No thermometer or non-functioning thermometer in refrigerator/freezer, but within range, +/-4 degrees	18VAC110-20-150 and 18VAC110-20-10	determined using inspector's calibrated thermometer
6. Rx department substantially not clean and sanitary and in good repair	18VAC110-20-160	must have picture documentation
7. Current dispensing reference not maintained	18VAC110-20-170	

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Guidance Document: 110-9

Revised: ~~3/9/11~~ 6/8/11

Minor Deficiency	Law/Regulation Cite	Conditions
8. Emergency access alarm code/key not maintained in compliance	18VAC110-20-190	
9. Expired drugs in working stock, dispensed drugs being returned to stock not in compliance, dispensed drugs returned to stock container or automated counting device not in compliance. (i.e. appropriate expiration date not placed on label of returned drug, mixing lot numbers in stock container)	54.1-3457 18VAC110-20-200 18VAC110-20-355	10% threshold
10. Storage of paraphernalia/Rx devices not in compliance	18VAC110-20-200	
11. Storage of will-call not in compliance	18VAC110-20-200	
12. Biennial taken late but within 30 days	54.1-3404 and 18VAC110-20-240	
13. Inventories taken on time, but not in compliance, i.e., no signature, date, opening or close, CII not separate	54.1-3404, 54.1-3434 and 18VAC110-20-240	
14. Records of receipt (invoices) not on site or retrievable	54.1-3404 and 18VAC110-20-240	
15. Other records of distributions not maintained as required	54.1-3404 and 18VAC110-20-240	
16. Prescriptions do not include required information. Prescriptions not transmitted as required (written, oral, fax, electronic, etc.)	54.1-3408.01, 54.1-3408.02, 54.1-3410, 18VAC110-20-280 and 18VAC110-20-285 ~~54.1-3408.01 and 54.1-3410~~	10% threshold
17. Minor 17 combined with Minor 16 – 6/2011 ~~Prescriptions not transmitted as required (written, oral, fax, electronic, etc.)~~	~~54.1-3408.01, 54.1-3408.02, 54.1-3410, 18VAC110-20-280 and 18VAC110-20-285~~	~~10% threshold~~

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Guidance Document: 110-9

Revised: ~~3/9/11~~ 6/8/11

Minor Deficiency	Law/Regulation Cite	Conditions
18. CII emergency oral prescriptions not dispensed in compliance	54.1-3410 and 18VAC110-20-290	>3
19. Not properly documenting partial filling	54.1-3412, 18VAC110-20-255, 18VAC110-20-310, and 18VAC110-20-320	
20. Offer to counsel not made as required	54.1-3319	
21. Prospective drug review not performed as required	54.1-3319	
22. Engaging in alternate delivery not in compliance	18VAC110-20-275	
23. Engaging in remote processing not in compliance	18VAC110-20-276 and 18VAC110-20-515	
24. Labels do not include all required information	54.1-3410, 54.1-3411 and 18VAC110-20-330	Review 25 prescriptions
25. Compliance packaging or labeling does not conform to USP requirements	18VAC110-20-340	
26. Special packaging not used or no documentation of request for non-special packaging	54.1-3426, 54.1-3427 and 18VAC110-20-350	10% threshold Review 25 prescriptions

Guidance Document: 110-9

Revised: ~~3/9/11~~ 6/8/11

Minor Deficiency	Law/Regulation Cite	Conditions
Repackaging, specialty dispensing, compounding:		
27. Repackaging records and labeling not kept as required or in compliance	18VAC110-20-355	10% threshold
28. Unit dose procedures or records not in compliance	18VAC110-20-420	
29. Robotic pharmacy systems not in compliance	18VAC110-20-425	
30. Required compounding/dispensing/distribution records not complete and properly maintained; compounded products not properly labeled or assigned appropriate expiration date	54.1-3410.2	
31. Required "other documents" for USP 797 listed on inspection report are not appropriately maintained	54.1-3410.2	30% threshold
32. Personnel performing CSPs do not comply with cleansing and garbing requirements	54.1-3410.2	30% threshold
33. Compounding facilities and equipment used in performing non-sterile compounds not in compliance	54.1-3410.2	
Hospital specific or long-term care specific:		
34. Policies and procedures for proper storage, security and dispensing of drugs in hospital not established or assured	18VAC110-20-440	
35. Policies and procedures for drug therapy reviews not maintained or followed	18VAC110-20-440	

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Guidance Document: 110-9

Revised: ~~3/9/11~~ 6/8/11

Minor Deficiency	Law/Regulation Cite	Conditions
36. After hours access or records not in compliance	18VAC110-20-450	10% threshold
37. Floor stock records not in compliance, pharmacist not checking, required reconciliations not being done	18VAC110-20-460	10% threshold
38. ADD loading, records, and monitoring/reconciliation not in compliance	54.1-3434.02, 18VAC110-20-490 and 18VAC110-20-555	
39. EMS procedures or records not in compliance	18VAC110-20-500	10% threshold
40. Emergency kit or stat-drug box procedures or records not in compliance	18VAC110-20-540 and 18VAC110-20-550	10 % threshold
41. Maintaining floor stock in LTCF not authorized	18VAC110-20-520 and 18VAC110-20-560	

DRAFT

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF AD HOC COMMITTEE REGARDING CQI PROGRAMS

May 18, 2011
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 11:45AM.

PRESIDING: Brandon Yi, Chairman

MEMBERS PRESENT:
John O. Beckner
Gill Abernathy
Ellen Shinaberry
Rick Baxter
Tim Musselman
Anila Xhixho

MEMBERS ABSENT: Michelle Lincoln

STAFF PRESENT:
Caroline D. Juran, Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director

PUBLIC COMMENTS: Hunter Jamerson representing EPIC pharmacies stated he would review the committee's decisions with his client, specifically the broad definition for "dispensing error", and offer comment during the regulatory process.

DRAFT REGULATIONS REGARDING CONTINUOUS QUALITY IMPROVEMENT PROGRAMS:

A committee representing various fields of pharmacy practice reviewed information contained in the agenda packet and concluded that HB 2220 requires the drafting of regulations for pharmacies to either implement a continuous quality improvement program or actively report to a patient safety organization. Discussion primarily focused on answering the questions, prepared by staff, regarding possible subject matter for inclusion in the regulations. It was determined that staff will prepare a draft of regulations to be presented to the Committee at a future date that will incorporate any identified subject matter resulting from the discussion. Final draft regulations will be presented to the full Board for consideration on September 22, 2011.

The Committee determined the following concepts shall be included in the draft regulations:

- Definition of "dispensing error" to mean
    1. a variation from the prescriber's prescription drug order, including, but not limited to:
        - Incorrect drug;
        - Incorrect drug strength;

- Incorrect dosage form;
- Incorrect patient; or
- inadequate or incorrect packaging, labeling, or directions;

2. a failure to identify and manage:
   - therapeutic duplication;
   - drug-disease contraindications, if known;
   - drug-drug interactions, if known;
   - incorrect drug dosage or duration of drug treatment;
   - drug-allergy interactions; or
   - a clinically significant delay in therapy;
3. a delivery of a medication to the wrong patient or unit, and the failure to detect and appropriately manage a significant actual or potential problem with a patient's drug therapy; and
4. a variation in bulk repackaging or filling of automated counting devices, including, but not limited to:
   - Incorrect drug;
   - Incorrect drug strength;
   - Incorrect dosage form; or
   - Inadequate or incorrect packaging or labeling;

- An immediate requirement to report a dispensing error to the pharmacist on-duty;
- A requirement to initiate documentation of the dispensing error as soon as possible, not to exceed 3 days from determining their occurrence;
- A requirement that the documentation shall include, at a minimum, a description of the event that is sufficient to permit categorization and analysis of the event;
- A requirement that the pharmacist-in-charge or designee shall review each reportable dispensing error, analyze data collected and documented, assess the cause and any factors contributing to the dispensing error, to include any recommendations for remedial changes;
- A requirement to notify patient and prescriber when a patient has self-administered or been administered an incorrect drug;
- Language required for protection from discovery;
- An allowance to rid of the documentation regarding a dispensing error after the quality assurance analysis has been performed;
- A requirement to maintain a record indicating dates when the quality assurance analyses were performed, names of participants, general description of dispensing error, and

corrective actions taken, if any;

- A requirement that the patient safety organization must be credentialed by the Agency for Healthcare Research Quality; and
- A definition of the term "actively reports" means documenting a dispensing error as soon as possible, not to exceed 3 days from determining their occurrence and reporting all reportable dispensing errors to the patient safety organization weekly.

ADJOURN: With all business concluded, the meeting adjourned at approximately 2:30PM.

Caroline D. Juran
Executive Director

Brandon Yi, Chairman

Date

2012 Legislation – Pharmacy

Rescheduling bill

In agenda package:

- Copy of draft legislation

Board action:

- Consider draft language
- Adopt draft legislation as proposed or with amendments

Board of Pharmacy
2012 Session of the General Assembly

Draft Legislation

A BILL to amend and reenact §54.1-3452 of the Code of Virginia, relating to the addition of carisoprodol and tramadol in Schedule IV.

Be it enacted by the General Assembly of Virginia:

1. That §54.1-3452 of the Code of Virginia is amended and reenacted as follows:

§ 54.1-3452. Schedule IV.

The controlled substances listed in this section are included in Schedule IV unless specifically excepted or listed in another schedule:

1. Any material, compound, mixture, or preparation which contains any quantity of the following substances having a potential for abuse associated with a depressant effect on the central nervous system:

Alprazolam;

Barbital;

Bromazepam;

Camazepam;

Carisoprodol;

Chloral betaine;

Chloral hydrate;

Chlordiazepoxide;

Clobazam;

Clonazepam;

Clorazepate;

Clotiazepam;

Cloxazolam;

Delorazepam;

Diazepam;

Dichloralphenazone;

Estazolam;

Ethchlorvynol;

Ethinamate;

Ethyl loflazepate;

Fludiazepam;

Flunitrazepam;

Flurazepam;

Halazepam;

Haloxazolam;

Ketazolam;

Loprazolam;

Lorazepam;

Lormetazepam;

Mebutamate;

Medazepam;

Methohexital;

Meprobamate;

Methylphenobarbital;

Midazolam;

Nimetazapam;

Nitrazepam;

Nordiazepam;

Oxazepam;

Oxazolam;

Paraldehyde;

Petrichloral;

Phenobarbital;

Pinazepam;

Prazepam;

Quazepam;

Temazepam;

Tetrazepam;

Triazolam;

Zaleplon;

Zolpidem;

Zopiclone.

2. Any compound, mixture or preparation which contains any quantity of the following substances including any salts or isomers thereof:

Fenfluramine.

3. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers (whether optical, position, or geometric), and salts of such isomers whenever the

existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

Cathine (+)-norpseudoephedrine;

Diethylpropion;

Fencamfamin;

Fenproprex;

Mazindol;

Mefenorex;

Modafinil;

Phentermine;

Pemoline (including organometallic complexes and chelates thereof);

Pipradrol;

Sibutramine;

SPA (-)-1-dimethylamino-1, 2-diphenylethane.

4. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as set forth below:

Dextropropoxyphene (alpha-(+)-4-dimethylamino-1, 2-diphenyl-3-methyl-2-propionoxy butane);

Not more than 1 milligram of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit.

5. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances, including their salts:

Butorphanol (including its optical isomers);

Pentazocine;

Tramadol.

6. The Board may except by regulation any compound, mixture, or preparation containing any depressant substance listed in subdivision 1 from the application of all or any part of this chapter if the compound, mixture, or preparation contains one or more active medicinal ingredients not having a depressant effect on the central nervous system, and if the admixtures are included therein in combinations, quantity, proportion, or concentration that vitiate the potential for abuse of the substances which have a depressant effect on the central nervous system.

Regulatory Actions

(As of May 27, 2011)

Board of Pharmacy

Chapter	Action / Stage Information
Virginia Board of Pharmacy Regulations [18 VAC 110 - 20]	Action: Administrative fees for duplicate licenses and verification Stage: NOIRA - *Register Date: 4/11/11; Comment closed 5/11/11 Board to adopt proposed regulations 6/8/11*
Virginia Board of Pharmacy Regulations [18 VAC 110 - 20]	Action: Amendments to address on-hold prescriptions Stage: NOIRA - *Register Date: 5/9/11; Comment closes 6/8/11 Board to adopted proposed regulations in Sept.*
Virginia Board of Pharmacy Regulations [18 VAC 110 - 20]	Action: Repackaging in CSB's and BHA's Stage: Proposed - *At Secretary's Office for 26 days Replacement of emergency regulations to expire on 12/19/11*
Virginia Board of Pharmacy Regulations [18 VAC 110 - 20]	Action: Elimination of alarm system for certain EMS agencies Stage: Fast-Track - *At Governor's Office for 304 days*

Fast-track for CE Requirements

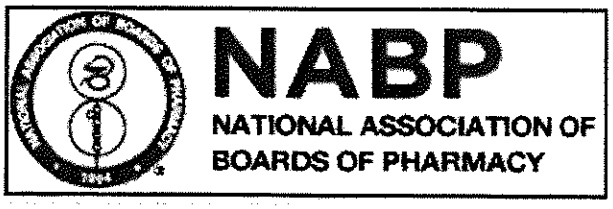
In agenda package:

- Background information from NABP regarding new CPE Monitor Service

Handout to be provided with draft proposed regulations

Board action:

- Consider draft language
- Adopt fast-track regulations as proposed or with amendments



Programs

CPE Monitor

- CPE Monitor Service
  - CPE Monitor Log In
  - Pharmacists
  - Technicians
  - FAQs

Examination Licensure Accreditation Assessment Consumer Protection Member Services

CPE Monitor Service

™ CPE Monitor is a national, collaborative effort by NABP and the Accreditation Council for Pharmacy Education (ACPE) to provide an electronic system for pharmacists and pharmacy technicians to track their completed continuing pharmacy education (CPE) credits. It will also offer state boards of pharmacy the opportunity to electronically authenticate the CPE units completed by their licensees, rather than requiring pharmacists and technicians to submit their proof of completion statements upon request or for random audits.

This initiative will streamline processes for pharmacy practitioners to ensure they are maintaining professional competency requirements. CPE Monitor is expected to save pharmacists, pharmacy technicians, state boards of pharmacy, and CPE providers time and money.

Get an Early Start!

To prepare for the new process, pharmacists and technicians are encouraged to obtain their NABP e-Profile ID now to ensure their e-Profile is properly setup. In the latter part of 2011, the e-Profile ID will be required to receive credit for anyCPE activities taken from ACPE-accredited providers.

Set up your NABP e-Profile to obtain your ID

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How it Works

Pharmacists and pharmacy technicians will receive a unique ID after setting up their e-Profile with NABP. Beginning in the latter part of 2011, they will provide their NABP e-Profile ID and date of birth to the ACPE-accredited provider when they register for CPE or submit a request for credit. The system will then direct electronic data from ACPE-accredited providers to ACPE and then to NABP, ensuring that CPE credit is officially verified by the providers. Once information is received by NABP, pharmacists and pharmacy technicians will be able to log in to access information about their completed CPE activities. After a transition period, ACPE-accredited CPE providers will no longer be required to distribute statements of credit.

In addition, boards of pharmacy will have the option of requesting reports on their licensees, eliminating the need for pharmacists and technicians to send paper copies of CPE statements of credit. Instead, records kept in CPE Monitor will be sent to the boards for CPE activities taken from ACPE-accredited providers.

In Phase 2 of the CPE Monitor initiative, CPE Monitor will add a function to record CPE from providers not accredited by ACPE in addition to CPE activities from ACPE-accredited providers. Until Phase 2 is completed, pharmacists and technicians will need to submit proof of completion of CPE from providers not accredited by ACPE directly to the board of pharmacy when required to do so.

Benefiting Pharmacists and Pharmacy Technicians

CPE Monitor will provide a secure, central system that maintains and tracks all continuing education credit from ACPE-accredited providers. This streamlined process will eliminate the need to file and maintain hard copy CPE statements of credit for CPE activities taken from ACPE-accredited providers. Instead, online access to their inventory of completed credits will allow pharmacists and pharmacy technicians to easily monitor their compliance with the CPE requirements of the state or states where they hold a license or registration. Licensees of participating boards will no longer have to mail hard copy proof of CPE statements of credit to those boards.

For added convenience, the NABP e-Profile is available 24/7 for pharmacists and technicians to view a comprehensive list of the CPE activities they have taken.

All information will be maintained in a highly secure environment. NABP will not distribute any personal information for commercial purposes without consent.

Assisting State Boards

This new program's central repository of CPE information will enable efficient verification of a pharmacist's or pharmacy technician's completed CPE upon board request. It may reduce the need to conduct state-based audits of board licensees. State boards of pharmacy that participate in the program will be able to use this new tool to assist them in ensuring that pharmacists and pharmacy technicians have completed state-mandated CPE requirements for re-licensure, re-certification, or re-registration.

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Recent News

- 2010-2011 Report of the Committee on Law Enforcement/Legislation Released
- 2010-2011 Report of the Task Force to Review and Recommend Revisions to the Controlled Substances Act Issued
- Task Force on Pharmacy Practice Technology Systems (Resolution 107-1-11)
- Information Exchange for Prescription Monitoring Programs (Resolution 107-2-11)
- Control and Accountability of Prescription Medications (Resolution 107-3-11)

More Newsroom Headlines »

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Proposed Regulations for New Administrative Fees

In agenda package:

- Copy of proposed regulations

Board action:

- Adopt proposed regulations as presented or with amendments

	VA.R. Document Number: R____-_____
	Virginia Register Publication Information Date: 4/11/2011 Issue: 16 Volume: 27
3/28/2011 10:13 am Date / Time filed with the Register of Regulations	

Transmittal Sheet: Notice of Intended Regulatory Action

Regulatory Coordinator: Elaine J. Yeatts

(804)367-4688

elaine.yeatts@dhp.virginia.gov

Promulgating Board: Board of Pharmacy

NOIRA Notice:	Notice is hereby given in accordance with § 2.2-4007.01 of the Code of Virginia that the Boa intends to consider amending the following regulations
Chapters Affected:	
18 vac 110 - 20:	Virginia Board of Pharmacy Regulations
18 vac 110 - 50:	Regulations Governing Wholesale Distributors, Manufacturers and Warehousers
Action Title:	Administrative fees for duplicate licenses and verification
Agency Summary:	The purpose of the proposed action is summarized as follows: Will add administrative fees for additional services requested by regulants for duplicate licen of licensure
Statutory Authority:	State: Chapters 33 and 34 of Title 54.1

Is a public hearing planned for the proposed stage? Yes

Public comments may be submitted until 5:00 p.m. on 5/11/2011.

Agency Contact:	Caroline Juran, RPh Executive Director (804)367-4416 (804)527-4472 caroline.juran@dhp.virginia.gov
Contact Address:	Department of Health Professions 9960 Mayland Drive Suite 300 Richmond, VA23233-1463
APA Compliance:	This regulation has been adopted in accordance with the Administrative Process Act.

Action ID: 3444 Staqe ID: 5818 RIS Project ID:

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BOARD OF PHARMACY

Addition of administrative fees

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	$90
10. Innovative program approval. 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.	$250
11. Approval of a pharmacy technician training program	$150
12. 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.	
11. Approval of a pharmacy technician training program	$75 every two years

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 or within two years in the case of a pharmacy technician training program. 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
10. Approval of a pharmacy technician training program	$15

F. Reinstatement fees. Any person or entity attempting to renew a license, permit, or registration more than one year after the expiration date, or more than two years after the expiration date in the case of a pharmacy technician training program, 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. Approval of a pharmacy technician training program	$75

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
3. Duplicate license or registration	$10
4. Verification of licensure or registration	$25

I. For the annual renewal due on the stated dates, the following fees shall be imposed for a license, permit or registration:

1. Pharmacist active license – December 31, 2009	$50
2. Pharmacist inactive license – December 31, 2009	$25
3. Pharmacy technician registration – December 31, 2009	$15
4. Pharmacy permit – April 30, 2010	$210
5. Physician permit to practice pharmacy – February 28, 2010	$210
6. Medical equipment supplier permit – February 28, 2010	$140
7. Humane society permit – February 28, 2010	$20
8. Nonresident pharmacy – April 30, 2010	$210
9. Controlled substances registrations – February 28, 2010	$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 February 28, 2010, 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

I. The fee for verification of license or permit shall be $25.

Petitions for Rulemaking

Automated dispensing devices

In agenda package:

- Copy of petitions

Board action:

- None required at this meeting

COMMONWEALTH OF VIRGINIA
Board of Health Professions

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

(804) 367-4603 (Tel)
(804) 527-4466 (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,) Fuller, Courtney M.		
Street Address 3008 Rugby Road	**Area Code and Telephone Number** 804-358-9577	
City Richmond	**State** VA	**Zip Code** 23221
Email Address (optional) Courtney.fuller@hcahealthcare.com	**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.

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

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

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

Propose an amended rule allowing for a complete inspection of automated devices under the above mentioned regulation to be waived under certain circumstances as follows:

- The automated dispensing device is capable and is set to automatically identify and isolate the location of each drug within the device by barcode identification, thereby automatically verifying proper location. A report can be provided verifying such settings.
- Proper storage is verified electronically by devices that are capable of continuous temperature tracking of refrigerated storage, with documented temperature ranges, variance, and resolution.
- Expiration dates are automatically tracked by automated devices that are equipped with such capability, eliminating the need to access each individual location each month for manual date auditing. Proactive reporting allows for replacement of expiring products prior to their expiry.
- Security of drugs is automatically verified by electronic detection of cabinet, drawer, and pocket malfunctions and failures and is a continuous process. These are reviewed and corrected as they occur in order for the device to operate; the default in the event of such failures is to lock out any further operation. There are reports available to review mechanical errors related to such errors.
- Access codes may be verified by a "BioID" system utilizing fingerprint as the "pass code" after initial log-on in order to eliminate sharing or theft of pass codes. BioID can automatically be verified in the system settings as a default.

Automation has been designed and updated to improve drug storage, security, and safety, while streamlining work processes and increasing efficiencies. The above stated advancements in technology easily and automatically accommodate these currently manual processes.

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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:
Courtney M. Fuller

Date:
16 May 2011

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,) Dunavant, Karen L.		
Street Address 10705 Burr Oak Way	**Area Code and Telephone Number** 703-250-5236	
City Burke	**State** VA	**Zip Code** 22015
Email Address (optional) Karen.dunavant@hcahealthcare.com	**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.

18VAC110-20-490 Automated devices for dispensing and administration of drugs
Section 5

2. Please summarize the substance of the change you are requesting and state the rationale or purpose for the new or amended rule.
Please consider changing the audit process and/or parameters decrease the amount of time required to comply with monthly controlled substance audits. Section 5 should allow for hospitals with access to software that analyzes automated dispensing machine transactions (examples: RxAuditor, Pandora, etc) to bypass parts of the manual reconcillation process. Hospitals would still need to manually review overrides to ensure there was a doctor's order or any machine that was not on Profile mode (where doctor's orders automatically cross from the hospital's clinical system into the Automated Dispensing Machine).
Utilizing RxAuditor reports – the hospital was able to identify 4 possible diverters off of 1 report covering a month's transactions. Utilizing the method set forward in the regulations, these 4 possible diverters would not have been identified as quickly, because the audit only covers 24 hours and 3 of the employees were part-time/prn. The current process set forth by the regulation requires about 48 man-hours every month with little or no result. The RxAuditor reports quickly identified people outside of the norm compared to their peers on the same nursing unit – the narrowed investigations still took time (about 8 hours per employee or 32 man-hours) but the results speak for themselves.

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.§ 54.1-3404. Inventories of controlled substances required of certain persons; contents and form of record.

Signature: Karen Dunavant **Date:** 5/17/11

COMMONWEALTH OF VIRGINIA
Board of Health Professions

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

(804) 367-4603 (Tel)
(804) 527-4466 (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,) Annette Basler Reichenbaugh		
Street Address 5360 Ashleigh Rd	Area Code and Telephone Number 703-689-9036	
City Fairfax	State VA	Zip Code 22030
Email Address (optional) Annette.Reichenbaugh@hcahealthcare.com	Fax (optional) 703-689-9110	

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.

   18VAC110-20-490. Automated devices for dispensing and administration of drugs.
   Section 5
   5.a – covers reconciliation of all quantities of Schedule II thru V
   5.b - covers each device per month all patients for a time period of not less than 24 consecutive hours.

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

1). I recommend reviewing the overrides daily looking for trends
2). Utilize Rx Auditor report to determine if a focus review is necessary . . . Based on specific criteria.
3). Perform a focused review

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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.

None

Signature:
Annette Basler Reichenbaugh

Annette Basler Reichenbaugh

Date: May 16, 2011

Continuous Quality Improvement

In agenda package:

- Refer to minutes from ad hoc committee meeting – pages 19-21
- Copy of HB 2220 – pages 59-60

Board action:

- Motion to adopt NOIRA as proposed in meeting minutes or with amendments

VIRGINIA ACTS OF ASSEMBLY -- 2011 SESSION

CHAPTER 124

An Act to amend and reenact § 54.1-3434.1 of the Code of Virginia and to amend the Code of Virginia by adding in Article 2 of Chapter 34 of Title 54.1 a section numbered 54.1-3434.03, relating to continuous quality improvement of pharmacies.

[H 2220]

Approved March 15, 2011

Be it enacted by the General Assembly of Virginia:

1. That § 54.1-3434.1 of the Code of Virginia is amended and reenacted and that the Code of Virginia is amended by adding in Article 2 of Chapter 34 of Title 54.1 a section numbered 54.1-3434.03 as follows:

§ 54.1-3434.03. Continuous quality improvement program.

Each pharmacy shall implement a program for continuous quality improvement, according to regulations of the Board. Such program shall provide for a systematic, ongoing process of analysis of dispensing errors that uses findings to formulate an appropriate response and to develop or improve pharmacy systems and workflow processes designed to prevent or reduce future errors. The Board shall promulgate regulations to further define the required elements of such program.

Any pharmacy that actively reports to a patient safety organization that has as its primary mission continuous quality improvement under the Patient Safety and Quality Improvement Act of 2005 (P.L. 109-41), shall be deemed in compliance with this section.

§ 54.1-3434.1. Nonresident pharmacies to register with Board.

A. Any pharmacy located outside the Commonwealth that ships, mails, or delivers, in any manner, Schedule II through VI drugs or devices pursuant to a prescription into the Commonwealth shall be considered a nonresident pharmacy, shall be registered with the Board, shall designate a pharmacist in charge who is licensed as a pharmacist in Virginia and is responsible for the pharmacy's compliance with this chapter, and shall disclose to the Board all of the following:

1. The location, names, and titles of all principal corporate officers and the name and Virginia license number of the designated pharmacist in charge, if applicable. A report containing this information shall be made on an annual basis and within 30 days after any change of office, corporate officer, or pharmacist in charge.

2. That it maintains, at all times, a current unrestricted license, permit, certificate, or registration to conduct the pharmacy in compliance with the laws of the jurisdiction, within the United States or within another jurisdiction that may lawfully deliver prescription drugs directly or indirectly to consumers within the United States, in which it is a resident. The pharmacy shall also certify that it complies with all lawful directions and requests for information from the regulatory or licensing agency of the jurisdiction in which it is licensed as well as with all requests for information made by the Board pursuant to this section.

3. As a prerequisite to registering with the Board, the nonresident pharmacy shall submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the jurisdiction in which it is located. The inspection report shall be deemed current if the inspection was conducted within the past five years. However, if the nonresident pharmacy has not been inspected by the regulatory or licensing agency of the jurisdiction in which it is licensed within the past five years, the Board may accept an inspection report or other documentation from another entity that is satisfactory to the Board or the Board may cause an inspection to be conducted by its duly authorized agent and may charge an inspection fee in an amount sufficient to cover the costs of the inspection.

4. For a nonresident pharmacy that dispenses more than 50 percent of its total prescription volume pursuant to an original prescription order received as a result of solicitation on the Internet, including the solicitation by electronic mail, that it is credentialed and has been inspected and that it has received certification from the National Association of Boards of Pharmacy that it is a Verified Internet Pharmacy Practice Site, or has received certification from a substantially similar program approved by the Board. The Board may, in its discretion, waive the requirements of this subdivision for a nonresident pharmacy that only does business within the Commonwealth in limited transactions.

5. That it maintains its records of prescription drugs or dangerous drugs or devices dispensed to patients in the Commonwealth so that the records are readily retrievable from the records of other drugs dispensed and provides a copy or report of such dispensing records to the Board, its authorized agents, or any agent designated by the Superintendent of the Department of State Police upon request within seven days of receipt of a request.

6. That its pharmacists do not knowingly fill or dispense a prescription for a patient in Virginia in violation of § 54.1-3303 and that it has informed its pharmacists that a pharmacist who dispenses a

prescription that he knows or should have known was not written pursuant to a bona fide practitioner-patient relationship is guilty of unlawful distribution of a controlled substance in violation of § 18.2-248.

7. That it maintains a continuous quality improvement program as required of resident pharmacies, pursuant to § 54.1-3434.03.

The requirement that a nonresident pharmacy have a Virginia licensed pharmacist in charge shall not apply to a registered nonresident pharmacy that provides services as a pharmacy benefits administrator.

B. Any pharmacy subject to this section shall, during its regular hours of operation, but not less than six days per week, and for a minimum of 40 hours per week, provide a toll-free telephone service to facilitate communication between patients in the Commonwealth and a pharmacist at the pharmacy who has access to the patient's records. This toll-free number shall be disclosed on a label affixed to each container of drugs dispensed to patients in the Commonwealth.

C. Pharmacies subject to this section shall comply with the reporting requirements of the Prescription Monitoring Program as set forth in § 54.1-2521.

D. The registration fee shall be the fee specified for pharmacies within Virginia.

E. A nonresident pharmacy shall only deliver controlled substances that are dispensed pursuant to a prescription, directly to the consumer or his designated agent, or directly to a pharmacy located in Virginia pursuant to regulations of the Board.

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.

3. That the Board of Pharmacy shall work cooperatively with pharmacists representing all areas of pharmacy practice in implementing the requirements of this act.

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On-Hold Prescriptions

In agenda package:

- Minutes from ad hoc committee meeting; pages 11-18

Board action:

- None required at this meeting

Routine Inspection Program

In agenda package:

- Refer to minutes from ad hoc committee meeting – pages 20-29

Board action:

- Consider proposed changes to guidance document 110-9 as attached to minutes
- Motion to adopt changes to guidance document 110-9 as proposed or with amendments

Delegated Authority for Disciplinary Cases

In Board package:

- Statistics for key performance measures
- Board of Nursing guidance document 90-12

Board action:

- Consider and discuss disciplinary circumstances when professional staff may be delegated authority to issue confidential consent agreements, pre-hearing consent orders, and perform probable cause review and case closure

- Motion to adopt guidance document authorizing delegated authority as determined in discussion

KEY MEASURES-Quarter Ending 3/31/11	Clearance Rate	Percent of Pending Case Load Older than 250 Business Days	Percent of Patient Care Cases Resolved within 250 Working Days	Percent of Positive Customer Satisfaction	Percent of Initial Applications Processed within 30 Days of Completion
Audiology/Speech Pathology	0%	0%	n/a	100% (4)	100.0%
Counseling	150%	12%	100%	81.5% (9)	100.0%
Dentistry	65%	9%	90%	89.6% (9)	97.1%
Funeral Directing	75%	20%	100%	100% (2)	100.0%
Long Term Care Administrator	114%	12%	94%	92.6% (6)	100.0%
Medicine	98%	11%	95%	95.6% (82)	100.0%
Nurse Aide	105%	20%	96%	96.3% (45)	100.0%
Nursing	104%	8%	97%	95.6% (214)	99.7%
Optometry	133%	0%	50%	100% (2)	100.0%
Pharmacy	41%	7%	65%	98.7% (49)	100.0%
Physical Therapy	50%	20%	100%	98.9% (15)	100.0%
Psychology	154%	24%	100%	87.0% (14)	100.0%
Social Work	211%	18%	100%	91.4% (18)	100.0%
Veterinary Medicine	103%	3%	97%	95.8% (2)	98.5%
AGENCY	97%	11%	95%	95.2% (472)	99.9%

Virginia Department of Health Professions

Patient Care Disciplinary Case Processing Times: Quarterly Performance Measurement, Q3 2007 - Q3 2011

Dianne Reynolds-Cane, M.D.
Director

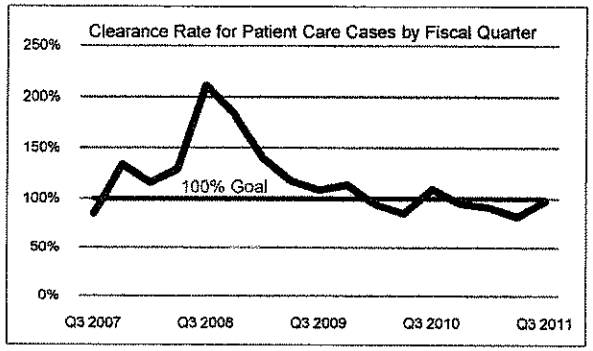
"To ensure safe and competent patient care by licensing health professionals, enforcing standards of practice, and providing information to health care practitioners and the public."
DHP Mission Statement

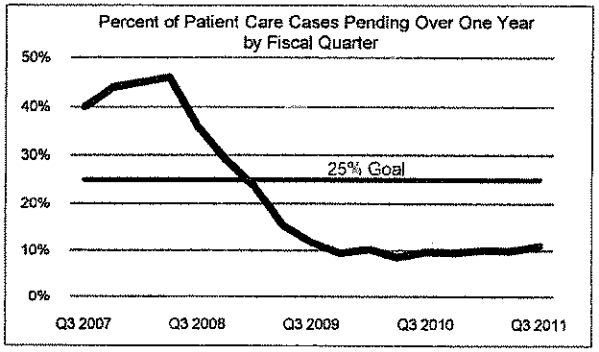
In order to uphold its mission relating to discipline, DHP continually assesses and reports on performance. Extensive trend information is provided on the DHP website, in biennial reports, and, most recently, on Virginia Performs through Key Performance Measures (KPMs). KPMs offer a concise, balanced, and data-based way to measure disciplinary case processing. These three measures, taken together, enable staff to identify and focus on areas of greatest importance in managing the disciplinary caseload; Clearance Rate, Age of Pending Caseload and Time to Disposition uphold the objectives of the DHP mission statement. The following pages show the KPMs by board, listed in order by caseload volume; volume is defined as the number of cases received during the previous 4 quarters. In addition, readers should be aware that vertical scales on the line charts change, both across boards and measures, in order to accommodate varying degrees of data fluctuation.

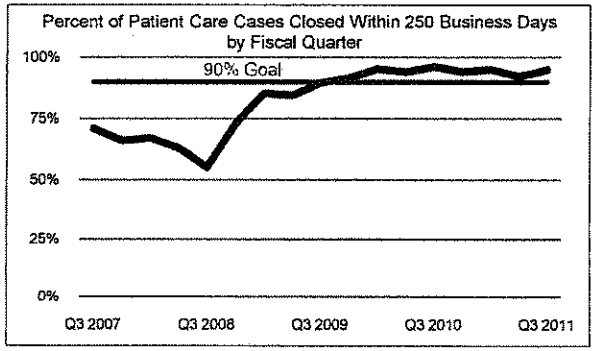
Clearance Rate - the number of closed cases as a percentage of the number of received cases. A 100% clearance rate means that the agency is closing the same number of cases as it receives each quarter. DHP's goal was to achieve a 100% clearance rate of allegations of misconduct by the end of FY 2009 and maintain 100% through the end of FY 2010. The current quarter's clearance rate is 97%, with 983 patient care cases received and 957 closed.

Age of Pending Caseload - the percent of open patient care cases over 250 business days old. This measure tracks the backlog of patient care cases older than 250 business days to aid management in providing specific closure targets. The goal is to reduce the percentage of open patient care cases older than 250 business days to no more than 25% by the end of FY 2010. The percent of cases pending over 250 business days has dropped dramatically over the few years, falling from 45% to 11%. For the last quarter shown, there were 1,986 patient care cases pending, with 220 pending over 250 business days.

Time to Disposition - the percent of patient care cases closed within 250 business days for cases received within the preceding eight quarters. This moving eight-quarter window approach captures the vast majority of cases closed in a given quarter and effectively removes any undue influence of the oldest cases on the measure. The goal is to resolve 90% of cases related to patient care within 250 business days by the end of FY 2010. The percent of cases resolved within 250 business days was 95% during the past quarter, exceeding the 90% goal for nine consecutive quarters. During the last quarter, there were 953 patient care cases closed, with 905 closed within 250 business days.







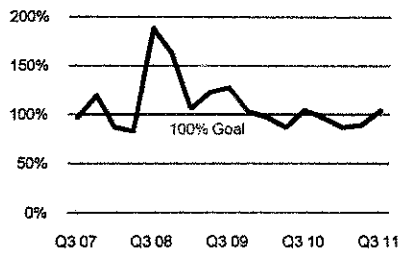
Submitted: 4/5/2011

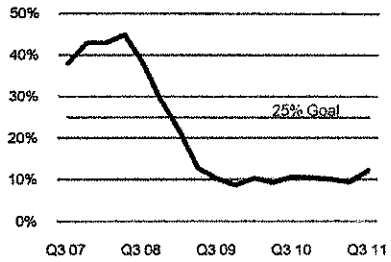
Prepared by: VisualResearch, Inc.

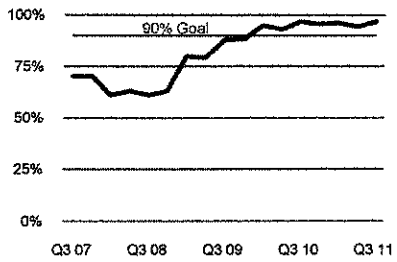
Virginia Department of Health Professions - Patient Care Disciplinary Case Processing Times, by Board

Clearance Rate | **Age of Pending Caseload** (percent of cases pending over one year) | **Percent Closed in 250 Business Days**

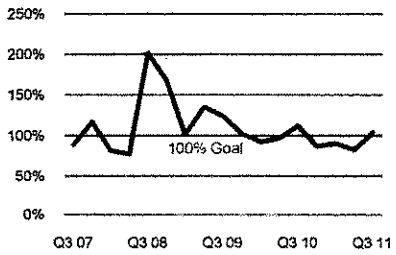
Nursing - In Q3 2011, the clearance rate was 104%, the Pending Caseload older than 250 business days was 12% and the percent closed within 250 business days was 97%.
Q3 2011 Caseloads:
Received=428, Closed=446
Pending over 250 days=112
Closed within 250 days=431

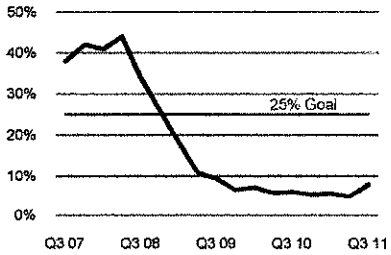


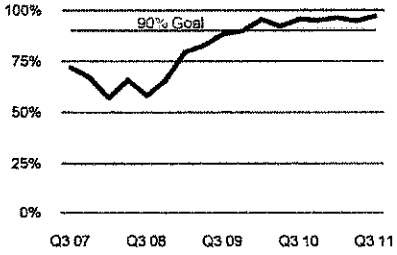




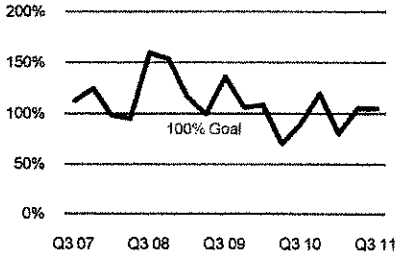
Nurses - In Q3 2011, the clearance rate was 104%, the Pending Caseload older than 250 business days was 8% and the percent closed within 250 business days was 97%.
Q3 2011 Caseloads:
Received=305, Closed=317
Pending over 250 days=48
Closed within 250 days=307

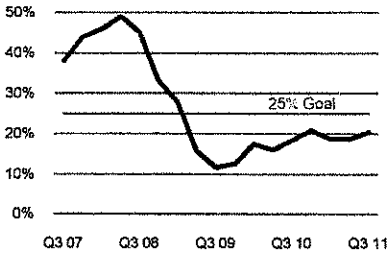


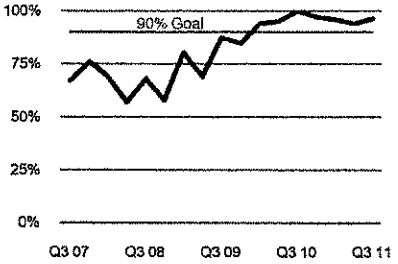




CNA - In Q3 2011, the clearance rate was 105%, the Pending Caseload older than 250 business days was 20% and the percent closed within 250 business days was 96%.
Q3 2011 Caseloads:
Received=123, Closed=129
Pending over 250 days=64
Closed within 250 days=124







Note: Vertical scales on line charts change, both across boards and measures, in order to accommodate varying degrees of data fluctuation.

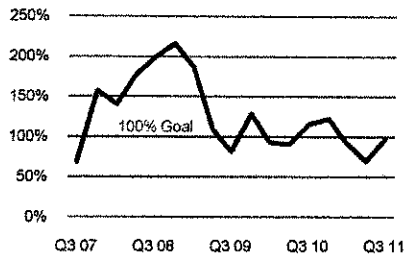
Submitted: 4/5/2011

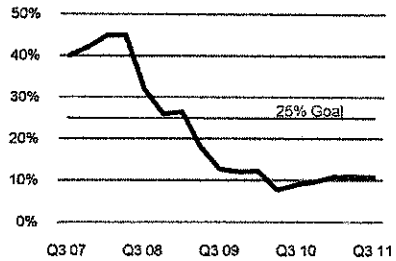
Prepared by: VisualResearch, Inc.

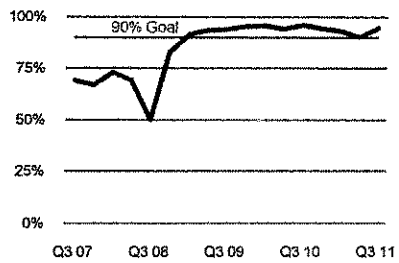
Virginia Department of Health Professions - Patient Care Disciplinary Case Processing Times, by Board

Clearance Rate | **Age of Pending Caseload** (percent of cases pending over one year) | **Percent Closed in 250 Business Days**

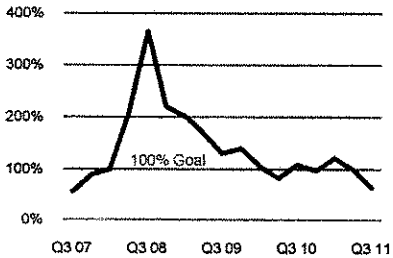
Medicine - In Q3 2011, the clearance rate was 98%, the Pending Caseload older than 250 business days was 11% and the percent closed within 250 business days was 95%.
Q3 2011 Caseloads:
Received=324, Closed=316
Pending over 250 days=59
Closed within 250 days=297

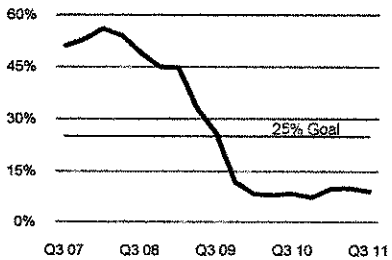


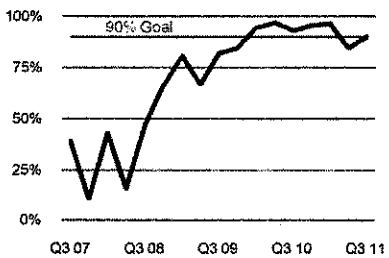




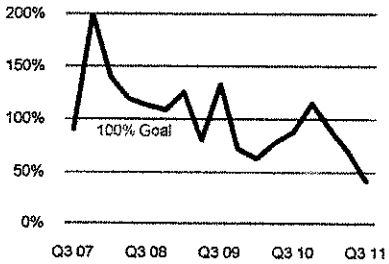
Dentistry - In Q3 2011, the clearance rate was 65%, the Pending Caseload older than 250 business days was 9% and the percent closed within 250 business days was 90%.
Q3 2011 Caseloads:
Received=96, Closed=62
Pending over 250 days=17
Closed within 250 days=55

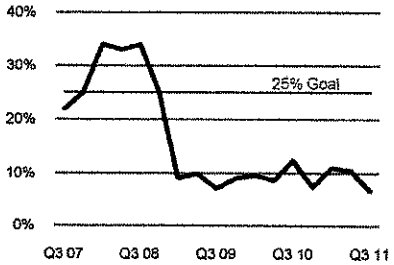


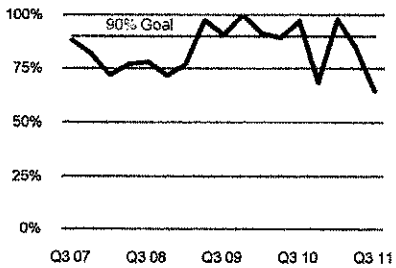




Pharmacy - In Q3 2011, the clearance rate was 41%, the Pending Caseload older than 250 business days was 7% and the percent closed within 250 business days was 65%.
Q3 2011 Caseloads:
Received=41, Closed=17
Pending over 250 days=9
Closed within 250 days=11







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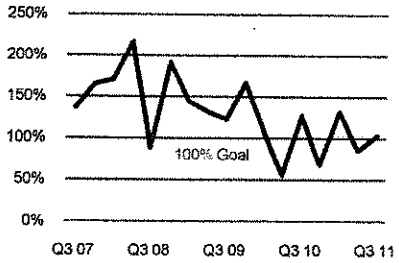
Submitted: 4/5/2011

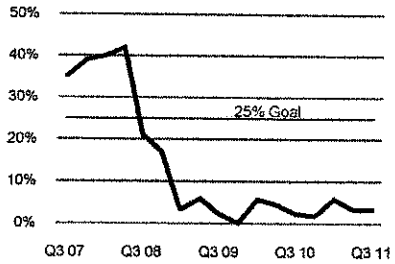
Prepared by: VisualResearch, Inc.

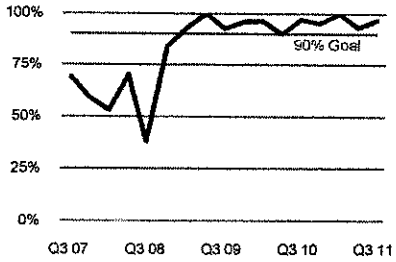
Virginia Department of Health Professions - Patient Care Disciplinary Case Processing Times, by Board

Clearance Rate | **Age of Pending Caseload** (percent of cases pending over one year) | **Percent Closed in 250 Business Days**

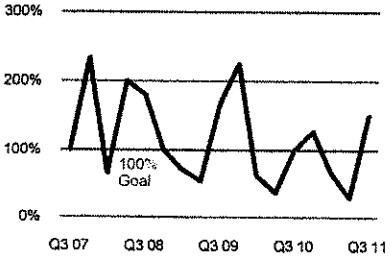
Veterinary Medicine - In Q3 2011, the clearance rate was 103%, the Pending Caseload older 250 business days was 3% and the percent closed within 250 business days was 97%.
Q3 2011 Caseloads:
Received=30, Closed=31
Pending over 250 days=2
Closed within 250 days=30

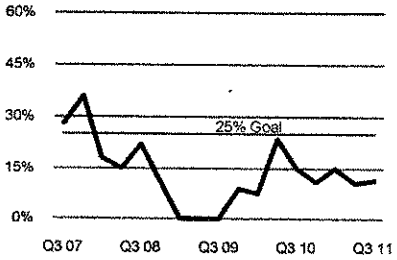


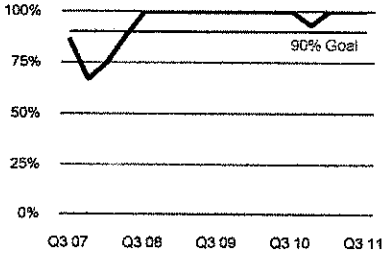




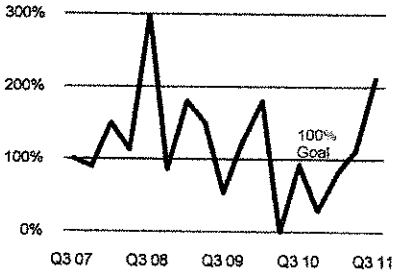
Counseling - In Q3 2011, the clearance rate was 150%, the Pending Caseload older than 250 business days was 12% and the percent closed within 250 business days was 100%.
Q3 2011 Caseloads:
Received=14, Closed=21
Pending over 250 days=3
Closed within 250 days=21

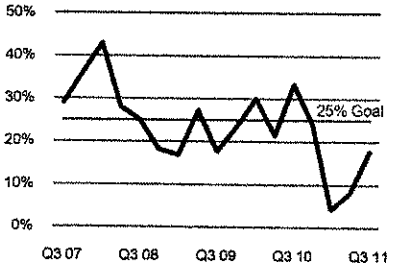


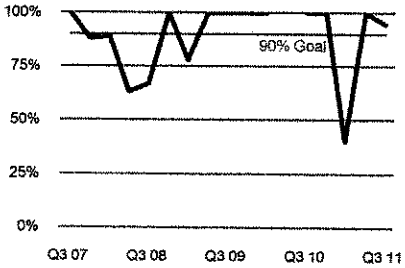




Social Work - In Q3 2011, the clearance rate was 211%, the Pending Caseload older than 250 business days was 18% and the percent closed within 250 business days was 95%.
Q3 2011 Caseloads:
Received=9, Closed=19
Pending over 250 days=3
Closed within 250 days=18







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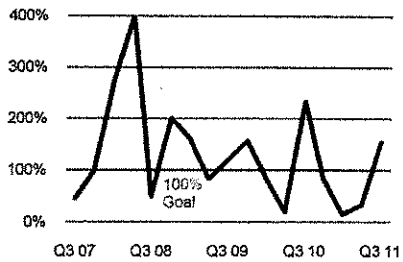
Submitted: 4/5/2011

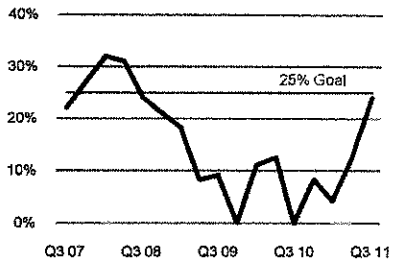
Prepared by: VisualResearch, Inc.

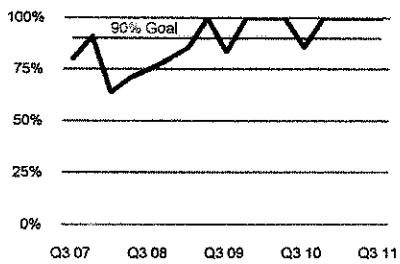
Virginia Department of Health Professions - Patient Care Disciplinary Case Processing Times, by Board

Clearance Rate | **Age of Pending Caseload** (percent of cases pending over one year) | **Percent Closed in 250 Business Days**

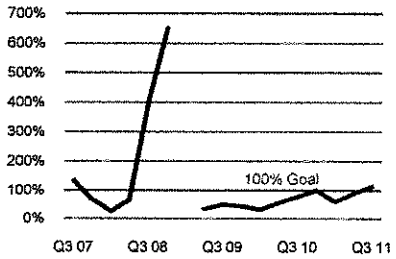
Psychology - In Q3 2011, the clearance rate was 154%, the Pending Caseload older than 250 business days was 24% and the percent closed within 250 business days was 100%.
Q3 2011 Caseloads:
Received=13, Closed=20
Pending over 250 days=6
Closed within 250 days=20

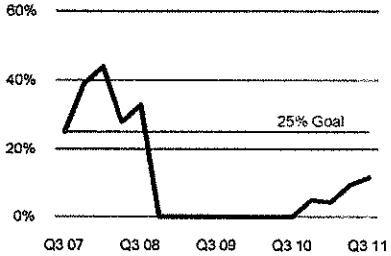


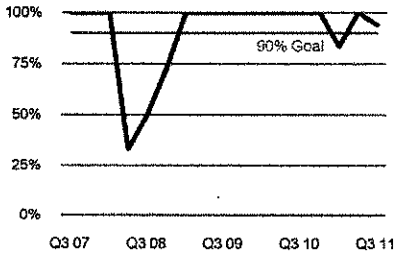




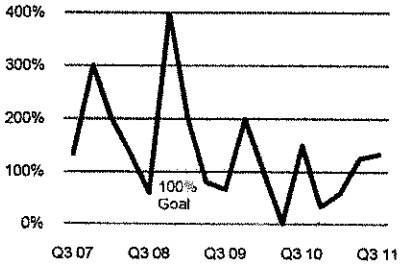
Long-Term Care Administrators - In Q3 2011, the clearance rate was 114%, the Pending Caseload older than 250 business days was 12% and the percent closed within 250 business days was 94%.
Q3 2011 Caseloads:
Received=14, Closed=16
Pending over 250 days=4
Closed within 250 days=15

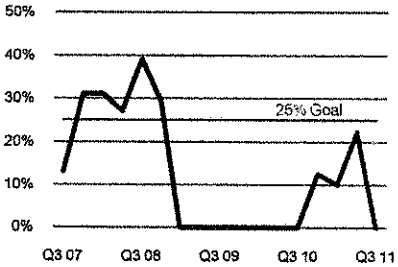


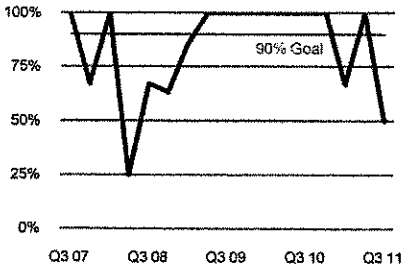




Optometry - In Q3 2011, the clearance rate was 133%, the Pending Caseload older than 250 business days was 0% and the percent closed within 250 business days was 50%.
Q3 2011 Caseloads:
Received=3, Closed=4
Pending over 250 days=0
Closed within 250 days=2







Note: Vertical scales on line charts change, both across boards and measures, in order to accommodate varying degrees of data fluctuation.

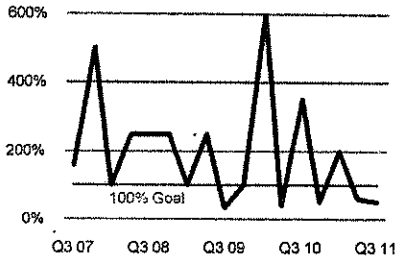
Submitted: 4/5/2011

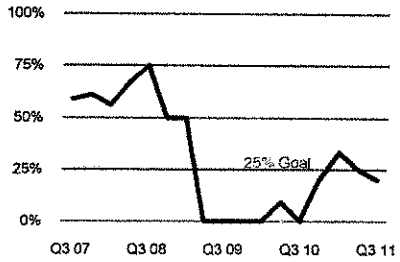
Prepared by: VisualResearch, Inc.

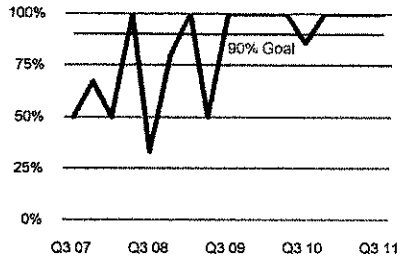
Virginia Department of Health Professions - Patient Care Disciplinary Case Processing Times, by Board

Clearance Rate | **Age of Pending Caseload** (percent of cases pending over one year) | **Percent Closed in 250 Business Days**

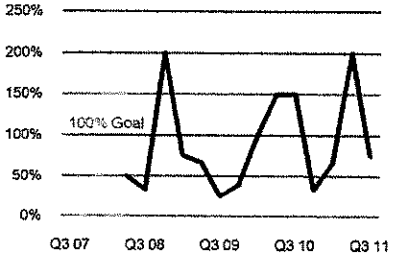
Physical Therapy - In Q3 2011, the clearance rate was 50%, the Pending Caseload older than 250 business days was 20% and the percent closed within 250 business days was 100%.
Q3 2011 Caseloads:
Received=4, Closed=2
Pending over 250 days=2
Closed within 250 days=2

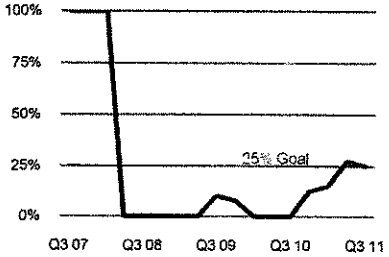


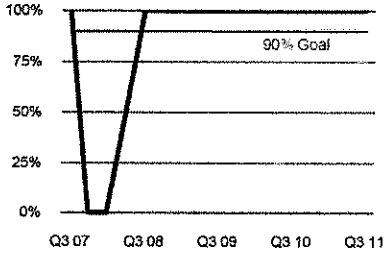




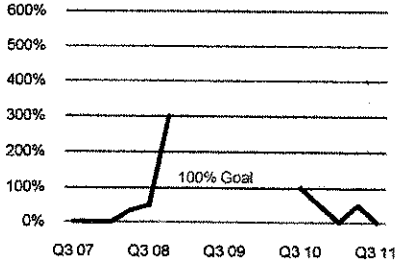
Funeral - In Q3 2011, the clearance rate was 75%, the Pending Caseload older than 250 business days was 25% and the percent closed within 250 business days was 100%.
Q3 2011 Caseloads:
Received=4, Closed=3
Pending over 250 days=3
Closed within 250 days=3

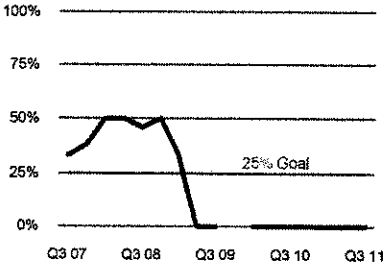


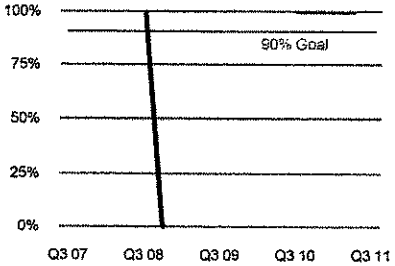




Audiology - In Q3 2011, the clearance rate was 0%, the Pending Caseload older than 250 business days was 0% and the percent closed within 250 business days was N/A.
Q2 2011 Caseloads:
Received=3, Closed=0
Pending over 250 days=0
Closed within 250 days=N/A







Note: Vertical scales on line charts change, both across boards and measures, in order to accommodate varying degrees of data fluctuation.

Submitted: 4/5/2011

Prepared by: VisualResearch, Inc.

Delegation of Authority to Board of Nursing
RN Discipline Staff

The Board of Nursing delegates to professional discipline staff the authority to offer prehearing consent orders (PHCO's) in the following circumstances:

- Discipline cases for R.N.s, L.P.N.s and C.N.A.s for sanctions consistent with the approved Sanction Reference Worksheet Guidelines (see Guidance Document 90-7).
- Termination of probation if all terms and conditions met.
- (Non)Compliance case of licensee on probation who has let license lapse (not working), may be closed undetermined. Board of Nursing data base would be flagged so if the license is being made current, staff would then offer PHCO with same terms as initial probation orders.
- Reinstatement applicant – applicant does not reveal prior criminal conviction (Board of Nursing is aware of conviction on another application, or learns of conviction from another source), offer PHCO to reprimand and approve for licensure (with the exception of cases resulting in mandatory suspension).
- Disciplinary/Health Practitioner Monitoring Program (HPMP) case – no prior Board history, no prior stay granted, compliant with HPMP contract and no issues other than impairment, offer PHCO to take no action contingent upon HPMP compliance (No IFC).
- Report received from HPMP committee – stay of disciplinary action vacated (but individual not dismissed from HPMP) and licensee now fully compliant with contract. Offer PHCO – take no action contingent upon continued compliance with HPMP. Include in findings of fact in order that stay was vacated.

- Cases involving HPMP participant that was ordered into program, but now unable to participate due to medical reasons and HPMP committee dismisses or accepts individuals resignation; offer PHCO to accept voluntary surrender for indefinite suspension.
- During any type of case investigated, licensee indicates to the investigator the desire to surrender, or individual mails in license during course of the investigation; offer PHCO to accept voluntary surrender for indefinite suspension.
- Cases resulting from mandatory/self reports of admission to hospital for mental health issues where there are no practice issues, staff are authorized to either: offer CCA with terms (i.e. quarterly reports from treating provider); close undetermined; or offer PHCO to take no action contingent upon entry into or remain in compliance with HPMP.
- Abandonment of patients by CNAs in a nursing home or other healthcare facility and where this is the only alleged issue. PHCO for reprimanded.
- One time failure to provide acceptable standard of care. PHCO reprimand
- Allegations of verbal/physical abuse with mitigating circumstances. PHCO reprimand for unprofessional conduct
- Action taken by another state board of nursing. PHCO with similar action or terms and conditions e.g. probation, HPIP
- Initial and reinstatement applicants
    1. PHCO with sanction or terms consistent with another state
    2. PHCO to reinstate and comply with HPMP when a lapsed licensee was under prior order to be in HPMP
    3. Applicants whose only cause for denial related to impairment issues. PHCO requiring HPMP participation

4. Reinstatement with same terms of probation for a probationer who allowed their license to lapse

- Authority to modify probation orders
- Authority to issue order of successful completion of HPMP/terms & issue unrestricted license following notification by HPMP committee, when previous order of take no action contingent upon HPMP.
- Unlicensed Practice – PHCO monetary penalty ranging $100 – 500; include reprimand if > one year (see Guidance Document # 90-38)

Confidential Consent Agreements – Staff authorized to offer CCA's in the following circumstances:

- Single medication error with no patient harm
- Unintentional falsification of employment application
- Unintentional falsification of initial licensure and/or reinstatement application (regarding past action, criminal convictions), where applicant misunderstood question and believed the Board already knew
- Standard of care violation "with little or no injury"
- Standard of care violation that may be in part due to systems issues
- Technical probation violations (i.e., late reports, etc.)
- Pre-employment positive drug screen without evidence it has affected practice
- Possible impairment without evidence that it has affected practice (i.e. coming to work with alcohol on breath & sent home; hospitalized for psychiatric or substance abuse treatment)
- CE violations for CMT's and LNPs (see also Guidance Document # 90-10 for LNPs)

- A single misdemeanor conviction involving moral turpitude, with no other issues (ex. Worthless check; shoplifting)
- Single incident of exceeding scope of practice – accepting assignment or agreeing to do a task without adequate training obtained or competency maintained and no patient harm
- Inappropriate verbal response that does not rise to the level of verbal abuse (i.e., "shut up")
- Single boundary violation with no patient harm (i.e., getting involved with patient finances) and not resulting in criminal conviction
- HPIP participant not eligible for a stay, but with minimal practice issues
- Vague "rough handling" where there is no patient harm & does not rise to the level of abuse
- Unintentional/inadvertent Practice Agreement violations for LNP's with Prescriptive Authority

Addendum: Probable Cause Review and Case Closure – Effective 7-17-07

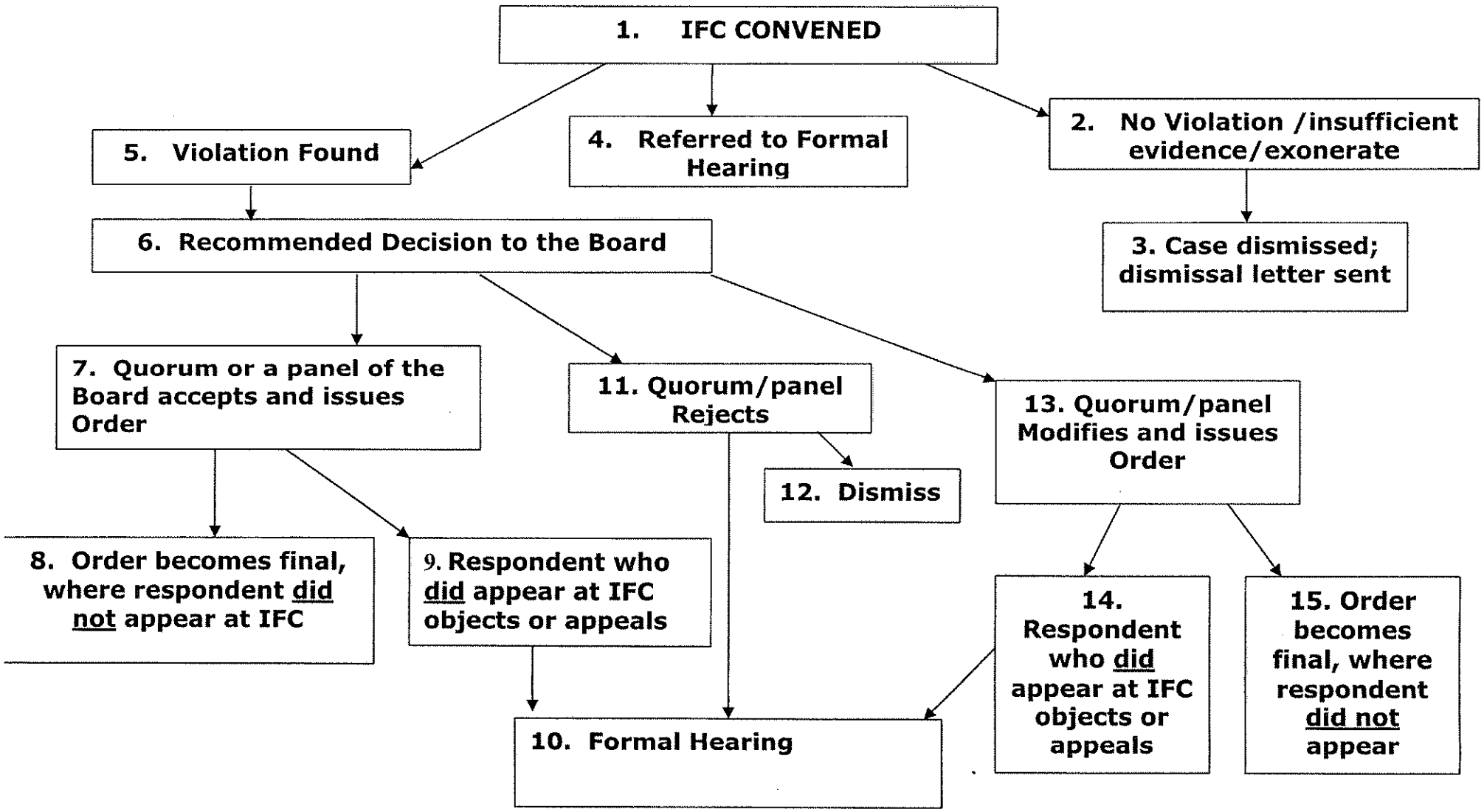
Effective 7-17-07, the Board of Nursing delegates to professional discipline staff the authority to close cases for insufficient evidence of a violation of law or regulation, or not rising to the level of disciplinary action by the Board. The Board further delegates professional discipline staff the authority to close cases undetermined for reconsideration when another similar complaint is received, or when the lapsed/suspended/revoked licensee applies to reinstate or late renew.

Revised on date:_____

Replaces Guidance Documents 90-33, 90-35, 90-39, 90-47, 90-48, 90-49, 90-50, 90-51

Board action 5/15/07, 7/17/07 and 5/18/2010

Guidance for Conduct of an Informal Conference by an Agency Subordinate of a Health Regulatory Board at the Department of Health Professions



Narrative explanation of Flow Chart on Delegation to an Agency Subordinate

This describes the process in which a subordinate hears a case at an informal conference up to a case that may be referred to a formal hearing.

1. Pursuant to a notice, the designated agency subordinate ("subordinate") will convene the informal conference ("IFC"). An IFC before a subordinate is conducted in the same manner as an IFC before a committee of the board. Following the presentation of information by the parties, the subordinate will consider the evidence presented and render a recommended decision regarding the findings of fact, conclusions of law, and if appropriate, the sanction to be imposed.

2. The subordinate may recommend that the respondent be exonerated, that there be a finding of no violation, or that insufficient evidence exists to determine that a statutory and/or regulatory violation has occurred.

3. If the subordinate makes such a finding, the case is dismissed and a dismissal letter is issued to the respondent notifying him of the determination.

4. The subordinate may decide that the case should be referred to a formal hearing. A hearing before the board would then be scheduled and notice sent to the respondent.

5. The subordinate may determine that a violation has occurred and recommend the findings of fact and conclusions of law along with an appropriate sanction.

6. With the assistance of APD, the subordinate drafts a recommended decision, which includes the findings of fact, conclusions of law and sanction. The recommendation is provided to the respondent and to the board and must be ratified by a quorum of the board or a panel consisting of at least five members of the board.

7. If the quorum or panel of the board accepts the recommended decision and:

8. If the respondent <u>did not appear</u> at the IFC, the board's decision becomes a final order that can only be appealed to a circuit court; or

9-10. If the respondent <u>did appear</u> at the IFC and objects to and appeals the order, he may request a

formal hearing before the board. A case referred to a formal hearing proceeds in the same manner as cases considered by special conference committees convened pursuant to Va. Code § 54.1-2400(10). If the respondent who appeared at the IFC does not request a formal hearing, the order becomes final after a specified timeframe.

11. A quorum or panel of the board may reject the recommended decision of the subordinate, in which case:

The quorum/panel may decide to refer the case for a formal hearing **(10)**; or the quorum/panel may decide to dismiss the case and a dismissal letter is issued to the respondent notifying him of the decision of the board **(12)**.

13. A quorum or panel of the board may modify the subordinate's recommended decision and issue an order reflecting the modified decision to the respondent.

15. If the respondent did not appear at the informal conference, then the board's decision becomes a final order that can only be appealed to a circuit court.

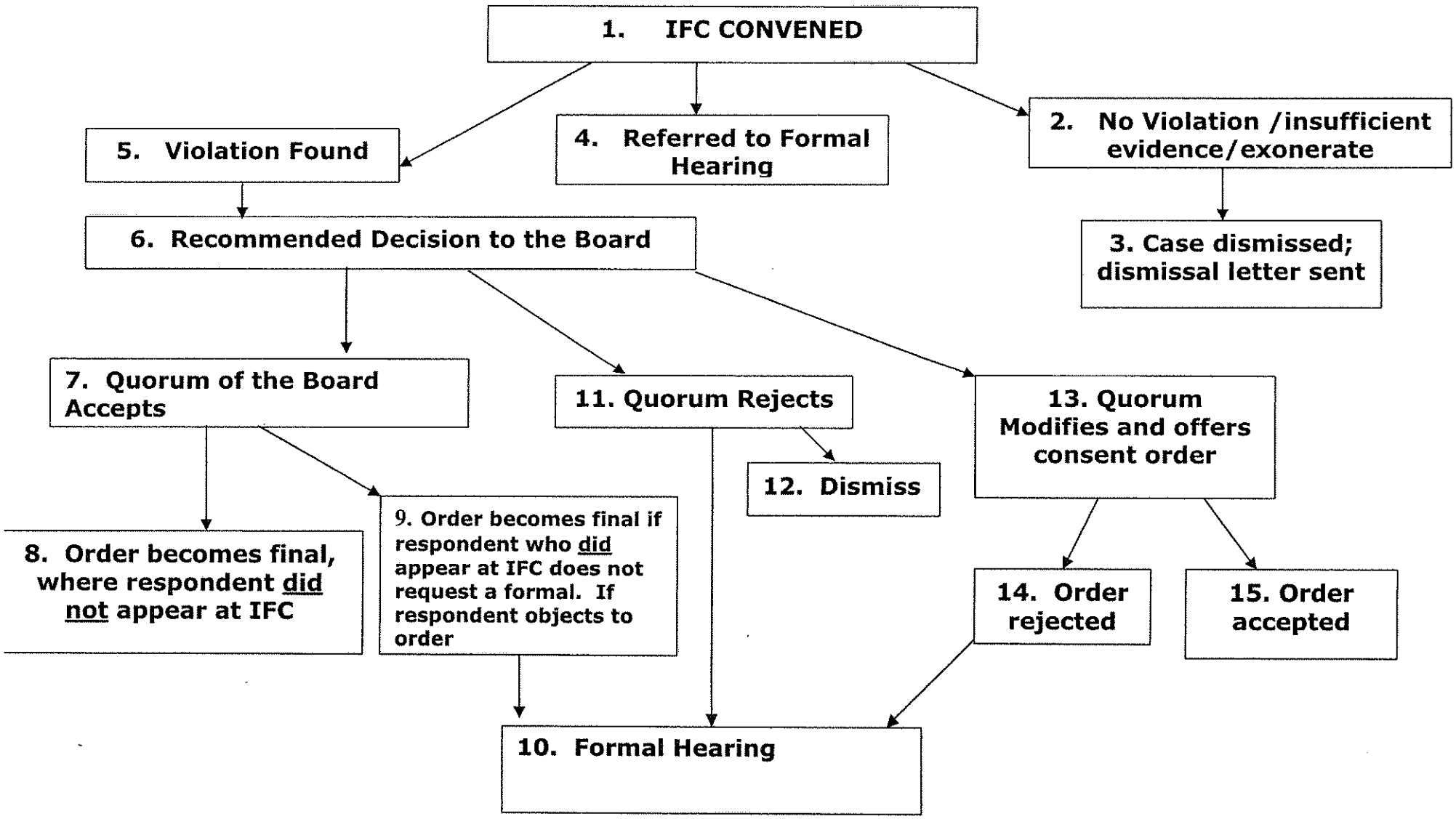
14-10. If the respondent did appear at the informal conference and objects to and appeals the order, he may request a formal hearing before the board. A case referred to a formal hearing proceeds in the same manner as cases considered by special conference committees convened pursuant to Va. Code § 54.1-2400(10). If the respondent who appeared at the IFC does not request a formal hearing, the order becomes final after a specified timeframe.

Pharmacy

Adopted 12/10/04

78

Guidance for Conduct of an Informal Conference by an Agency Subordinate of a Health Regulatory Board at the Department of Health Professions



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2. The subordinate may recommend that the respondent be exonerated, that there be a finding of no violation, or that insufficient evidence exists to determine that a statutory and/or regulatory violation has occurred.

> **3.** If the subordinate makes such a finding, the case is dismissed and a dismissal letter is issued to the respondent notifying him of the determination.

4. The subordinate may decide that the case should be referred to a formal hearing. A hearing before the board would then be scheduled and notice sent to the respondent.

5. The subordinate may determine that a violation has occurred and recommend the findings of fact and conclusions of law along with an appropriate sanction.

> **6.** With the assistance of APD, the subordinate drafts a recommended decision, which includes the findings of fact, conclusions of law and sanction. The recommendation is provided to the respondent and to the board and must be ratified by a quorum of the board.

7. If a quorum of the board accepts the recommended decision and:

> **8.** If the respondent <u>did not appear</u> at the IFC, the board's decision becomes a final order that can only be appealed to a circuit court; or
>
> **9-10.** If the respondent <u>did appear</u> at the IFC and objects to the order, he may request a formal hearing before the board. A case referred to a formal hearing proceeds in the same manner as cases considered by special conference committees convened pursuant to Va. Code § 54.1-2400(10). If the respondent who appeared at the IFC does not request a formal hearing, the order becomes final after a specified timeframe.

11. A quorum of the board may reject the recommended decision of the subordinate, in which case:

> The board may decide to refer the case for a formal hearing **(10)**; or the board may decide to dismiss the case and a dismissal letter is issued to the respondent notifying him of the decision of the board **(12)**.

13. A quorum of the board may modify the subordinate's recommended decision, and a consent order reflecting the modified decision is presented to the respondent:

> If the respondent accepts the consent order, it is duly entered **(15)**; or if the respondent rejects the consent order **(14)**, the case proceeds to a formal hearing before the board **(10)**.

Need for Additional Hours of Practical Experience

Background:

- Applicant for pharmacist license via score transfer passed NAPLEX on his fourth attempt; however, he did not obtain 1,000 hours of additional practical experience after failing the examination on three occasions as required in Regulation 18VAC110-20-60C. Because an applicant via score transfer must satisfy the same pre-licensure requirements as an applicant via examination, he was no longer eligible to obtain a pharmacist license via score transfer. He could, however, obtain a pharmacist license via endorsement and he was advised of this. Because his resident state did not require additional hours of practical experience, had issued him a pharmacist license after passing the examination, and there is an increased cost associated with performing a license transfer, he requested that the Board consider amending its regulation to allow a future applicant in similar circumstances to obtain a pharmacist license via score transfer without having to obtain the 1,000 hours of additional practical experience.

In Board package:

- Regulation 18VAC110-20-60 C
- Guidance document 110-2

Board action:

- Consider request to amend regulation
- No action required if choose not to amend regulation or need motion to adopt NOIRA

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

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

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

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

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

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

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

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

a. A letter of request from the candidate that specifies the testing accommodation requested;

b. A written report of an evaluation (educational, psychological, or physical) within the preceding two years from a qualified professional that states a diagnosis of the disability, describes the disability, recommends specific accommodations, and provides justification that the accommodation is appropriate and necessary for the diagnosed disability. If the comprehensive evaluation was done more than two years ago and the condition is one that is not subject to change, the original evaluation report may be submitted along with a current letter from the qualified professional stating that there has been no change in the condition since the time of the evaluation; and

c. A written statement from the appropriate person at the applicant's school of pharmacy that describes any testing accommodations made while the student was enrolled, if applicable.

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

VIRGINIA BOARD OF PHARMACY
Information for Applicants for a License as a Pharmacist

1. Licensure by Examination:

Application
The application form is available on the Board of Pharmacy website at www.dhp.virginia.gov/pharmacy, it must be completely executed, and must be sent with the fee as designated on the form to the address on the form. Incomplete applications will be promptly returned, however application fees are non-refundable.

Practical Experience Requirements
An applicant shall have accumulated a minimum of 1,500 hours of practical experience as a pharmacy intern. The applicant must have registered with the Board as a pharmacy intern prior to beginning to obtain practical experience. Credit will not be given for more than 50 hours in any one week, and not for less than an average of 20 hours per week averaged over a month. 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 1,500 hours of practical experience, shall meet the board's practical experience requirements for licensure as a pharmacist. All practical experience credit gained outside of an ACPE-accredited school of pharmacy program shall only be gained after successful completion of the equivalent of at least two semesters in an ACPE-accredited school of pharmacy, or in the case of graduates of foreign colleges of pharmacy (see Guidance Document 110-17), after obtaining the FPGEC. All practical experience shall be gained within the United States.

Certificates of Practical Experience

- For practical experience gained within the college experiential program, documentation should be recorded and certified under the "College Affidavit" section of the application. No further affidavits are needed for this experience.

- Affidavits of experience gained in Virginia, outside the college experiential program, must be signed by the supervising pharmacists, and attached to the application (if not previously submitted to the Board).

- Certificates or documentation of practical experience gained in another state must be certified by the board of pharmacy in that state and must be received by this Board directly from that state. This documentation must show actual dates of employment, total hours worked, place of employment and name of supervising pharmacists, and the certifying Board shall verify current, unrestricted licensure status of the supervising pharmacists. In the event that a state does not use internships to gain practical experience in pharmacy but relies on the pharmacy school to certify the hours of experience, an affidavit from the pharmacy school certifying the above information may be accepted in lieu of board certification.

Taking the NAPLEX
Applicants must directly register with and pay the required fee to the National Association of Boards of Pharmacy (NABP) in order to take the NAPLEX examination at www.nabp.net. NAPLEX is the competency assessment examination for initial pharmacist licensure that is accepted by all 50 states, the District of Columbia, and Puerto Rico. An applicant may either take NAPLEX in Virginia, or register with NABP to score transfer to Virginia. However, an applicant will not be allowed to schedule taking NAPLEX until he has been approved by the Board.

The Board notifies NABP once a week of any applicants that have registered with NABP and have been approved by the Board. Unless there are problems with an application, the application is usually approved within a day or two of receipt by the Board, a letter of approval is sent to the applicant, and the approval forwarded to NABP during the weekly submission. Additional details about NAPLEX are also available on the NABP website.

2. Licensure by Endorsement (Reciprocity):

Virginia does allow licensure by a process called "endorsement" in which an applicant may transfer a pharmacist license from another state, provided the applicant's credentials for licensure in the other state meet Virginia's credentialing requirements with respect to education, practical experience, and required examinations, and provided grounds do not exist to deny an application such as disciplinary action by another state or criminal convictions. Applicants will need to go through the NABP license transfer process in order to do this. Instructions and forms for this may be found at www.nabp.net. Once the preliminary application and fee is submitted to NABP, NABP will partially complete the official application for Virginia, and send it back to the applicant. Then the applicant finishes completing the form and submits it to the Virginia Board of Pharmacy. Once the application has been received by this Board and approved, the applicant will then be approved to take the Virginia law exam and notified by letter of such approval with instructions as to how to pay for and schedule the exam.

3. Virginia Pharmacy Law Examination Required for Licensure by Examination or Endorsement:

Virginia does not use the MPJE. Once an application has been approved, the Board will notify the applicant by letter of the approval, and also notify the contractor for the law examination of such approval. The applicant must make arrangements directly with that testing contractor to pay the fee and schedule the examination. Instructions for doing this are sent in the approval letter and are also in the study guide that is available as a separate document link on the Board's website. The law exam may be taken either before or after the NAPLEX. The examination is a computerized examination that the applicant may schedule at any time that the requested testing center is open and has availability. There are testing centers in various parts of Virginia and throughout the United States. **Applicable state laws and regulations are on the Board's website and the Prescription Monitoring Program website. Applicable sections of federal law may also be found on the internet by searching for the Code of Federal Regulations or U.S. Code or U.S. Public Law.**

4. Denial Of An Application For Grounds:

Grounds to deny a license may be found in §54.1-3316 of the Code of Virginia on the Board's website.
If grounds exist to deny an application for licensure as a pharmacist, the application will not be approved by Board staff, and the applicant will be so notified and offered an opportunity to meet with an informal conference committee of the Board to determine if the license should be denied, issued, or issued conditionally. An applicant will not be allowed to take any required examinations if grounds exist to deny the application, until reviewed and approved by the Board.

Pharmacist Workforce Survey

Instructions:		
The following survey will assist policymakers at the state, federal and local levels assess the adequacy of the current pharmacy workforce and project future workforce trends in relation to Virginia's changing population and health needs. It will help us to improve the health of all Virginians and develop policies that support the practice of Pharmacy. By law, information collected as part of this survey is anonymous. The Healthcare Workforce Data Center only releases this information in the aggregate and has taken legal and practical measures to ensure any information released is not personally identifiable. Participation in this survey is voluntary.		
The survey questions are designed to allow comparisons across professions, and among state and federal data collection efforts. Some of the questions, particularly the questions pertaining to race and ethnicity, match Federal data collection standards.		
Education and Background		
1	Where did you attend high school (secondary school)?	*Dropdown*
		Outside of the US or Canada
		Canada
		57 US States and Territories
2	Where did you complete your undergraduate degree?	*Dropdown*
		Did not obtain an undergraduate degree
		Outside of the US or Canada
		Canada
		57 US States and Territories
3	Where did you obtain your initial pharmacy degree?	*Dropdown*
		Outside of the US or Canada
		Canada
		57 US States and Territories

4a	Which pharmacy degrees have you attained as of today?	*Check all that apply*
		BS Pharm
		PharmD
4b	Which post-graduate programs have you completed as of today?	*Check all that apply*
		Residency
		Fellowship
		Certification Program
		Masters
		PhD
	If you completed a residency, please indicate your area:	*Check all that apply*
5a	PGY1:	
		Health Systems
		Managed Care
		Community Settings
		Ambulatory Care
		Other
5b	PGY2:	
		Managed Care Pharmacy Systems
		Health Administration Pharmacy
		Ambulatory
		Cardiology
		Critical Care
		Drug Information
		Emergency Medicine
		Geriatric
		HIV
		Infectious Disease
		Internal Medicine
		Medication Use Safety
		Nephrology
		Nuclear

		Nutrition Support
		Oncology
		Palliative Care/Pain Management
		Other
5c	If you chose "other" for either PGY1 or PGY2 residency, please provide a brief description of your specialty area:	*Open-ended*
6a	Please indicate any Board Certifications for pharmacists you have attained as of today:	*Check all that apply*
		BPS-Ambulatory Care
		BPS-Nuclear Pharmacy
		BPS-Nutrition
		BPS-Oncology
		BPS- Pharmacotherapy
		BPS-Psychiatric
		CCGP-Geriatrics
		ABAT-Applied Toxicology
6b	Please indicate any other (non-Board) certifications for pharmacists you have attained as of today:	*Check all that apply*
		Ambulatory Care
		Nuclear Pharmacy
		Nutrition
		Oncology
		Pharmacotherapy
		Psychiatric
		Geriatrics
		Applied Toxicology
		Diabetic Educator
		Anticoagulation
		Immunization

7	Within the past 12 months, have you worked, volunteered, taught or practiced, in any environment related to pharmacy or in any position that drew on your knowledge of pharmacy? (if only occasional practice--less than 100 hrs--please select "No")	*Check One: Yes/No*
	Please note: Answer "yes" for any pharmacy-related activities, including administrative, educational, regulatory or other activities.	

If you answered "No" to Question 7, please go to Question 33 in the Demographics section. If you answered "Yes", please continue.

Primary Work Location

Question 8 through Question 15 refer to your primary place of employment, work or practice. This is the place where you spend the most work hours during an average workweek, or where you spent the most weeks working in the past 12 months. Please use these questions to describe a particular work location, not an employer. Temporary or traveling workers who spend or spent a significant amount of time at a particular location should use that location as his or her primary work location. Persons who consistently work in multiple locations (i.e. temporary workers, locum tenens) should indicate this in Question 8.

8	Please select the location of your primary place of employment, work or practice:	*Dropdown:*
		List of Virginia's Cities and Counties
		Several localities (temporary, mobile clinic, etc.)
		Outside of US
		Virginia Border State/DC
		Other US State
9	Approximate number of weeks at which at least some time was spent at this work location within the past twelve months (exclude vacation, medical leave, etc.)	*Fill in Blank (2-digit numeric, not more than 52 or less than 1)*
10a	Please select the type of practice setting:	*Dropdown:*
		Independent Community Pharmacy (1-4 stores)

		Small Chain Community Pharmacy (4-10 stores)
		Large Chain Community Pharmacy (10+ stores)
		Mass Merchandiser (i.e. Big Box Store)
		Supermarket Pharmacy
		Clinic-Based Pharmacy
		Mail Service Pharmacy
		Government Hospital / Health System, Inpatient
		Government Hospital / Health System, Outpatient
		Non-government Hospital / Health System, Inpatient
		Non-government Hospital / Health System, Outpatient
		Nursing Home, Long Term Care
		Home Health / Infusion
		Pharmacy Benefit Administration (e.g. PBM, managed care)
		Academic Institution
		Other For-profit Corporation / Organization
		Other Non-profit Corporation / Organization
10b	If you selected Other For-profit or Non-profit Corporation / Organization, please provide a brief descripiton:	*Open-ended*
11a	Do you provide any of the following services for another pharmacy at this location?	*Check all that apply*
	If you do not perform any remote services at this location, please proceed to Question 12.	Remote order processing
	Telepharmacy: Off-site collaboration using telephone, video or other telecommunications devices.	Central filling
		Remote consulting/telepharmacy

11b	If you checked any of the boxes in number 11a, how would you describe your remote, telepharmacy, or remote consulting services client population?	*Dropdown*
		State/local
		Regional
		National
		International
11c	If you checked any of the boxes in number 11a, what proportion of your remote, telepharmacy or remote consulting services are spent serving clients in Virginia?	*Dropdown*
		All or almost all
		Most
		About half
		Some
		None or only occasional
12	How many hours did you work at this location during your average workweek?	*Fill in Blank, 2 spaces, numeric*
13	In the average workweek, what percentage of your working hours were spent in the following roles:	
		000: Medication Dispensing
		000: Patient Care (including direct patient care, patient education and reviewing charts)
		000: Third party payor billing & coordination
		000: Business/Organization management, Administration, Recordkeeping
		000: Formal Research (including practice-based research)
		000: Education (including preceptoring)
		000: Other

		000: Average weekly hours for location: (Automatically sum first five)
		000: Other
14	How are you paid for your services at your primary work location?	*Check all that apply*
		Salary
		Hourly wage
		Profits (owner/part owner)
		Volunteer/Not paid
15	Do you currently receive reimbursements for non-dispensing services such as medication therapy management at this location?	*Dropdown: yes/no*
If you only have one practice location, please skip to question 25. If you have additional practice locations, please continue.		
Secondary Practice Setting		
Question 16 through Question 23 refer to your secondary place of employment, work or practice. This is the place where you spend the second most work hours during an average workweek, or where you spent the second most weeks working in the past 12 months. Please use these questions to describe a particular work location, not an employer. Temporary or traveling workers who can identify a second location where he or she spends or spent a significant amout of time should use this as his or her secondary work location. Persons who consistently work in multiple locations (i.e. temporary workers, locum tenens) should indicate		
16	Please select the location of your secondary place of employment, work or practice:	*Dropdown:*
		List of Virginia's Cities and Counties
		Several localities (temporary, mobile clinic etc)
		Outside of US
		Virginia Border State/DC
		Other US State

17	Approximate number of weeks at which at least some time was spent at this work location within the past twelve months (exclude vacation, medical leave, etc.)	*Fill in Blank (2-digit numeric, not more than 52 or less than 1)*
18a	Please select the type of practice setting:	*Dropdown:*
		Independent Community Pharmacy (1-4 stores)
		Small Chain Community Pharmacy (4-10 stores)
		Large Chain Community Pharmacy (10+ stores)
		Mass Merchandiser (i.e. Big Box Store)
		Supermarket Pharmacy
		Clinic-Based Pharmacy
		Mail Service Pharmacy
		Government Hospital / Health System, Inpatient
		Government Hospital / Health System, Outpatient
		Non-government Hospital / Health System, Inpatient
		Non-government Hospital / Health System, Outpatient
		Nursing Home, Long Term Care
		Home Health / Infusion
		Pharmacy Benefit Administration (e.g. PBM, managed care)
		Academic Institution
		Other For-profit Corporation / Organization
		Other Non-profit Corporation / Organization
18b	If you selected Other For-profit or Non-profit Corporation / Organization, please provide a brief descripiton:	*Open-ended*

19a	Do you provide any of the following services for another pharmacy at this location?	*Check all that apply*
	If you do not perform any remote services at this location, please proceed to Question 20.	Remote order processing
	Telepharmacy: Off-site collaboration using telephone, video or other telecommunications devises.	Central filling
		Remote consulting/telepharmacy
19b	How would you describe your remote, telepharmacy, or remote consulting services client population?	*Dropdown*
		State/local
		Regional
		National
		International
19c	What proportion of your remote, telepharmacy or consulting services are spent serving clients in Virginia?	*Dropdown*
		All or almost all
		Most
		About half
		Some
		None or only occasional
20	How many hours did you work at this location during your average workweek?	*Fill in Blank, 2 spaces, numeric*
21	In the average workweek, what percentage of your working hours were spent in the following roles:	
		000: Medication Dispensing
		000: Patient Care (including direct patient care, patient education and reviewing charts)
		000: Third party payor billing & coordination

		000: Business/Organization management, Administration, Recordkeeping
		000: Formal Research (including practice-based research)
		000: Education (including preceptoring)
		000: Other
		000: Average weekly hours for location: (Automatically sum first five)
		000: Other
22	How are you paid for your services at your primary work location?	*Check all that apply*
		Salary
		Hourly wage
		Salary
		Profits (owner/part owner)
		Volunteer/Not paid
23	Do you currently receive reimbursements for non-dispensing services such as medication therapy management at this location?	*Dropdown: yes/no*
If you only have two practice locations, please skip to question 25. If you have additional practice locations, please continue.		
Other Practice Setting(s)		
24	Total hours of patient care services provided at all other locations in the past 12 months:	*Fill in Blank (numeric, 2 digits)*
Employment Information		
25	Within the past 12 months, have you:	Check all that apply
		Ceased working for an employer or practice?
		Begun working for a new employer or practice?

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		Transferred to a new work location with the same employer or practice?
26	Do you perform or participate in any of the following activities?	*Check all that apply:*
		Provide immunizations
		Participate in a collaborative practice agreement
		Precept pharmacy students
		Use multi-setting Electronic Health Records
		Participate in Virginia's Prescription Monitoring Program
		CLIA waived laboratory tests
		Other laboratory tests or diagnostics
		Sterile compounding
		Nonsterile compounding
		Telepharmacy/Remote Consulting
27	What is your estimated hourly income from your work as a Pharmacist over the past 12 months?	*Dropdown:*
		Volunteer work only
		<$12/hr
		$12.01-$24.00/hr
		$24.01-$36.00/hr
		$36.01-$48.00/hr
		$48.01-$60.00hr
		$60.01-$72.00/hr
		$72.01-$84.00/hr
		$84.01-$96.00/hr
		$96.01-$108.00/hr
		$108.01-$120.00/hr
		$120.01-$122.00/hr
		$122.01-$144.00/hr
		>$144.00/hr

28	Do you receive any of the following benefits from your current employer(s)?	*Check all that apply:*
		Paid Vacation
		Paid Sick Leave
		Paid Disability Leave
		Health Insurance
		Dental Insurance
		Stock options
		Retirement (401k, Pension, etc)
		Group Life Insurance
		Signing/retention bonus
		No Benefits
29	What is your estimated current educational debt?	*Dropdown*
		None
		<$10,000
		$10,001-$20,000
		$20,001-$30,000
		$30,001-$40,000
		$40,001-$50,000
		$50,001-$60,000
		$60,001-$70,000
		$70,001-$80,000
		$80,000-$90,000
		$90,000-$100,000
		$100,000-$110,000
		$110,000-$120,000
		>$120,000+
30	At what age do you predict you will retire (if you do not expect to ever retire, please put "NA"):	*Fill in blank:* __
31	Within the next two years do you plan to do any of the following:	*Check all that apply*
		Retire
		Cease working in the field of Pharmacy.

		Continue working or teaching in the field of Pharmacy, but cease doing so in Virginia
		Increase hours working in patient care and/or medical dispensing
		Decrease hours working in patient care and/or medical dispensing
		Increase time spent teaching pharmacy students in an academic setting
		Decrease time spent teaching pharmacy students in an academic setting
		Pursue additional pharmacy-related education
		Begin precepting pharmacy students
		Cease precepting pharmacy students
32	Within the next five years do you plan to do any of the following:	*Check all that apply*
		Retire
		Cease working in the field of Pharmacy.
		Continue working or teaching in the field of Pharmacy, but cease doing so in Virginia
		Increase hours working in patient care and/or medical dispensing
		Decrease hours working in patient care and/or medical dispensing
		Increase time spent teaching pharmacy students in an academic setting
		Decrease time spent teaching pharmacy students in an academic setting
		Pursue additional pharmacy-related education
		Begin precepting pharmacy students
		Cease precepting pharmacy students
Demographic Questions		
33	Year of Birth	*Fill-in (4 Digit Year, numeric)*
34	Sex	*Dropdown: Male/Female*

	Please select the items that best describe your race/ethnicity. Please answer both question 35a about Hispanic origin and 35b about race/ethnicity.	
35a	*Select One:*	*Check one:*
		Hispanic, Latino or Spanish origin
		Not Hispanic, Latino or Spanish origin
		Prefer not to respond
35b	*Select all that apply:*	
		American Indian of Alaska Native
		Asian
		Black or African American
		Native Hawaiian or Other Pacific Islander
		White
		Some other race
		Prefer not to respond
35c	If some other race, please describe:	*Fill in blank*
End of Questionnaire for working Pharmacists. Thank you! If you answered "No" to Question 7, please continue.		
36	If you did not practice or teach pharmacy within the past twelve months, did/are you. . .?	*Check all that apply:*
		I am retired.
		Practice occasionally for charity/consultation/special patients?
		Pursue specialty education?
		Pursue non-pharmacy education?
		Work in another profession?
		Experience temporary **voluntary** unemployment (including for medical reasons)?
		Experience temporary **involuntary** unemployment?

37	Do you expect to begin working in the pharmacy field in Virginia? If so, when?	*Dropdown:*
		Not currently planning to practice/work in Virginia.
		Yes, within the next year
		Yes, within 1-2 years
		Yes, within 3-5 years
		Yes, in more than 5 years
		Yes, do not know when

Pharmacy Technician Workforce Survey

Education and Background		
1	Where did you attend high school (Secondary School)?	*Dropdown*
		Outside of the US or Canada
		Canada
		57 US States and Territories
2	What is the highest level of education you have attained as of today?	*Check all that apply*
		High School/GED
		Associate Degree
		Baccalaureate Degree
		Masters Degree
		Ph.D.
3	Do you hold either of the following national pharmacy technician certifications as of today?	*Check all that apply:*
		Pharmacy Technician Certification Board (PTCB)
		Exam for Certification of Pharmacy Technicians (ExCPT)
		None of the Above
4	Within the past 12 months, have you worked, volunteered, taught or practiced, in any environment related to pharmacy technicians or in any position that drew on your knowledge of pharmacy? (if only occasional practice--less than 100 hrs--please select "No")	*Check One: Yes/No*
	Please note: Answer "yes" for any pharmacy-related activities, including administrative, educational, regulatory or other activities.	
If you answered "No" to Question 7, please go to Question 25 in the Demographics section. If you answered "Yes", please continue.		

Primary Work Location		
Question 5 through Question 10 refer to your primary place of employment, work or practice. This is the place where you spend the most work hours during an average workweek, or where you spent the most weeks working in the past 12 months. Please use these questions to describe a particular work location, not an employer. Temporary or traveling workers who spend or spent a significant amount of time at a particular location should use that location as his or her primary work location. Persons who consistently work in multiple locations (i.e. temporary workers, locum tenens) should indicate this in Question 5.		
5	Please select the location of your primary place of employment, work or practice:	*Dropdown:*
		List of Virginia's Cities and Counties
		Several localities (temporary, mobile clinic, etc.)
		Outside of US
		Virginia Border State/DC
		Other US State
6	Approximate number of weeks at which at least some time was spent at this work location within the past twelve months (exclude vacation, medical leave, etc.)	*Fill in Blank (2-digit numeric, not more than 52 or less than 1)*
7a	Please select the type of practice setting:	*Dropdown:*
		Independent Community Pharmacy (1-4 stores)
		Small Chain Community Pharmacy (4-10 stores)
		Large Chain Community Pharmacy (10+ stores)
		Mass Merchandiser (i.e. Big Box Store)
		Supermarket Pharmacy
		Clinic-Based Pharmacy
		Mail Service Pharmacy
		Government Hospital / Health System, Inpatient
		Government Hospital / Health System, Outpatient
		Non-government Hospital / Health System, Inpatient
		Non-government Hospital / Health System, Outpatient
		Nursing Home, Long Term Care
		Home Health / Infusion
		Pharmacy Benefit Administration (e.g. PBM, managed care)

		Academic Institution
		Other For-profit Corporation / Organization
		Other Non-profit Corporation / Organization
7b	If you selected Other For-profit or Non-profit Corporation / Organization, please provide a brief descripiton:	*Open-ended*
8	How many hours did you work at this location during your average workweek?	*Fill in Blank, 2 spaces, numeric*
9	In the average workweek, what percentage of your working hours were spent in the following roles:	
		000: Medication Dispensing (including counting, labeling, repackaging, placing drugs in counting devices or robots)
		000: Customer Service (including cashiering, receiving written prescriptions)
		000: Supervisory/Staff management/Scheduling tasks
		000: Third party payor billing & coordination
		000: Other Clerical and Administrative tasks (including assisting with proper maintenance of records, billing patients, stocking/restocking drug inventory)
		000: Teaching a board-approved pharmacy technician training program
		000: Other
		000: Average weekly hours for location: (Automatically sum first five)

10	How are you paid for your services at your primary work location?	*Check all that apply*
		Salary
		Hourly wage
		Profits (owner/part owner)
		Volunteer/Not paid
If you only have one practice location, please skip to question 18. If you have additional practice locations, please continue.		
Secondary Practice Setting		
Question 11 through Question 16 refer to your secondary place of employment, work or practice. This is the place where you spend the second most work hours during an average workweek, or where you spent the second most weeks working in the past 12 months. Please use these questions to describe a particular work location, not an employer. Temporary or traveling workers who can identify a second location where he or she spends or spent a significant amout of time should use this as his or her secondary work location. Persons who consistently work in multiple locations (i.e. temporary workers, locum tenens) should indicate this in Question 11.		
11	Please select the location of your secondary place of employment, work or practice:	*Dropdown:*
		List of Virginia's Cities and Counties
		Several localities (temporary, mobile clinic etc)
		Outside of US
		Virginia Border State/DC
		Other US State
12	Approximate number of weeks at which at least some time was spent at this work location within the past twelve months (exclude vacation, medical leave, etc.)	*Fill in Blank (2-digit numeric, not more than 52 or less than 1)*
13a	Please select the type of practice setting:	*Dropdown:*
		Independent Community Pharmacy (1-4 stores)
		Small Chain Community Pharmacy (4-10 stores)
		Large Chain Community Pharmacy (10+ stores)
		Mass Merchandiser (i.e. Big Box Store)

		Supermarket Pharmacy
		Clinic-Based Pharmacy
		Mail Service Pharmacy
		Government Hospital / Health System, Inpatient
		Government Hospital / Health System, Outpatient
		Non-government Hospital / Health System, Inpatient
		Non-government Hospital / Health System, Outpatient
		Nursing Home, Long Term Care
		Home Health / Infusion
		Pharmacy Benefit Administration (e.g. PBM, managed care)
		Academic Institution
		Other For-profit Corporation / Organization
		Other Non-profit Corporation / Organization
13b	If you selected Other For-profit or Non-profit Corporation / Organization, please provide a brief descripiton:	*Open-ended*
14	How many hours did you work at this location during your average workweek?	*Fill in Blank, 2 spaces, numeric*
15	In the average workweek, what percentage of your working hours were spent in the following roles:	
		000: Medication Dispensing (including-counting, labeling, repackaging, placing drugs in counting devices or robots)
		000: Customer Service (including cashiering, receiving written prescriptions)
		000: Supervisory/Staff management/Scheduling tasks
		000: Third party payor billing & coordination
		000: Other Clerical and Administrative tasks (including assisting with proper maintenance of records, billing patients, sotcking/restocking drug inventory)
		000: Teaching a board-approved pharmacy technician training program
		000: Other

		000: Average weekly hours for location: (Automatically sum first five)
16	How are you paid for your services at your secondary work location?	*Check all that apply*
		Salary
		Hourly wage
		Profits (owner/part owner)
		Volunteer/Not paid
If you only have two practice locations, please skip to question 18. If you have additional practice locations, please continue.		
Other Practice Setting(s)		
17	Total hours of pharmacy technician services provided at all other locations in the past 12 months:	*Fill in Blank (numeric, 2 digits)*
Employment information		
18	What is your estimated hourly income from your work as a pharmacy technician over the past 12 months?	*Dropdown:*
		Volunteer work only
		$7.25-9.00/hr
		$9.01-$11.00/hr
		$11.01-$13.00/hr
		$13.01-$15.00/hr
		$15.01-$17.00hr
		$17.01-$19.00/hr
		$19.01-$21..00/hr
		More than $21.00/hr
		Prefer not to respond
19	Do you receive any of the following benefits from your current employer(s)?	*Check all that apply:*
		Paid Vacation

		Paid Sick Leave
		Paid Disability Leave
		Health Insurance
		Dental Insurance
		Stock options
		Retirement (401k, Pension, etc)
		Group Life Insurance
		Signing/retention bonus
		No Benefits
20	Do any of your employers require you to maintain a national certification? If so, which certification?	*Check all that apply*
		No, my employer(s) do not require a national certification.
		Yes, Pharmacy Technician Certification Board (PTCB)
		Yes, Exam for Certification of Pharmacy Technicians (ExCPT)
21	Have any of your employers provided you with increased pay for obtaining a national certification?	*Dropdown: yes/no/Do not hold a national certification.*
22	What is your estimated current educational debt?	*Dropdown*
		No educational debt
		Less than $2,000
		$2,001-$4,000
		$4,001-$6,000
		$6,001-$8,000
		$8,001-$10,000
		$10,001-$12,000
		$12,001-$15,000
		$15,001-$20,000
		More than $20,000
		Prefer not to respond
23	At what age do you predict you will retire (if you do not expect to ever retire, please put "NA"):	*Fill in blank:* __

24	Within the next two years do you plan to do any of the following:	*Check all that apply*
		Retire
		Cease working as a pharmacy technician.
		Virginia
		Increase hours working as a pharmacy technician
		Decrease hours working as a pharmacy technician
		Obtain national certification
		Attend a school of pharmacy to become a pharmacist
		Pursue additional education in a non-Pharmacy related field
25	Within the next five years do you plan to do any of the following:	*Check all that apply*
		Retire
		Cease working as a pharmacy technician.
		Continue working as a pharmacy technician, but cease doing so in Virginia
		Increase hours working as a pharmacy technician
		Decrease hours working as a pharmacy technician
		Obtain national certification
		Attend a school of pharmacy to become a pharmacist
		Pursue additional education in a non-Pharmacy related field
Demographic Questions		
26	Year of Birth	*Fill-in (4 Digit Year)*
27	Sex	*Dropdown: Male/Female*
	Please select the items that best describe your race/ethnicity. Please answer both question 28a about Hispanic origin and 28b about race/ethnicity.	
28a	*Select One:*	*Check one:*
		Hispanic, Latino or Spanish origin

		Not Hispanic, Latino or Spanish origin
		Prefer not to respond
28b	*Select all that apply:*	
		American Indian of Alaska Native
		Asian
		Black or African American
		Native Hawaiian or Other Pacific Islander
		White
		Some other race
		Prefer not to respond
28c	If some other race, please describe:	*Fill in blank*
End of Questionnaire for working Pharmacy Technicians. Thank you! If you answered "No" to Question 4, please continue.		
29	If you did not practice, teach or otherwise work as a pharmacy technician in Virginia within the past twelve months, did/are you . . .?	*Check all that apply:*
		I am retired.
		Work in a state bordering Virginia or in the District of Columbia?
		Work in another state (not bordering Virginia)?
		Work in another country?
		Work as part of the US Uniformed Services or the US Peace Corps?
		Work outside of Virginia with a religious or non-profit organization?
		Work occasionally for charity/consultation/special patients?
		Pursue pharmacy-related education, excluding required continuing education requirements
		Pursue non-pharmacy education?
		Work in another profession?
		reasons)?
		Experience temporary **involuntary** unemployment?
		Required to hold registration as part of a management position?

30	Do you expect to begin working in the pharmacy field in Virginia? If so, when?	*Dropdown:*
		Not currently planning to practice/work in Virginia.
		Yes, within the next year
		Yes, within 1-2 years
		Yes, within 3-5 years
		Yes, in more than 5 years
		Yes, do not know when