



COMMONWEALTH OF VIRGINIA

Meeting of the Board of Pharmacy

Perimeter Center, 9960 Mayland Drive, Second Floor
Henrico, Virginia 23233

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Tentative Agenda of Meeting

September 20, 2011

9:00AM

TOPIC

PAGE(S)

Call to Order: Gill Abernathy, Chairman

- Welcome
- Introductions
- Recognition of new board members: R. Crady Adams and Emsy Munden
- Reading of emergency evacuation script
- Approval of Agenda
- Approval of previous Board meeting minutes:
 - June 8, 2011, Full Board Meeting 1-12
 - July 25, 2011, Telephone Conference Call 13-15
 - August 16, 2011 Panel Formal Hearing *19-22
 - August 25, 2011, Ad hoc Committee – CQI 23-30

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

DHP Director’s Report: Diane Reynolds-Cane, M.D.

Regulations: Elaine Yeatts and Caroline Juran

- Approval to extend emergency regulations for CSBs, BHAs, and crisis stabilization units 31-33
- Adoption of proposed regulations for on-hold prescriptions 34-47
- Adoption of emergency regulations for continuous quality improvement programs 48-59
- Consideration of petitions for rulemaking regarding automated dispensing devices 60-74
- Review “run dry” requirement for automated counting devices in 18VAC110-20-355 75-77

Update on Action Items: Caroline Juran and Cathy Reiniers-Day

- Statistics regarding delegated authority Handout

Miscellaneous:

- Consider amending guidance document 110-9, Major 24, regarding definition of "low volume" 78-85
- Guidance for reconciliation of perpetual inventories 86-94
- Review Joint Commission's study recommendations, HB1961 and HB1966 Handout
- Discuss concerns expressed by pharmacist and ISMP regarding 15-minute prescription guarantee dispensing policy 95-98
- Schedule dates for 2012 full board meetings 99
- Examination accommodation request Handout

Reports:

- Report from PMP
 - Legislative Proposal – Elaine Yeatts 100-103
 - Regulatory action, interoperability – Carolyn McCann, Deputy Director, PMP 104-105
- Chairman's Report – Gill Abernathy
 - Announcement of committee appointments 106
- Report on Board of Health Professions – Robbie Rhodes
- Report on Licensure Program – Sammy Johnson Handout
- Report on Disciplinary Program – Cathy Reiniers-Day Handout
- Executive Director's Report - Caroline D. Juran

New Business**Consideration of consent orders (if any)****Formal Hearings:**

- 1:00PM Brian P. Musgrove 107-108
- 2:00PM Philip D. Richard 109-110

Adjourn

***Pages 16-18 deleted from agenda packet prior to publishing.**

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

(DRAFT/UNAPPROVED)

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

June 8, 2011
Second Floor
Board Room 2

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: The meeting was called to order at 9:18 AM.

PRESIDING: Brandon Yi, Chairman

MEMBERS PRESENT: Gill B. Abernathy
Jody H. Allen
John O. Beckner
Gerard Dabney
David C. Kozera
Robert M. Rhodes
Leo H. Ross
Ellen B. Shinaberry
Pratt P. Stelly

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

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

APPROVAL OF AGENDA: An amended agenda was presented and approved by the Board with one additional request from staff for guidance on the handling of a possible disciplinary matter.

APPROVAL OF MINUTES: The Board reviewed draft minutes for March 9, 2011 (board meeting); May 17, 2011 (Ad Hoc Committee, On-Hold Prescriptions); May 18, 2011 (Ad Hoc Committee, Pharmacy Inspections); and May 18, 2011 (Ad Hoc Committee, CQI Program). There was one minor correction to the minutes for May 17, 2011, in that the commencement time should be 12:35 P.M., instead of 12:35 A.M.

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

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

LEGISLATION:

- Legislation update

Ms. Yeatts discussed the legislative proposal for placing tramadol and carisoprodol into Schedule IV. In 2010, the Board denied a petition for rulemaking since there was hesitation to schedule drugs in rule versus legislation. Instead, the Board recommended a legislative proposal to place tramadol and carisoprol into Schedule IV. The legislative proposal was not carried by the Administration. There was discussion whether the Board wanted to again recommend the legislative proposal for the upcoming General Assembly session.

Motion:

The Board voted unanimously to recommend the legislative proposal to place tramadol and carisoprodol into Schedule IV. (motion Stelly, second by Ross)

REGULATIONS:

- Regulation update

Ms. Yeatts gave an update regarding the status of current regulatory action. The comment period for the proposed regulations to impose administrative fees for duplicate licenses and verifications closed on May 11, 2011, and the Board could adopt the proposed regulations later during this meeting. Additionally, she stated that the comment period for the NOIRA to amend regulations to address on-hold prescriptions closed later that day at 5pm and therefore, the Board cannot adopt proposed regulations until the September full Board meeting. The regulations to replace the emergency regulations regarding repackaging in a community service board or behavioral health authority are currently in the Secretary's office and the regulations regarding the elimination of an alarm system for certain emergency medical services agency are currently in the Governor's office.

- Fast- Track for CE Requirements:

Ms. Yeatts explained that the National Association of Boards of Pharmacy and the Accreditation Council for Pharmacy Education (ACPE) are collaborating to offer the CPE Monitor Service, an electronic system for pharmacists and pharmacy technicians to receive and track their completed continuing pharmacy education (CPE) credits. Because ACPE will cease providing a certificate of completion to the individual sometime in the next year and will solely provide electronic documentation of completion to the CPE Monitor Service, Ms. Yeatts stated that regulations 18 VAC 110-20-90 and 18 VAC 110-20-100 that require the provision and maintenance of an original certificate of completion need to be amended.

Motion:

The Board voted unanimously to adopt the fast-track regulatory amendments to Regulations 18VAC110-20-90 and 18VAC110-20-100 as presented regarding continuing education certificates. (motion Beckner, second by Kozera)

- Adoption of Proposed Regulations of New Administrative Fees:

Ms. Yeatts reported that the Board needed to consider adopting regulations for adding new administrative fees. The additions include a \$10.00 fee for a duplicate license or registration and a \$25.00 fee for verification of licensure or registration.

Motion:

The Board voted unanimously to adopt the proposed regulations for new administrative fees for duplicate licenses or registrations and verifications of licensure or registration. (motion Kozera, second by Beckner)

- Petitions for Rulemaking Regarding Automated Dispensing Devices:

Ms. Yeatts reported that the Board has received three petitions for rulemaking concerning Regulation 18VAC110-20-490 which addresses automated dispensing devices. Because a petition for rulemaking requires at least a 21-day comment period, the Board cannot consider the petitions until the September 22, 2011 meeting.

- Guidance Document 110-11-Proof of Identity when Dispensing Schedule II Drugs:

Ms. Yeatts explained that the amendments to the proof of identity requirements found in § 54.1-3420.1 resulting from the passing of HB2256 will become effective July 1, 2011. Therefore, guidance document 110-11 would either need to be amended to reflect the statutory changes or repealed. After some discussion, the Board concluded that the guidance document should not be repealed since further clarification of the statute was needed, but it should be amended to conform to the statutory changes.

Motion:

The Board voted unanimously to amend guidance document 110-11 to conform to changes in § 54.1-3420.1, effective July 1, 2011, and for staff to amend the document accordingly. (motion Kozera, second by Beckner)

UPDATE ON ACTION ITEMS:

- Ad-Hoc committee for continuous quality improvement program

Ms. Juran provided an update regarding the ad-hoc committee meeting that was held on May 18, 2011, concerning the drafting of emergency regulations for pharmacies to implement a continuous quality improvement program as required by the passing of HB2220. Suggested key concepts to be included in the draft regulations have been identified by the committee and were listed in the committee meeting's minutes. Because emergency regulations become effective for one year once adopted and there is no opportunity for public comment, Ms. Yeatts explained that the Board may wish to consider adopting a notice of intended regulatory action (NOIRA) to give public a 30-day opportunity to

offer comment on the key concepts which may be included in the emergency regulations.

Motion:

The Board voted unanimously to adopt a NOIRA consistent with the key concepts identified in the minutes from the ad-hoc committee meeting for continuous quality improvement programs. (motion Beckner, second by Kozera)

- Ad-Hoc committee for on-hold prescriptions

Ms. Juran provided an update from the ad-hoc committee meeting held on May 17, 2011 and briefly reviewed the committee's suggested regulatory changes as outlined in the committee meeting's minutes. There was no Board action required at this time

- Ad-Hoc committee for routine inspection program

Sammy Johnson presented the ad-hoc committee's suggested amendments to Guidance Document 110-9 as determined during the May 18, 2011 ad-hoc committee meeting for the routine inspection program. The Board offered the following specific recommendations to the suggested amendments:

- Clarify the suggested language in Major Deficiency 17 regarding refill authorizations since not permissible for Schedule II drugs;
- Reword the suggested conditions for Major Deficiency 24 to read "Low volume defined as 15 or less hazardous drug CSP/week or as defined by USP. Review 2 months records."
- Add a 10% threshold to the conditions for Minor Deficiency 24; and,
- Add a condition to Minor Deficiency 38 to read "Cite if no documentation of monitoring. Review ADD in areas that do not utilize patient specific profile. Review 3 months of records – 30% threshold. Cite if exceeds threshold. Describe in comment section steps pharmacy is taking to comply. Educate regarding requirements."

The committee's other suggested amendments were accepted by the Board as presented.

Motion:

The Board voted unanimously to amend Guidance Document 110-9 as discussed. (motion Ross, second by Rhodes)

Mr. Johnson reminded the Board that the new inspection process has been "live" in community pharmacies since July 1, 2010, and has been piloted in hospital and other institutional pharmacies since July 1, 2010. Because Board staff and inspectors feel comfortable with the new inspection report for hospitals and other institutions, staff recommended that the Board consider going "live" with the new inspection process in all other pharmacies beginning July 1, 2011. Ms. Abernathy requested that staff notify pharmacists and pharmacy technicians of this decision prior to July 1.

Motion: The Board voted unanimously to go “live” with the new inspection process in all pharmacies beginning July 1, 2011. (motion Kozera, second by Beckner)

Action Item: Board staff will send an email notification to all pharmacists and pharmacy technicians who have voluntarily provided an email address to the Board indicating that the new inspection process will go “live” in all pharmacies beginning July 1, 2011. Additionally, staff will post a similar notification on the Board’s website.

REPORTS: Dr. Elizabeth Carter, Director, DHP Healthcare Workforce Data Center, gave an update to the Board regarding the workforce surveys. Dr. Carter stated that any public feedback concerning the surveys would need to be received no later than July 1, 2011. She also requested a member of the Board of Pharmacy to consider serving on the workforce council.

Action Item: The Board Chairman will appoint a member of the Board of Pharmacy to participate on the healthcare workforce council.

MISCELLANEOUS:

- Methods for handling disciplinary matters- Review of statistics for key performance measures and the need to improve case clearance rate
Ms. Juran reported the statistics for key performance measures in the third quarter of 2011. The clearance rate was reported at 41% (goal = 100%), the pending caseload older than 250 business days was 7% (goal = 25% or less), and the percent closed within 250 business days was 65% (goal = 90%). Ms. Reiniers-Day explained that the clearance rate was low partly due to a process which will no longer be used by staff. The process required cases which had technically been closed by the Board to be placed into a “pending closure” status during the thirty-day period appeal time. Ms. Reiniers-Day stated that other Boards do not use a “pending closure” status for this purpose, and that the Board’s clearance rate in the third quarter of 2011 unofficially increased to 83% after eliminating the use of a “pending closure” status. Further, she stated that a review of cases closed for the time period April 1, 2011 to June 7, 2011 unofficially indicated a clearance rate of 96%, and she expected the Board to maintain a high percentage rate.

- Review of other Boards methods of delegating authority to professional staff
Ms. Juran stated that the Boards of Nursing and Medicine have delegated authority to professional staff to process certain disciplinary matters. While the scope of delegated authority is rather broad for these Boards due to a greater need to efficiently process a higher volume of cases, Ms. Juran believed this Board’s needs are more limited based on the number of disciplinary cases.

- Discussion of
A handout was provided outlining the request for delegated

delegating authority to
Board of Pharmacy
professional staff

authority which included the following:

The Board of Pharmacy delegates to the Executive Director the authority to offer a prehearing consent order (PHCO) in the following circumstances:

1. Action taken by another state board of pharmacy. PHCO would require compliance with the other state's actions.
2. A single dispensing error with no patient harm involving an individual who is a minor or medically compromised, or a drug with a narrow therapeutic index. PHCO would require hours of continuing education in the subject of dispensing errors.
3. An inspection report as part of an investigation which resulted in the citing of deficiencies as identified in guidance document 110-9.

The delegation of authority to professional staff would also allow the Executive Director to offer confidential consent agreements for the following circumstances:

1. A single dispensing error with no patient harm, except as noted in #2 above. The CCA would require hours of continuing education in the subject of dispensing errors.

Additionally, it was requested that the Board delegate to the Executive Director the authority to close cases that have insufficient evidence of a violation of law or regulation.

The Board considered the request, and there was some discussion regarding the appropriate disciplinary action to be taken for a single dispensing error involving no patient harm. While Ms. Abernathy stated that she was comfortable with the concept of delegating authority, she believed that the act resulting in a dispensing error is the same no matter the patient or drug involved and therefore, she questioned whether the disposition of such cases should be the same barring any other violations of law. To aid the Board in possible future discussions on this topic, Ms. Juran offered to provide the Board with a historical perspective of statistics at the September meeting summarizing the Board's disposition of cases over the last year involving a single dispensing error involving no patient harm.

Action Item:

To aid the Board in possible future discussions, Ms. Juran will provide the Board with statistics at the September meeting summarizing the Board's disposition of cases over the last year

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involving a single dispensing error with no patient harm.

Motion:

The Board voted nine to one to adopt a guidance document delegating authority to the Executive Director to handle certain disciplinary cases as requested for a six-month trial period with a report being provided by Ms. Juran at each full board meeting summarizing the disposition of cases during the trial period. (motion Kozera, second by Beckner; opposed Abernathy).

- Update of Guidance Document for use of agency subordinate

Ms. Yeatts reviewed suggestions for amending guidance document 110-37 regarding use of an agency subordinate explaining that the other boards within the agency have adopted such changes. Specifically, the Board of Nursing, who has actively used agency subordinates for several years, has found the changes to be very helpful. Ms. Juran reminded the Board that it has been interested in implementing agency subordinates and that the proposed changes to the guidance document would assist the process when in place.

Motion:

The Board voted unanimously to adopt the proposed changes as presented to guidance document 110-37 regarding the use of agency subordinates. (motion Abernathy, second by Ross)

- Request to waive regulation to allow acceptance of score transfer without obtaining additional hours of practical experience after failing NAPLEX three or more times

Ms. Juran discussed with the Board a situation where an individual licensed in another state, who did not pass NAPLEX until his fourth attempt, requested that he be allowed to obtain a pharmacist license in Virginia via score transfer without having to obtain the additional 1,000 hours of practical experience as required in Regulation 18VAC110-20-60. The Board believed the requirement to obtain additional hours of practical experience after having failed NAPLEX three times should apply to all applicants and therefore, denied the request to waive such requirement. It was stated that there is a mechanism in place for such an applicant and that he may apply for a pharmacist license in Virginia via license transfer or reciprocity.

- Board budget

Ms. Juran reported that she had been requested by the Finance Department to inform the Board that Dr. Cane has begun the formal process in the development of the agency's 2012-2014 biennium budgets. Ms. Juran provided the Board with a handout which outlined certain Board expenditures, excluding expenditures such as salaries, insurance, building rental, fiscal services, etc. She informed the Board that she did not believe the Board needed to request additional funds from Dr. Cane at this time.

REQUESTS FOR
EXAMINATION
ACCOMMODATION:

Motion for closed meeting:

The Board voted unanimously to convene a closed meeting pursuant to § 2.2-3711(A)(15) of the Code of Virginia for the purpose of consideration and discussion of medical/mental health records contained in an accommodation request that are excluded from the Freedom of Information Act by Virginia Code Section 2.2-3705(A)(5) and that Caroline Juran, Sammy Johnson, Cathy Reiniers-Day, Howard Casway, Heather Hurley and David Gustin attend the closed meeting because their presence was deemed necessary and would aid the Board in its deliberations. (motion by Beckner, second by Kozera).

Motion to certify the purpose of the closed meeting:

The Board voted unanimously that only public business matters lawfully exempted from open meeting requirements under the Virginia Freedom of Information Act and only such public business matters as were identified in the motion for executive meeting were heard, discussed, or considered during the closed session just concluded. (motion by Beckner, second by Kozera).

Motions:

The Board voted unanimously to approve the examination accommodation request from Jamie Dalton allowing her twice the normally allotted amount of time for completing the examinations and a private room or partitioned area with limited distractions for completing the exams with a proctor appropriately monitoring her testing experiences. (motion by Kozera, second by Dabney).

The Board voted unanimously to approve the examination accommodation request from Michael Girgis allowing him to use a magnifying device when taking NAPLEX and authorizing the testing contractor to provide the examination in a larger computer font such as 16 point. The request for a paper format of NAPLEX was denied since the examination is not offered in a paper format as the security of the examination may be more easily compromised. (motion by Beckner, second by Kozera).

The Board held a working lunch from 1:55pm to 2:30pm

REPORTS:

- Report on Board of

Mr. Kozera reported that the Board of Health Professions was in the

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Health Professions

process of recommending genetic counselors to become licensed under an advisory board of the Board of Medicine with an exemption for physicians and registered nurses who provide this type of service. Also, he stated that there is ongoing discussion on expanding the scope of practice for various types of licensees. The scopes of practice for pharmacists and pharmacy technicians are scheduled to be reviewed later this Fall. Additionally, the Board of Health Professions met with Neil Carter concerning sanction reference studies possibly addressing cases involving social media and the fact that if a licensee does not show for a disciplinary hearing should not be used as a scoring item. There was also a discussion whether a copy of the sanction reference worksheet must be included with the Order when provided to the licensee. Mr. Casway interjected that the agency's policy is still under development.

- Report on disciplinary matters

Ms. Reiniers-Day stated that, as of June 2, 2011, there were 280 cases docketed for the Board of Pharmacy. Three cases were at the entry level, 70 at the investigation level, 70 at the probable cause level, 11 at APD, five at the informal conference level, none at the formal hearing level and 121 at the pending closure level. These numbers include the cases docketed as a result of an inspection with an offered pre-hearing consent order.

Further, Ms. Reiniers-Day stated that all board members had been sufficiently exposed to disciplinary issues and the board could resume having two Special Conference Committees, meeting alternate months to provide monthly coverage. The first Committee included Mr. Kozera and Ms. Allen with Mr. Rhodes as the alternate; and the second Committee included Mr. Yi and Ms. Stelly with Ms. Shinaberry as the alternate. Ms. Reiniers-Day advised these board members that she would e-mail dates to them to begin the scheduling process.

- Report on licensure matters

Mr. Johnson reported that the board issued 877 licenses for the period of March 1 through May 31, 2001, including 110 pharmacist licenses and 505 pharmacy technician registrations. One pilot program was implemented at Dulles Urgent Care Center. The pilot utilizes the InstyMeds Automated Prescription Dispensing System.

- Executive Director's Report

Ms. Juran reported that in April she was involved in several discussions regarding whether pharmacists may compound 17 alpha hydroxyprogesterone caproate, an injectable drug indicated to prevent pre-term labor. Pharmacies had previously compounded this drug for years at approximately \$10-20 per dose, however, recently FDA granted KV Pharmaceuticals orphan drug status with

a 7-year exclusivity for manufacturing Makena. The initially announced price for Makena was \$1500 per dose. Several groups including the US Congress initiated conversations with the manufacturer regarding the high cost for Makena which was ultimately reduced by approximately fifty percent. Additionally, the FDA announced that it would not enforce its enforcement provisions on any pharmacist compounding the drug when compounded in a safe and compliant manner. The Department of Medical Assistance Services concluded that it could not legally reimburse pharmacists for compounding 17 alpha hydroxyprogesterone caproate, but Board counsel advised that pharmacists may legally compound the drug within specific circumstances as identified in § 54.1-3410.2 of the Drug Control Act.

Additionally, Ms. Juran announced that DEA's second national take-back day was a success. DEA reported 376, 593 pounds of unwanted, unused, and potentially harmful drugs were collected nationwide, a 50% increase from the first initiative held last September. In Virginia, it was reported that 9,504.2 pounds were collected. DEA is planning a third take-back event to be held this Fall.

A letter of support, as requested, was sent in April to the Virginia Department of Health, Division of Immunization, for a grant funding opportunity. The grant is for developing or improving state or local public health immunization program relationships with pharmacies and the Board agreed to publish an e-newsletter article or send a blast email educating pharmacists and pharmacy technicians on this subject, if needed.

Ms. Juran asked Mr. Beckner to provide an update on the invitational meeting, the Pharmacy Transformation Conference, recently attended by Ms. Juran and Mr. Beckner. Mr. Beckner explained that this meeting was sponsored by the School of Pharmacy at the Virginia Commonwealth University. It was well-attended with several national speakers and the intent of the meeting was to begin a dialogue for what action may be necessary to review the current practice of pharmacy and implement possible changes consistent with any opportunities resulting from healthcare reform.

Ms. Juran reported that she attended the NABP Annual Meeting in May held in San Antonio, TX. She stated it was very informative and she reviewed the resolutions passed by the NABP voting members. Other travels will include Ms. Juran attending an invitational DEA Annual meeting later this month to be held in Ft. Worth, TX. The purpose of the meeting is to facilitate an exchange

of information between DEA and states that enforce controlled substance laws. Additionally, Ms. Juran will attend a one-day meeting in Chicago, IL in July, sponsored and paid for by NABP. It is designed to orient new executive officers to NABP processes.

Also, Ms. Juran stated that the Executive Director or his designee is required under statute to sit on the Board of Forensic Science and that she has recently been elected Chairman of the Board for the upcoming year beginning July 1, 2011.

Lastly, she reminded everyone that the date for the September full Board meeting has been changed to September 22, 2011.

RECONITION OF BOARD
MEMBERS :

Mr. Yi and other members of the Board recognized the three Board members whose terms either had or were expiring and thanked them for their years of service and dedication to the Board and to the citizens of Virginia. Mr. Leo Ross' second full term expired on June 30, 2010 and Mr. Beckner will complete his second full term on June 30, 2011. Neither is eligible for reappointment. Additionally, Mr. Dabney will complete his first full term on June 30, 2011. He is eligible for reappointment.

ELECTION OF OFFICERS:

Mr. Kozera nominated Gill B. Abernathy for the office of Chairman, with a second from Mr. Rhodes. No other nominations were made. The Board voted unanimously to elect Ms. Abernathy as Chairman for the term July 1, 2011 through June 30, 2012.

Ms. Abernathy nominated David C. Kozera for the office of Vice-Chairman, with second from Mr. Ross. No other nominations were made. The Board voted unanimously to elect Mr. Kozera as Vice-Chairman for the term July 1, 2011 through June 30, 2012.

NEW BUSINESS:

There was no new business

APPROVAL OF CONSENT
ORDERS:

Motion for closed meeting:

The Board voted unanimously, to enter into closed meeting pursuant to § 2.2-3711(A) (28) of the Code of Virginia for the purpose of deliberation to reach a decision regarding a Consent Order. Additionally, it was moved that Cathy Reiniers-Day, Caroline Juran, Sammy Johnson, Howard Casway, and Heather Hurley attend the closed meeting because their presence was deemed necessary and would aid the Board in its deliberation. (motion by Beckner, second by Kozera)

Motion to certify the
purpose of the closed

The Board voted unanimously that only public business matters lawfully exempted from open meeting requirements

meeting: and only such public business matters as were identified in the motion for closed meeting were heard, discussed, or considered during the closed meeting. (motion by Beckner, second by Dabney)

Motion: The Board voted unanimously to accept the consent order as presented by Ms. Reiniers-Day in the matter of Thomas R. Eddy, Pharmacist. (motion by Kozera, second by Allen)

ADJOURN: With all business concluded, the meeting adjourned at 2:50 P.M.

Brandon Yi, Board Chairman

Caroline D. Juran, Executive Director

Date

Date

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(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF TELEPHONE CONFERENCE CALL

Monday, July 25, 2011

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

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

TIME & PURPOSE: Pursuant to § 54.1-2400(13) of the Code of Virginia, a telephone conference call of the Virginia Board of Pharmacy ("TCC") was held at 3:00 p.m., on July 25, 2011, to consider the summary suspension of the license of James V. Ettare to practice as a pharmacist; Valley Compounding Pharmacy to conduct a pharmacy; and the registrations of Laura J. Gray and Amanda L. Jenkins to practice as pharmacy technicians in the Commonwealth of Virginia.

PRESIDING: Gill B. Abernathy, Chair

MEMBERS PRESENT: Jody H. Allen
John O. Beckner
Gerard Dabney
David C. Kozera
Leo H. Ross
Pratt P. Stelly
Brandon K. Yi

STAFF PRESENT: Cathy M. Reiniers-Day, Deputy Executive Director
Caroline D. Juran, Executive Director
Eusebia L. Joyner, Disciplinary Program Specialist
Howard Casway, Senior Attorney General
Mykl Egan, DHP Adjudication Specialist
Wayne T. Halbleib, Senior Attorney General

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

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

JAMES V. ETTARE
License No. 0202-206317

Wayne T. Halbleib presented a summary of the evidence in this case.

Upon a motion by Mr. Kozera and duly seconded by Mr. Beckner, the Board unanimously voted that, with the evidence presented, the practice as a pharmacist by James V. Ettare poses a substantial danger to the public; and therefore, said license shall be summarily suspended; and that a Notice of Hearing shall be sent with the Order.

VALLEY COMPOUNDING
PHARMACY
Permit No. 0201-004203

Wayne T. Halbleib presented a summary of the evidence in this case.

Upon a motion by Mr. Beckner and duly seconded by Mr. Kozera, the Board unanimously voted that, with the evidence presented, the conduct of Valley Compounding Pharmacy as a pharmacy poses a substantial danger to the public; and therefore, said permit of Valley Compounding Pharmacy shall be summarily suspended; and that a Notice of Hearing shall be sent with the Order.

LAURA J. GRAY
Registration No. 0230-002211

Wayne T. Halbleib presented a summary of the evidence in this case.

Upon a motion by Mr. Beckner and duly seconded by Mr. Dabney, the Board unanimously voted that with the evidence presented, the practice as a pharmacist technician by Laura J. Gray poses a substantial danger to the public; and therefore, that the registration of Ms. Gray to practice as a pharmacy technician be summarily suspended; and that, with the Notice of Hearing, a Consent Order be offered to Ms. Gray for the indefinite suspension of her registration for not less than one year.

AMANDA L. JENKINS
Registration No. 0230-018494

Wayne T. Halbleib presented a summary of the evidence in this case.

Upon a motion by Mr. Kozera and duly seconded by Mr. Beckner, the Board unanimously voted that, with the evidence presented, the practice as a pharmacy technician by Amanda L. Jenkins poses a substantial danger to the public; and therefore, that the registration of Ms. Jenkins to practice as a pharmacy technician be summarily suspended;

and that, with the Notice of Hearing, a Consent Order be offered to Ms. Jenkins for the indefinite suspension of her registration as a pharmacy technician.

Cathy M. Reiniers-Day
Deputy Executive Director

Eusebia L. Joyner
Disciplinary Program Specialist

Gill B. Abernathy, Chair

Date

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(DRAFT/UNAPPROVED)

**VIRGINIA BOARD OF PHARMACY
MINUTES OF A PANEL OF THE BOARD**

August 16, 2011
Second Floor
Board Room 2

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: A meeting of a panel of the Board of Pharmacy ("Board") was called to order at 10:00 a.m.

PRESIDING: Gill B. Abernathy, Chair

MEMBERS PRESENT: Crady Adams
Jody Allen
Gerard Dabney
David C. Kozera
Empsy Munden
Ellen B. Shinaberry

STAFF PRESENT: Caroline D. Juran, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
Eusebia L. Joyner, Administrative Assistant
Howard Casway, Senior Assistant Attorney General
Wayne T. Halbleib, Senior Assistant Attorney General
Mykl Egan, DHP Adjudication Specialist

QUORUM: With seven (7) members of the Board present, a panel was established.

JAMES V. ETTARE
License # 0202-206317

A formal hearing was held in the matter of James V. Ettare following the summary suspension of his pharmacist license on August 1, 2011, and to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy in Virginia.

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

Donald M. Jackson, DHP Senior Pharmacy Inspector, and Christopher Klein, Pharmacy Intern, testified on behalf of the Commonwealth.

Mr. Ettare appeared with Gerald C. Canaan II, Esquire.

Closed Meeting: Upon a motion by Mr. Kozera and duly seconded by Mr. Dabney, the panel voted 7-0, to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia ("Code"), for the purpose of

deliberation to reach a decision in the matter of James V. Ettare. Additionally, he moved that Cathy Reiniers-Day, Caroline Juran, Eusebia Joyner and Howard Casway attend the closed meeting.

Reconvene:

Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the panel re-convened in open meeting and announced the decision.

Decision:

Upon a motion by Mr. Kozera and duly seconded by Mr. Dabney, the panel voted 7-0 to accept the Findings of Fact and Conclusions of Law as proposed by Mr. Halbleib and amended by the panel and read by Mr. Casway.

Upon a motion by Mr. Kozera and duly seconded by Ms. Shinaberry, the panel voted 7-0 that Mr. Ettare's license to practice as a pharmacist be indefinitely suspended for not less than one year from the date of entry of the August 1, 2011, Order of Summary Suspension.

VALLEY COMPOUNDING
PHARMACY
Permit # 0201-004203

A formal hearing was held in the matter of Valley Compounding Pharmacy following the summary suspension of the permit to conduct a pharmacy on August 1, 2011, and James V. Ettare, co-owner and pharmacist-in-charge, appeared to discuss allegations that Valley Compounding Pharmacy may have violated certain laws and regulations governing the conduct of a pharmacy in Virginia.

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

Donald M. Jackson, DHP Pharmacy Inspector, testified on behalf of the Commonwealth.

Mr. Ettare appeared with Gerald C. Canaan II, Esquire.

Closed Meeting:

Upon a motion by Mr. Kozera and duly seconded by Mr. Dabney, the panel voted 7-0, to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia ("Code"), for the purpose of deliberation to reach a decision in the matter of Valley Compounding Pharmacy. Additionally, he moved that Cathy Reiniers-Day, Caroline Juran, Eusebia Joyner, and Howard Casway attend the closed meeting.

Reconvene:

Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the panel re-convened in open meeting and announced the decision.

AMANDA L. JENKINS
Registration # 0230-018494

A formal hearing was held in the matter of Amanda L. Jenkins following the summary suspension of her pharmacy technician registration on August 1, 2011, and to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians in Virginia.

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

Donald M. Jackson, DHP Senior Pharmacy Inspector, testified on behalf of the Commonwealth.

Ms. Jenkins appeared with Gerald C. Canaan II, Esquire.

Closed Meeting:

Upon a motion by Mr. Kozera and duly seconded by Mr. Dabney, the panel voted 7-0, to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia ("Code"), for the purpose of deliberation to reach a decision in the matter of Amanda L. Jenkins. Additionally, he moved that Cathy Reiniers-Day, Caroline Juran, Eusebia Joyner, and Howard Casway attend the closed meeting.

Reconvene:

Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the

Code, the panel re-convened in open meeting and announced the decision.

Decision:

Upon a motion by Mr. Kozera and duly seconded by Mr. Dabney, the panel voted 7-0 to accept the Findings of Fact and Conclusions of Law as proposed by Mr. Halbleib and amended by the panel and read by Mr. Casway.

Upon a motion by Mr. Kozera and duly seconded by Mr. Dabney, the panel voted 7-0 that Ms. Jenkins' pharmacy technician registration be reprimanded and reinstated with certain terms and conditions.

Adjourn:

With all business concluded, the meeting adjourned at 7:00 p.m.

Gill Abernathy, Board Chairman

Cathy M. Reiniers-Day, Deputy Executive Director

Date

Date

22

(DRAFT/UNAPPROVED)

**VIRGINIA BOARD OF PHARMACY
MINUTES OF AD HOC COMMITTEE FOR
CONTINUOUS QUALITY IMPROVEMENT (CQI) PROGRAM**

August 25, 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 10:10AM.

PRESIDING: Gill Abernathy, Chairman

MEMBERS PRESENT: John O. Beckner
Ellen Shinaberry
Rick Baxter
Tim Musselman
Michelle Lincoln

MEMBERS ABSENT: Anila Xhixho
Brandon Yi

STAFF PRESENT: Caroline D. Juran, Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director
Elaine Yeatts, Senior Policy Analyst

PUBLIC COMMENTS: Michele Thomas, Pharmacy Services Manager, Division of Services and Supports, Department of Behavioral Health and Developmental Services, asked questions for clarification regarding the intent of the regulations and the committee responded by explaining the requirements placed on the Board to promulgate regulations pursuant §54.1-3434.03.

EMERGENCY REGULATIONS FOR PHARMACIES IMPLEMENTING CQI PROGRAM: The committee reviewed a draft of emergency regulations prepared by staff and based on the recommendations of the committee from the first meeting held on May 18, 2011. While reviewing the entire draft several edits were made. The final document will be presented to the full Board on September 20, 2011 with the opportunity to adopt the emergency regulations as recommended by the committee. (Attachment 1)

ADJOURN: With all business concluded, the meeting adjourned at 1:05PM.

Gill Abernathy, Board Chairman

Caroline D. Juran, Executive Director

Date

Date

23

RECOMMENDED ROPOSED REGULATIONS FOR CONTINUOUS QUALITY IMPROVEMENT PROGRAMS

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.

"Actively reports" means reporting all dispensing errors and analyses of such errors to a patient safety organization as soon as practical or at least within 30 days of identifying the error.

"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.

"Analysis" means a review of the findings collected and documented on each dispensing error, assessment of the cause and any factors contributing to the dispensing error, and any recommendation for remedial action to improve pharmacy systems and workflow processes to prevent or reduce future errors.

"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.

"Dispensing error" means one or more of the following discovered after the final verification by the pharmacist:

1. Variation from the prescriber's prescription drug order, including, but not limited to:

- a. Incorrect drug;
- b. Incorrect drug strength;
- c. Incorrect dosage form;
- d. Incorrect patient; or
- e. Inadequate or incorrect packaging, labeling, or directions.

2. Failure to exercise professional judgment in identifying and managing:

- a. Therapeutic duplication;
- b. Drug-disease contraindications, if known;
- c. Drug-drug interactions, if known;
- d. Incorrect drug dosage or duration of drug treatment;
- e. Drug-allergy interactions;
- f. A clinically significant, avoidable delay in therapy; or
- g. Any other significant, actual or potential problem with a patient's drug therapy.

3. Delivery of a medication to the wrong patient.

4. Variation in bulk repackaging or filling of automated devices, including, but not limited to:

- a. Incorrect drug;
- b. Incorrect drug strength;
- c. Incorrect dosage form; or
- d. Inadequate or incorrect packaging or labeling.

"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.

"Patient safety organization" means an organization that has as its primary mission continuous quality improvement under the Patient Safety and Quality Improvement Act of 2005 (P.L. 109-41) and is credentialed by the Agency for Healthcare Research and Quality.

"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.

18VAC110-20-417. Continuous quality improvement program.

A. Notwithstanding practices constituting unprofessional practice indicated in 18VAC110-20-25, any pharmacy that actively reports dispensing errors and the analysis of such errors to a patient safety organization consistent with §54.1-3434.03 and 18VAC110-20-10 shall be deemed in compliance with this section. Documentation of reporting the analysis of errors shall be maintained for 12 months from the date of reporting.

B. Pharmacies not actively reporting to patient safety organizations, consistent with §54.1-3434.03 and 18VAC110-20-10, shall implement a program for continuous quality improvement in compliance with this section.

1. Notification requirements:

a. A pharmacy intern or pharmacy technician who identifies or learns of a dispensing error shall immediately notify a pharmacist on-duty of the dispensing error.

b. A pharmacist on-duty shall appropriately respond to the dispensing error in a manner that protects the health and safety of the patient.

c. A pharmacist on-duty shall immediately notify the patient or the person responsible for administration of the drug to the patient and communicate steps to avoid injury or mitigate the error if the patient is in receipt of a drug involving a dispensing error which may cause patient harm or affect the efficacy of the drug therapy. Additionally, reasonable efforts shall be made to determine if the patient self-administered or was administered the drug involving the dispensing error. If it is known or reasonable to believe the patient self-administered or was administered

the drug involving the dispensing error, the pharmacist shall immediately assure that the prescriber is notified.

2. Documentation and record requirements; remedial action:

- a. Documentation of the dispensing error must be initiated as soon as practical, not to exceed three days from identifying the error. Documentation shall include, at a minimum, a description of the event that is sufficient to allow further investigation, categorization and analysis of the event.
- b. The pharmacist-in-charge or designee shall perform a systematic, ongoing analysis, as defined in 18 VAC 110-20-10, of dispensing errors.
- c. The pharmacist-in-charge shall inform pharmacy personnel of changes made to pharmacy policies, procedures, systems, or processes as a result of the analysis.
- d. Documentation associated with the dispensing error need only to be maintained until the systematic analysis has been completed. Prescriptions, dispensing information, and other records required by federal or state law shall be maintained accordingly.
- e. A separate record shall be maintained and available for inspection, to ensure compliance with this section, for 12 months from the date of the analysis of dispensing errors and shall include the following information:
 - (1) Dates the analysis was initiated and completed;
 - (2) Names of the participants in the analysis;
 - (3) General description of remedial action taken to prevent or reduce future errors; and
 - (4) Documentation that a quality improvement analysis has been performed at least quarterly, whether or not an error has occurred.

Approval to extend emergency regulations for CSBs, BHAs, and crisis stabilization units

Emergency regulations effective 12/20/10 to 12/19/11. Replacement permanent regulations will not become final prior to 12/19/11. Board may consider approving request for 6-month extension of emergency regulations.

In agenda packet:

- Copy of emergency regulations

Board action:

- Approve request for 6-month extension of emergency regulations



Virginia
Regulatory
Town Hall

townhall.virginia.gov

Request to Extend Life of Emergency Regulation up to Six Months

According to § 2.2-4011.D of the Code of Virginia (effective 7/1/07): **In the event that an agency concludes that despite its best efforts, a replacement regulation [for an emergency regulation] cannot be adopted before expiration of the 12-month period..., it may seek the prior written approval of the Governor to extend the duration of the emergency regulation for a period of not more than six additional months.**

Any such request must be submitted to the Governor at least 30 days prior to the scheduled expiration of the emergency regulation and shall include a description of the agency's efforts to adopt a replacement regulation together with the reasons that a replacement regulation cannot be adopted before the expiration of the emergency regulation. Upon approval of the Governor, the duration of the emergency regulation shall be extended for a period of no more than six months. Such approval shall be in the sole discretion of the Governor and shall not be subject to judicial review. Agencies shall notify the Registrar of Regulations of the new expiration date of the emergency regulation as soon as practicable.

Agency name	Board of Pharmacy, Department of Health Professions
Regulation Title/ VAC Citation	18VAC110-20 Regulations Governing the Practice of Pharmacy
Action title	Possession and repackaging of drugs in certain mental health facilities
Stage	Proposed – replacement of emergency regulations
Town Hall action/stage #	3255 / 5827
Date emergency reg expires	12/19/11
Requested new expiration date	6/18/11

Rationale

*Please describe the **agency's** best efforts to promulgate a permanent regulation before the expiration of the emergency regulation and provide the reason(s) why the effective period of this emergency regulation should be extended up to 18 months.*

Chapter 28 (HB150) of the 2010 Acts of the Assembly required the Board of Pharmacy to promulgate regulations to authorize community services boards and behavioral health authorities to possess, repackage and deliver or administer medications and crisis stabilization units to store

and administer a stock of drugs needed for emergency treatment. Regulations promulgated pursuant to the legislative mandate set forth requirements for registration of a community service board (CSB) or behavioral health authority (BHA) to possess, repackage and deliver or administer drugs and for a program to train non-pharmacists in repackaging for CSB's or BHA's.

Emergency regulations were submitted on Townhall on 3/31/10; the Governor's approval was received on 12/9/10. The NOIRA to replace emergency regulations was published simultaneously with the emergency regulations with comment requested from 1/3/11 to 2/2/11.

Proposed regulations were adopted at the next board meeting and submitted on Townhall on 3/17/11; DPB approval was given on 5/1/11. *The proposed regulations have been awaiting the Governor's approval since that date.*

In order to have final regulations in effect by the 12/19/11 deadline, the final regulations would have had to be adopted, submitted, approved by DPB, the Secretary and the Governor by 10/19/11.

It is now impossible for the Board to replace the emergency regulations within the statutory deadline of 12 months. Therefore, the Board of Pharmacy must vote at its meeting on September 20, 2011 to request a six-month extension to ensure that the repackaging of drugs by CSB's and BHA's, as mandated by the Code of Virginia, does not expire.

Adoption of proposed regulations for on-hold prescriptions

In agenda packet:

- Copy of NOIRA
- Copy of comments on NOIRA
- Copy of draft proposed regulations from ad hoc committee of May 17, 2011

Board action:

- Adopt proposed regulations as recommended or with amendments to draft regulations

4/7/2011 10:57 am Date / Time filed with the Register of Regulations	VA.R. Document Number: R_____ - _____
	Virginia Register Publication Information
	Date: 5/9/2011 Issue: 18 Volume: 27

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 Board of Pharmacy intends to consider amending the following regulations
Chapters Affected:	
18 vac 110 - 20:	Virginia Board of Pharmacy Regulations
Action Title:	Amendments to address on-hold prescriptions
Agency Summary:	The purpose of the proposed action is summarized as follows: Regulations do not specifically address when the data entry of on-hold prescriptions must be performed, so some pharmacies store this prescriptions in a single file until needed. Others perform data entry of the prescription and file by the date of entry into the computer which is non-compliant with the current regulation, but find it burdensome to retrieve and move the prescription to the file associated with the date of initial dispensing. Additionally, when the data entry is performed on a separate date than the date of initial dispensing a pharmacist may not be verifying the accuracy of the data entered at the time of entry. The Board will consider amendments to clarify the requirements.
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 6/8/2011.	
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: 3451 Stage ID: 5829 RIS Project ID: 002768

Kaiser Permanente

2101 East Jefferson Street
Pharmacy, 3-West
Rockville, MD 20852

June 7, 2011

Ms. Caroline Juran, RPh
Executive Director, Board of Pharmacy
9960 Mayland Drive, Suite 300
Richmond, Virginia 23233

Dear Ms. Juran:

Thank you for the opportunity to provide comments on the Notice Of Intended Regulatory Action, published in the Virginia Register of Regulations, May 9, 2011, indicating the Board of Pharmacy ("Board") intends to consider amending **18VAC110-20, Virginia Board of Pharmacy Regulations**. I provided an opinion, July 21, 2010, on behalf of Kaiser Permanente of the Mid-Atlantic States, in support of the petition to amend requirements for filing prescriptions. We maintain that position, for the reasons previously stated, and ask that the Board allow filing by date of initial dispensing or date of initial entry into the electronic record keeping system, if such system is employed by the pharmacy.

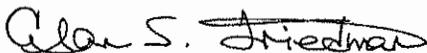
Kaiser Permanente pharmacies make use of computerized systems, which are linked and have a shared database, and most of our members' prescriptions are filled using this integrated network of pharmacies. Physicians, who practice in our medical facilities, use electronic prescribing for Schedule VI prescriptions. We encourage the Board to continue exploring opportunities to maintain paperless prescriptions, for those pharmacies that have the ability to process prescriptions in that manner.

There are a number of reasons why a consumer may choose to have their prescription retained at a pharmacy for initial dispensing on a future date, and we support the ability to file prescriptions by the date entered. Kaiser Permanente endorses appropriate pharmacist reviews and verifications on prescriptions, and a requirement that suitable documentation be maintained.

The pharmacy profession continues to evolve at a rapid pace. Work-related processes, and regulatory requirements to support them, need to align with the changing landscape. We approve of the Board's intent to modify and clarify regulatory requirements for **18VAC 110-20, Virginia Board of Pharmacy Regulations**, and look forward to providing comments to those proposed changes in the future.

Please feel free to contact me should you have questions.

Sincerely,



Alan S. Friedman, RPh
Regulatory, Quality and Professional Affairs Manager
Department of Pharmacy Services

36

Townhall Comments on On-Hold Prescriptions

Action	Amendments to address on-hold prescriptions
Stage	<u>NOIRA</u>
Comment Period	Ends 6/8/2011

All comments for this forum

5/13/11
17569

Commenter: Angela Brittle *

on hold prescriptions

Allowing pharmacists to accept prescriptions from patients, enter them in the computer, and file them according to the date they were entered has advantages. Many prescriptions are misplaced by patients when they don't have them filled and this creates a great deal of confusion when a fill is needed. The pharmacy contacts the prescriber for a refill, the prescriber states that they gave one to the patient, the pharmacy attempts to contact the patient back asking for a prescription the prescriber gave them months ago. And the search begins.

In many cases, the new "on hold" prescription can be linked to the previous RX allowing a seamless fill for the pharmacy and the patient.

An on hold prescription should go through the same checks that a filled prescription does, a pharmacist needs to review the information and sign off that it is indeed correct regardless of who does that data entry. When the prescription is needed, it will be treated as if it was a refill.

Pharmacies that are accepting these prescriptions from their patients for convenience have to do twice the work, because they have to retrieve that original prescription, deactivate it, update the number again, fill it and re-file just so it is filed in the right place! The same thing would occur if a patient doesn't pick up a prescription in a timely manner and it is returned to stock, only to want it filled again at a later date. It is redundant and over burdensome on pharmacy staff.

The regulation stating that prescriptions must be filed in chronological order from the date filled is simply left over from a time before computers. That made the most logical sense at that point in time. With today's data bases we can pull information out in a variety of ways. We can search by patient, prescriber, medication, date filled, date written, etc. Retrieving information is no longer limited.

There is no good reason to file prescriptions by date filled any longer.

5/13/11
17570

Commenter: william w. wilkes,rph *

on hold rx's

I truly think this regulation is both unnecessary and redundant considering the current technology in place in most pharmacies. I certainly could see the possible need for this before the advent of computers prior to when we had readily retrievable data. These days, we are able to access data almost instantly so to have to duplicate effort by making new numbers on on-hold rxs is both archaic and unnecessary. Thank you for allowing me to comment on this matter.

5/13/11
17571

Commenter: Deanna Rotenberry *

"on hold" prescriptions

We as a profession need to strive to keep our laws and regulations current with new practices that have evolved with the multitude of technologies that have improved our practice. The regulation regarding "on hold" prescriptions is an example of Law/Regulations that needs to be updated. This regulation not only increases non-productive work for physicians and pharmacies but also could increase drug diversion with lost prescriptions. Thanks!

5/27/11
17603

Commenter: Winston Chapman, Moneta Pharmacy *

On Hold Prescriptions

Placing prescriptions "on hold" makes sense for a couple of reasons. Both Pharmacists and patients recognize that the patient is not the best person to keep up with a prescription. By turning the prescription over to the Pharmacist to hold, the patient has a secure, and dependable method to track their prescription. In addition, placing a prescription on hold allows a more accurate record of the date the prescription was originally generated. If a patient holds a prescription for six months before turning it in, it may possibly be out of date before it is utilized. Remember, genius is often the same as simplicity.

DRAFT Proposed Regulations

On-Hold Prescriptions

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 § 54.1-341 1.1 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.

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

"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 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.
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. sSuch 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.

Adoption of emergency regulations for continuous quality improvement programs

In agenda packet:

- Copy of legislation
- Copy of draft emergency regulations resulting from two taskforce meetings held on May 18, 2011 and August 25, 2011

Board action:

- Adopt emergency regulations as recommended or with amendments
- Approve publication of 2nd NOIRA

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VIRGINIA ACTS OF ASSEMBLY — CHAPTER

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

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.

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57 6. That its pharmacists do not knowingly fill or dispense a prescription for a patient in Virginia in
58 violation of § 54.1-3303 and that it has informed its pharmacists that a pharmacist who dispenses a
59 prescription that he knows or should have known was not written pursuant to a bona fide
60 practitioner-patient relationship is guilty of unlawful distribution of a controlled substance in violation of
61 § 18.2-248.

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

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

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

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

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

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

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

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

PROPOSED REGULATIONS FOR CONTINUOUS QUALITY IMPROVEMENT PROGRAMS

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.

"Actively reports" means reporting all dispensing errors and analyses of such errors to a patient safety organization as soon as practical or at least within 30 days of identifying the error.

"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.

"Analysis" means a review of the findings collected and documented on each dispensing error, assessment of the cause and any factors contributing to the dispensing error, and any recommendation for remedial action to improve pharmacy systems and workflow processes to prevent or reduce future errors.

"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.

"Dispensing error" means one or more of the following discovered after the final verification by the pharmacist:

1. Variation from the prescriber's prescription drug order, including, but not limited to:

- a. Incorrect drug;
- b. Incorrect drug strength;
- c. Incorrect dosage form;
- d. Incorrect patient; or
- e. Inadequate or incorrect packaging, labeling, or directions.

2. Failure to exercise professional judgment in identifying and managing:

- a. Therapeutic duplication;
- b. Drug-disease contraindications, if known;
- c. Drug-drug interactions, if known;
- d. Incorrect drug dosage or duration of drug treatment;
- e. Drug-allergy interactions;
- f. A clinically significant, avoidable delay in therapy; or
- g. Any other significant, actual or potential problem with a patient's drug therapy.

3. Delivery of a medication to the wrong patient.

4. Variation in bulk repackaging or filling of automated devices, including, but not limited to:

- a. Incorrect drug;
- b. Incorrect drug strength;
- c. Incorrect dosage form; or
- d. Inadequate or incorrect packaging or labeling.

"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.

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"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.

"Patient safety organization" means an organization that has as its primary mission continuous quality improvement under the Patient Safety and Quality Improvement Act of 2005 (P.L. 109-41) and is credentialed by the Agency for Healthcare Research and Quality.

"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.

18VAC110-20-417. Continuous quality improvement program.

A. Notwithstanding practices constituting unprofessional practice indicated in 18VAC110-20-25, any pharmacy that actively reports dispensing errors and the analysis of such errors to a patient safety organization consistent with §54.1-3434.03 and 18VAC110-20-10 shall be deemed in compliance with this section. A record indicating the date a report was submitted to a patient safety organization shall be maintained for 12 months from the date of reporting. If no dispensing errors have occurred within the past 30 days, a zero report with date shall be recorded on the record.

B. Pharmacies not actively reporting to patient safety organizations, consistent with §54.1-3434.03 and 18VAC110-20-10, shall implement a program for continuous quality improvement in compliance with this section.

1. Notification requirements:

a. A pharmacy intern or pharmacy technician who identifies or learns of a dispensing error shall immediately notify a pharmacist on-duty of the dispensing error.

b. A pharmacist on-duty shall appropriately respond to the dispensing error in a manner that protects the health and safety of the patient.

c. A pharmacist on-duty shall immediately notify the patient or the person responsible for administration of the drug to the patient and communicate steps to avoid injury or mitigate the error if the patient is in receipt of a drug involving a dispensing error which may cause patient harm or affect the efficacy of the drug therapy. Additionally, reasonable efforts shall be made to determine if the patient self-administered or was administered the drug involving the dispensing error. If it is known or reasonable to believe the patient self-administered or was administered the drug involving the dispensing error, the pharmacist shall immediately assure that the prescriber is notified.

2. Documentation and record requirements; remedial action:

a. Documentation of the dispensing error must be initiated as soon as practical, not to exceed three days from identifying the error. Documentation shall include, at a minimum, a description of the event that is sufficient to allow further investigation, categorization and analysis of the event.

b. The pharmacist-in-charge or designee shall perform a systematic, ongoing analysis, as defined in 18 VAC 110-20-10, of dispensing errors. An analysis of each dispensing error shall be performed within 30 days of identifying the error.

c. The pharmacist-in-charge shall inform pharmacy personnel of changes made to pharmacy policies, procedures, systems, or processes as a result of the analysis.

d. Documentation associated with the dispensing error need only to be maintained until the systematic analysis has been completed. Prescriptions, dispensing information, and other records required by federal or state law shall be maintained accordingly.

e. A separate record shall be maintained and available for inspection to ensure compliance with this section for 12 months from the date of the analysis of dispensing errors and shall include the following information:

(1) Dates the analysis was initiated and completed;

(2) Names of the participants in the analysis;

(3) General description of remedial action taken to prevent or reduce future errors;
and

(4) A zero report with date shall be recorded on the record if no dispensing errors have occurred within the past 30 days.

Date / Time filed with the Register of Regulations	VA.R. Document Number: R _____ - _____
	Virginia Register Publication Information Date:

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 Board of Pharmacy intends to consider amending the following regulations
Chapters Affected:	
18 vac 110 - 20:	Virginia Board of Pharmacy Regulations
Action Title:	Continuous quality improvement programs
Agency Summary:	The purpose of the proposed action is summarized as follows: As mandated by Chapter 124 of the 2011 General Assembly, the Board has specified the elements of a continuous quality improvement program in a pharmacy in Emergency Regulations. The Board is seeking comment on its Intended Regulatory Action to replace the emergency regulations with permanent regulations. The regulation may be viewed at: www.townhall.virginia.gov .
Statutory Authority:	State: Chapters 33 and 34 of Title 54.1 Federal:
Is a public hearing planned for the proposed stage? Yes	
Public comments may be submitted until 5:00 p.m. on	
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.

Consider approval of petition for rulemaking regarding automated dispensing devices

In Board agenda packet:

- Copies of three petitions for rulemaking regarding monthly audit requirements in Regulation 18 VAC 110-20-490
- Copy of Regulation 18 VAC 110-20-490
- Copies of comments on petitions

Board action:

- Approve petition for rulemaking and adopt Notice of Intended Regulatory Action (NOIRA), **OR**
- Deny petition for rulemaking and state reasons for denial



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 reconciliation 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:

5/27/11



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,)
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.

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

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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

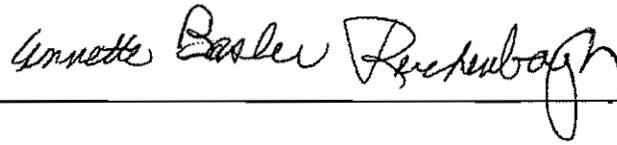
July 2004
64

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



Date: May 16, 2011

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

A hospital may use automated devices for the dispensing and administration of drugs pursuant to § 54.1-3301 of the Code of Virginia and §§ 54.1-3401 and 54.1-3434.02 of the Drug Control Act and in accordance with 18VAC110-20-270, 18VAC110-20-420, or 18VAC110-20-460 as applicable. The following conditions shall apply:

1. Prior to removal of drugs from the pharmacy, a delivery record shall be generated for all drugs to be placed in an automated dispensing device which shall include the date; drug name, dosage form, and strength; quantity; hospital unit and a unique identifier for the specific device receiving the drug; initials of the person loading the automated dispensing device; and initials of the pharmacist checking the drugs to be removed from the pharmacy and the delivery record for accuracy.

2. Automated dispensing devices in hospitals shall be capable of producing a hard-copy record of distribution which shall show patient name, drug name and strength, dose withdrawn, dose to be administered, date and time of withdrawal from the device, and identity of person withdrawing the drug.

3. The PIC or his designee shall conduct at least a monthly audit to review distribution and administration of Schedule II through V drugs from each automated dispensing device as follows:

a. The audit shall reconcile records of all quantities of Schedule II through V drugs dispensed from the pharmacy with records of all quantities loaded into each device to detect whether any drugs recorded as removed from the pharmacy were diverted rather than being placed in the proper device.

b. A discrepancy report shall be generated for each discrepancy in the count of a drug on hand in the device. Each such report shall be resolved by the PIC or his designee within 72 hours of the time the discrepancy was discovered or, if determined to be a theft or an unusual loss of drugs, shall be immediately reported to the board in accordance with § 54.1-3404 E of the Drug Control Act.

c. The audit shall include a review of a sample of administration records from each device per month for possible diversion by fraudulent charting. A sample shall include all Schedule II-V drugs administered for a time period of not less than 24 consecutive hours during the audit period.

d. The audit shall include a check of medical records to ensure that a valid order exists for a random sample of doses recorded as administered.

e. The audit shall also check for compliance with written procedures for security and use of the automated dispensing devices, accuracy of distribution from the device, and proper recordkeeping.

f. The hard-copy distribution and administration records printed out and reviewed in the audit shall be initialed and dated by the person conducting the audit. If nonpharmacist personnel conduct the audit, a pharmacist shall review the record and shall initial and date the record.

4. If an automated dispensing device is used to obtain drugs for dispensing from an emergency room, a separate dispensing record is not required provided the automated record distinguishes dispensing from administration and records the identity of the physician who is dispensing.

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.

6. Personnel allowed access to an automated dispensing device shall have a specific access code which records the identity of the person accessing the device.

7. Proper use of the automated dispensing devices and means of compliance with requirements shall be set forth in the pharmacy's policy and procedure manual.

8. All records required by this section shall be filed in chronological order from date of issue and maintained for a period of not less than two years. Records shall be maintained at the address of the pharmacy providing services to the hospital except:

a. Manual Schedule VI distribution records may be maintained in offsite storage or electronically as an electronic image that provides an exact image of the document that is clearly legible provided such offsite or electronic records are retrievable and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.

b. Distribution and delivery records and required signatures may be generated or maintained electronically provided:

(1) The system being used has the capability of recording an electronic signature that is a unique identifier and restricted to the individual required to initial or sign the record.

(2) The records are maintained in a read-only format that cannot be altered after the information is recorded.

(3) The system used is capable of producing a hard-copy printout of the records upon request.

c. Schedule II-V distribution and delivery records may only be stored offsite or electronically as described in subdivisions 9 a and b of this section if authorized by DEA or in federal law or regulation.

d. Hard-copy distribution and administration records that are printed and reviewed in conducting required audits may be maintained at an off-site location or electronically provided they can be readily retrieved upon request; provided they are maintained in a read-only format that does not allow alteration of the records; and provided a separate log is maintained for a period of two years showing dates of audit and review, the identity of the automated dispensing device being audited, the time period covered by the audit and review, and the initials of all reviewers.

Townhall Comments on Petitions for Rulemaking

Automated Dispensing Devices

Commenter: Mary Scott Garrett Parham Doctors' Hospital *

I fully support this change. Technology has become so much more sophisticated that expiration dates

are readily retrievable and problems with drawers identified via automatic notification on the cabinet., with error messages on the main console. There is little need for monthly review by the pharmacy staff.

6/20/11
17655

Commenter: Joe Ciezkowski, Director of Pharmacy, LewisGale Medical Center *

Comment on petition of amend requirements for reviewing automated dispensing machines

I support the proposed regulation amendment for the following reasons:

1. Hospital pharmacies have quality control systems in place to look for many of the same items that are required by the Board in 18VAC 110-20-490. However, it is rare that these quality control audits must be done monthly, since variance is unusual. While I agree that these audits are important and necessary, requiring that the audits be performed monthly is time-consuming, and takes away time that could be used for other, more productive, activities.

2. Specifically, 18VAC 110-20-490.5. requires monthly audits for 5 items that are actually reviewed by virtue of the very use of the machines. Outdated drugs, location of drugs within the device, etc., are vital components of the drug delivery system, and must be part of the day-to-day operation of the department. It would be more useful for the Board to know that the drug distribution system addresses these items on an ongoing basis than to see the results of monthly audits.

I hope the Board will consider revising these requirements.

6/21/11
17658

Commenter: Anita Atkins, CJW Medical Center--JW Campus *

Automated Dispensing Cabinets in Hospitals

I fully support the changes proposed for the regulation. Automation offers mechanisms for expiration dates to be monitored, security to remain in tact, and ability to run audit reports as needed.

6/28/11
17665

Commenter: Karen Dunavant, Reston Hospital Center *

Comment on Petition for change to Automated Dispensing Cabinet requirements

I fully support a change in 18VAC110-20-490 section 5. The current process takes 40 to 60 man-hours each month to complete all audits required and does not identify possible diversion effectively.

Using a reconciliation software program similar to RxAuditor, Pandora or others - a 24-hour audit of all transactions for controlled substances becomes obsolete. These programs show statistical analysis over a month. Using the process set by the regulation, identifying possible diversion was hit or miss. Using

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RxAuditor, we can identify specific employees to audit based on peer-to-peer comparisons of use for their unit. This is a more effective use of the auditors time and addresses the diversion concerns.

Combine this with a facility using their ADC on "profile" mode, where a pharmacist must enter the order into the hospital's Clinical System before the drug is available to the nurse (order verification). The use of Controlled Substance perpetual inventory management systems (i.e. CII-Safe, NarcStation, etc) where issues remain open until appropriately stocked into the receiving ADC (narrowing the focus of audits for issue/restock). Overrides and Open Discrepancies may be reviewed easily and in a more timely manner.

Thank you for your consideration.

6/28/11
17666

Commenter: Karen Dunavant, Reston Hospital Center *

Comment on Petition for change to Automated Dispensing Cabinet requirements

I fully support a change in 18VAC110-20-490 section 5. The current process takes 40 to 60 man-hours each month to complete all audits required and does not identify possible diversion effectively.

Using a reconciliation software program similar to RxAuditor, Pandora or others - a 24-hour audit of all transactions for controlled substances becomes obsolete. These programs show statistical analysis over a month. Using the process set by the regulation, identifying possible diversion was hit or miss. Using RxAuditor, we can identify specific employees to audit based on peer-to-peer comparisons of use for their unit. This is a more effective use of the auditors time and addresses the diversion concerns.

Combine this with a facility using their ADC on "profile" mode, where a pharmacist must enter the order into the hospital's Clinical System before the drug is available to the nurse (order verification). The use of Controlled Substance perpetual inventory management systems (i.e. CII-Safe, NarcStation, etc) where issues remain open until appropriately stocked into the receiving ADC (narrowing the focus of audits for issue/restock). Overrides and Open Discrepancies may be reviewed easily and in a more timely manner.

Thank you for your consideration.

7/7/11
17682

Commenter: Dana H. Anderson, Virginia Hospital Center *

Comment on Petition for change to Automated Dispensing Cabinets

I fully support a change in 18VAC110-20-490 section 5. My facility has 72 unique ADC locations and requires a full time pharmacy employee to perform the 24 hour audits. These audits are not an effective method of identifying potential diversion as the audit is a 24 hour snap shot within a months worth of activity.

I currently utilize a program that does statistical analysis on controlled substance activity over a 30 day period. This statistical report identifies specific employees for each unique location and compares activity peer-to-peer. This is an efficient and effective process and reviews a broader time frame to identify potential diversion.

In addition, orders are reviewed by a pharmacist and entered into the electronic MAR prior to the end user having access to the medication. The use of a Controlled Substance perpetual inventory management system provides additional safe guards for potential diversion review.

I appreciate your consideration of this petition.

7/7/11
17683

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Commenter: Michael Nyame-Mireku, Virginia Hospital Center *

Comment on Petition for change to Automated Dispensing Cabinet requirements

I am completely in support of changing 18VAC110-20-490 section 5. With increasing use of eMAR, CPOE, and other third party monitoring programs, users could effectively and efficiently be tracked and monitored. C2 Safe now allows perpetual inventory of controlled substances with easy electronic auditing.

The number of Pyxis machines being used in hospitals have increased significantly, requiring significant resources to keep up with the paper auditing.

I appreciate your consideration of this petition.

7/7/11
17684

Commenter: Noel Hodges, HCA Virginia *

18VAC110-20-490

I am in full support to change 18VAC110-20-490 section 5. The current process takes valuable pharmacist man-hours each month that could be used to promote patient care.

The manual audits required are not the most effective or efficient way to identify possible diversion. Using a reconciliation software program (i.e. RxAuditor, Pandora) quickly provides an audit of all transactions for controlled substances. These programs show statistical analysis for each user and medication. Using such a system, pharmacies can identify specific employees to audit based on peer-to-peer comparisons.

Thank you for your consideration.

7/7/11
17685

Commenter: Margaret Rowe Fauquier Health *

Proposed change r/t auditing ADD's on a monthly basis

I would like to add my voice to those who have already commented in favor of this change. I feel that the process of performing these audits consumes valuable resources with very little to show for the effort in terms of uncovering diversion. Systems such as Pandora or RxAuditor provide much more powerful and statistically relevant data for us.

Thank you!

7/7/11
17686

Commenter: Margaret Rowe Fauquier Health *

Proposed change r/t auditing ADD's on a monthly basis

I would like to add my voice to those who have already commented in favor of this change. I feel that the process of performing these audits consumes valuable resources with very little to show for the effort in terms of uncovering diversion. Systems such as Pandora or RxAuditor provide much more powerful and statistically relevant data for us.

Thank you!

7/7/11
17688

Commenter: Deborah Smith, PharmD, Director of Pharmacy, LewisGale Montgomery *

Consideration of Automated Dispensing Audit.

As a longterm Pharmacist who has worked in a variety of settings I have had the opportunity to explore the potential requirements of the monthly audits as currently outlined.

In the face of diverse checks and balances in place provided by automated dispensing cabinets daily as well as services such as RX Auditor, I find the additional auditing currently in the regs duplicative and labor-intense. In addition reports such as Compare within PYXIS as well as daily all station reports for controlled substances, we have capability to already do this process on a prospective basis in our daily functions.

I am happy to expand upon this should additional information be required.

I therefore respectfully request consideration to consider this audit requirement a limitation rather than enhancement of monitoring in the face of current automation as we know it in pharmacy practice

Thank you for your consideration.

7/8/11
17692

Commenter: Frederik Friis

Comment on Petition for change to Automated Dispensing Cabinet requirements (Like Mr Caren donavan)

I agree with you Mr Caren donavan, i think I fully support a change in 18VAC110-20-490 section 5. The current process takes 40 to 60 man-hours each month to complete all audits required and does not identify possible diversion effectively.

Using a reconciliation software program similar to RxAuditor, Pandora or others - a 24-hour audit of all transactions for controlled substances becomes obsolete. These programs show statistical analysis over a month. Using the process set by the regulation, identifying possible diversion was hit or miss. Using RxAuditor, we can identify specific employees to audit based on peer-to-peer comparisons of use for their unit. This is a more effective use of the auditors time and addresses the diversion concerns.

Combine this with a facility using their ADC on "profile" mode, where a pharmacist must enter the order into the hospital's Clinical System before the drug is available to the nurse (order verification). The use of Controlled Substance perpetual inventory management systems (i.e. CII-Safe, NarcStation, etc) where issues remain open until appropriately stocked into the receiving ADC (narrowing the focus of audits for issue/restock). Overrides and Open Discrepancies may be reviewed easily and in a more timely manner.

Thank you for your consideration.

Makeityourring Diamond Engagement Rings

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7/8/11
17697

Commenter: Jerry W. Martin - Chippenham Hospital *

Auditing Automated Dispensing Cabinets

I am in support of modifications to 18 VAC 110-20. The software upgrades that are available to monitor expiration dates as well as statistically analyze individual users is far superior to antiquated manual methods of audit and much more dependable in providing the evidence required to control narcotic misuse and diversion. The shift in man-hours and staffing to more valuable clinical functions would further support the true role of pharmacist and pharmacy technicians in the healthcare environment.

Thank you for considering modifications to this regulation.

7/8/11
17698

Commenter: Annette Basler Reichenbaugh, Reston Hospital Center *

Auditing automated dispensing cabinets

Please revise regulation to allow for some kind of automated program to be used (RX Auditor, etc) to be used as the first level of review to detect diversion. Once we receive the Rx Auditor we would then follow up on the activity of employees found to be 3 or 4 or 5 standard deviations above the rest of similar employees. We have been auditing acudoses for years and found little diversion in this fashion. Once we started with RX Auditor we found and terminated 4 employees for diversion (and yes reported them to the Board!). Auditing individual cabinets monthly is very labor intensive. I feel we get more bang for the buck with Rx Auditor.

Thanks

7/11/11
17701

Commenter: Brian Caruth, Virginia Hospital Center *

Supporting Change to Automated Dispensing Cabinet Regulations

I support a change in 18VAC110-20-490 section 5. My hospital currently performs all required 24 hour audits on ADC's AND uses a statistical analysis program to evaluate controlled substance activity. Compared to the 24 hour audits, the statistical analysis software produces more data and detailed actionable information to identify potential diversion. In addition to identifying potential diversion, the statistical analysis software also provides a level of reassurance that employees ARE properly accessing and accounting for controlled substances.

It appears that other institution currently employ both 24 hour audits of ADC's and statistical analysis programs. The comprehensive data sets produced by the statistical analysis programs provide more value when compared to 24 hour audits of ADC's. Better alignment of Pharmacy auditing responsibilities with Board requirements would likely result with the proposed regulatory changes to 18VAC110-20-490 section 5.

7/11/11
17702

Commenter: Kimberli Burgner, HCA Virginia *

18VAC110-20-490 section 5

I am in full support to change 18VAC110-20-490 section 5. The current process takes valuable pharmacist time each month that could be used to promote "Best Practice".

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The manual audits required are not the most effective or efficient way to identify possible diversion. It has been researched and shown that using a reconciliation software program (i.e. RxAuditor, Pandora) quickly provides an audit of all transactions for controlled substances. These programs show statistical analysis for each user and medication. Using such a system, pharmacies can identify specific employees to audit based on peer-to-peer comparisons. This has moved diversion monitoring to a new level.

Thank you for your consideration.

7/11/11
17703

Commenter: Debra Ryan, Reston Hospital Center *

Auditing Automated Dispensing Cabinets

Technology has and continues to change the pharmacy landscape that we work in, especially in the area of monitoring inventory and reconciliation of medication transactions. Currently available software programs give pharmacists the ability to assess and manage the entire drug supply chain from acquisition to administration to an individual patient. This includes the tracking and evaluation of controlled drug activity for an entire time period versus looking at a slice of activity and extrapolating the information obtained in that 24 hour period to an entire month. Hoping that diversion is not taking place on the dates not audited. In my experience an individual involved in diversion rationalizes and is willing to take a chance that they won't be caught on a routine audit. The methods and resources we had in the past for detecting diversion supported that rationalization.

There is the old adage that a system is only as good as the information it contains. Pharmacy resources would be better spent perfecting and tailoring the available software programs to meet the profile of our individual hospitals. Available programs give us the capability of looking at all transactions and then to use the power of statistics to identify where to concentrate our in-depth audits. I support this change in regulation.

7/11/11
17704

Commenter: Barbara S. Wiggins *

Automated Dispensing Machines

I am in support of the modifications to 18 VAC 110-20. There is data available to monitor/audit these stations that is far less time intensive and labor intensive. Removing this requirement will free up staff to provide more valuable clinical services.

Thank you for considering modifications to this regulation.

7/11/11
17705

Commenter: Michaiiah Parker, CJW Medical Center *

Support changes

I agree that automated dispensing cabinets and barcoded technology have allowed much of the experiential data information to be captured electronically. As a clinical specialist that is expected to profile review 34 ICU patient beds, participate in interdisciplinary and bedside surgical rounding on patients daily, and focus on other medication safety issues / medication use evaluation development / and patient/staff education, having to spend time monthly for dispensing cabinet audits detracts from my ability to address critical issues in my sick

73

patients. If the technology has shown that it is effective in this aspect of pharmacy management, it would be much needed to free pharmacists up to focus on clinical services.

7/11/11
17706

Commenter: Kim Biggers Hayes, Henrico Doctors' Hospital *

Commetn on Petition for change to Automated Dispensing Cabinet Requirements

I fully support a change in 18VAC110-20-490 section 5. My facility has 43 unique ADC locations. The manual audits are not an effective method of identifying potential diversion as the audit is a 24 hour snap shot within a 30 day period of activity.

We current utilize a program that completes statistical analysis on controlled substance activity over a 30 day period. This statistical report identifies specific exmployees for each unique location and compares peer-to-peer activity. This is an efficient, effective and more thorough process and reviews a broader time frame to identify potential diversions.

Enhanced further is the use of an ADC in "profile" mode, where a pharmacist must enter the medication order into the hospital's clinical informatics system before the drug is available to the nurse in the ADC. The use of controlled substance perpetual inventory management systems such as CII Safe or NarcStation where issues remain open until appropriately stocked into the receivng ADC also support a more improved process over a manual review. Technology is available to meet the intent of the regulation.

I believe the combination of profile dispensing ADCs, automated controlled substance inventory systems and controlled substance statistical analysis software provide a much greater diversion tracking system than the current regulations of a manual review over a limited period of time.

Thank your for considering modifications to this regulation.

7/11/11
17707

Commenter: Daniel Miller, John Randolph Medical Center *

In Support of Changes

I support the proposed changes to 18VAC110-20-490 section 5. These changes will free valuable pharmacist man hours that can be dedicated to enhancing patient care without compromising the ability to detect diversion.

**Review “run dry” requirement for automated counting devices in
18VAC110-20-355**

Board received comment from Delegate Chris Jones that there is an increasing trend to use counting device bins to more securely store certain slow-moving drugs which may not inherently run dry every 60 days, and therefore, the requirement for a bin to “run dry” every 60 days under certain circumstances may be overly burdensome. Requested consideration of this current requirement.

In Board agenda packet:

- Copy of Regulation 18 VAC 110-20-355

Board action:

- Adopt Notice of Intended Regulatory Action (NOIRA), OR
- Deny request for rulemaking

18VAC110-20-355. Pharmacy repackaging of drug; records required; labeling requirements.

A. Pharmacies in which bulk reconstitution of injectable, bulk compounding or the repackaging or prepackaging of drugs is performed shall maintain adequate control records for a period of one year or until the expiration, whichever is greater. The records shall show the name of the drug(s) used; strength, if any; date repackaged; quantity prepared; initials of the pharmacist verifying the process; the assigned lot or control number; the manufacturer's or distributor's name and lot or control number; and an expiration date.

B. The drug name; strength, if any; the assigned lot or control number or the manufacturer's or distributor's name and lot or control number; and an appropriate expiration determined by the pharmacist in accordance with USP guidelines shall appear on any subsequently repackaged or reconstituted units.

C. Pharmacies using automated counting devices or dispensers in which drugs are removed from manufacturer's original packaging and placed in bulk bins shall comply with the following requirements:

1. A bin filling record shall be maintained, manually or in a computerized record for a period of one year from the date of filling from which information can be readily retrieved, for each bin including:
 - a. The drug name and strength, if any;
 - b. The name of the manufacturer or distributor;
 - c. Manufacturer's control or lot number(s) and expiration date for all lots placed into the bin at the time of filling;
 - d. Any assigned lot number;
 - e. An expiration date determined according to USP guidelines for repackaging;
 - f. The date of filling; and
 - g. The pharmacist's initials verifying the accuracy of the process.
2. If more than one lot is added to a bin at the same time, the lot which expires first shall be used to determine the expiration date if shorter than a calculated date based on USP guidelines.
3. Each bin shall be labeled in such a manner as to cross-reference the information on the filling record with the correct expiration date.
4. If only one lot is added to a bin at one time, but a subsequent lot may be added before the first has cleared, the automated device shall be constructed to reasonably dispense the first lot before the second lot is dispensed, the expiration date on the bin's label shall reflect the expiration date assigned to the earlier lot, and the bin shall be allowed to "run dry" where all product is completely removed prior to filling at least once every 60 days with a record made of the run dry dates.

D. A pharmacy may return a dispensed drug to stock for redispensing that has never left the pharmacy premises or the control of the pharmacy delivery agent pursuant to § 54.1-3411.1 A 3 of the Code of Virginia under the following conditions:

1. An expiration date shall be placed on the label prior to returning the drug to stock. In the absence of stability data to the contrary, the date on the label may not exceed the expiration date on the manufacturer's container or one year from the date the drug was originally dispensed and placed in the prescription vial, whichever date is earlier.
2. The restocked drug shall be used to fill the next prescription received for that product. In the event that the drug is not dispensed prior to the new assigned expiration date, it shall be removed from working stock as expired, and disposed of in accordance with 18VAC110-20-210.
3. If there is no lot number on the label of a drug returned to stock or on the prescription records that can be cross-referenced from the prescription label, the drug shall be removed from stock upon any recall of that drug product and returned to the manufacturer or otherwise disposed of in accordance with 18VAC110-20-210.

**Consider amending guidance document 110-9, Major 24, regarding definition of
"low volume"**

In Board agenda packet:

- Copy of letter from Containment Technologies Group, Inc. to consider amending definition of "low volume" within guidance document 110-9
- Copy of relevant section from guidance document 110-9

Board action:

- Amend definition in guidance document, **OR**
- Deny request to amend definition, **OR**
- Request staff to conduct further research and table issue until December board meeting



July 1, 2011

Virginia Board of Pharmacy
ATTN: Caroline Juran, Executive Director
9960 Mayland Drive
Suite 300
Henrico, Virginia 23233-1463

RE: Sterile Compounding of Hazardous Drugs

Dear Ms. Juran,

Thank you for speaking with me on July 1st in regards to the Virginia Board of Pharmacy Guidance Document 11-9 item number 24. Currently this document defines conditions of "Low Volume" for compounding hazardous drugs as no more than 15 CSP's per week or as defined by USP.

The volume of hazardous drugs that can be compounded safely is a direct function of the containment capability of the engineering control utilized in compounding. Currently there are two classes of engineering controls used in compounding hazardous drugs. The Class II biological safety cabinet and what USP <797> describes as CACI's (Containment Aseptic Compounding Isolator). Within the CACI there are several different manufacturers' designs.

The traditional engineering control used in pharmacy compounding since the 1980's until present day has been the class II biological safety cabinet, this engineering control was not tested for containment capabilities in compounding hazardous drugs until the late 1990's. Tests¹ conducted at six cancer centers found this technology incapable of containing the compounded preparations.

CACI's as a primary engineering control came to the United States in the 1990's. Depending on the design of the CACI it can provide a much greater containment than BSC's but like all engineering controls should be tested to determine its capability.

Containment Technologies Group, Inc. has documented the containment capability of its MIC Isolator (CACI) through two independent studies. The studies were conducted by SafeBridge Consultants² and have been included in the supporting documentation attached to this letter. The second study also conducted by SafeBridge was observed by NIOSH personnel involved in the hazardous drug communication document.

The data generated in the two studies show conclusively that the containment capabilities of the MIC Isolator that is manufactured by CTG, Inc. far exceeds the low volume benchmark of 15 CSP's as defined within Guidance Document 11-9. The validated studies and resultant data show that the low volume benchmark while performing hazardous compounding within the MIC negative pressure isolator is 150 doses per person per 8-hour shift. Our proprietary technology is

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quite different from a BSC or an exhaust type isolator. Our MIC Family of isolators are considered to be a non-exhaust, gas-tight, re-circulating isolator. Following this engineering design allows the practitioner to perform hazardous compounding in a much safer environment.

I am sure that the intent of the Board's Guidance Document was not to limit innovation through regulation. USP when composing the <797> standard used the term "low volume" because they had not attempted to contact equipment manufacturers and was looking for a simple answer to a complex question. A definitive number needs to be scientifically supported by data such as the studies conducted on the MIC because each individual engineering control design has specific capabilities.

In the introduction of the 797 chapter, it states "The use of technologies, techniques, materials and procedures other than those described in this chapter is not prohibited so long as they have been proven to be equivalent or superior with statistical significance to those described herein". This statement appears to be a clear and welcomed stance from USP to encourage and drive innovation and continuous improvements. The end goal is of course a continuous effort to improve patient safety, provider safety, and environmental safety.

An option could be for the Virginia Board would be to require all engineering control manufacturers to provide proof of the capabilities of the equipment. Place the burden of proof on the manufacturer to state the low-volume benchmark and to of course back this statement with independently produced data and studies. Each compounding facility would be required to maintain this documentation on file for review and audit by the state inspectors.

We are willing to provide any assistance or detailed review of our documentation at any time. I am personally willing to meet with your board or with USP to further discuss the information provided by CTG, Inc.

Sincerely,

Hank Rahe
Technical Director
Containment Technologies Group, Inc.
317-713-8203 (office)
317-753-5312 (cell)
hrahe@mic4.com

Attachments: CTG documentation two CD's and print copies of the referenced studies

1. **Surface contamination with antineoplastic agents in six cancer treatment centers in Canada and the United States** Am J Health Syst Pharm July 1, 1999 56:1427-1432
2. SafeBridge Consultants, Inc , 1924 Old Middlefield Way, Mountain View CA 94043
Phone 650 961-4820

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Attachments

Butler Study - Testing of the MIC barrier isolator for containment.

Purpose: Testing by SafeBridge Consultants was conducted at Butler University in their sterile products teaching laboratory to determine the following:

1. The airborne concentration of the surrogate marker inside the MIC.
2. Determine the surface concentration of surrogate marker inside the MIC.
3. Determine the surface concentration of surrogate marker present on piggybacks prepared according to protocols normally used for preparation of IV admixtures (no protection of the piggyback inside the MIC).
4. Determine the surface concentration of surrogate marker present on piggybacks prepared according to protocols, which covered the piggyback with a zip lock bag during preparation (protection of the piggy back inside the MIC).
5. Determine the airborne concentration that occurs during the "spiking" of a pre primed set with a piggyback contained the surrogate.
6. Determine the surface contamination created during the "spiking" of a pre-primed set with a piggyback containing the surrogate.

Test conditions were the MIC operating with negative pressure of 0.02 inches of water column in an air-conditioned room. The surrogate marker was naproxen sodium that has a detection level of 2 nanograms per cubic meter using a HPLC analytical method.

The instructor that teaches the sterile products courses at Butler University, a practicing pharmacist conducted the manipulations for all the above testing protocols. Protocols for the testing were reviewed by and NIOSH personnel involved with the Hazardous Drug Alert observed the testing.

Summary of results

1. **Determine the airborne concentration of the surrogate marker inside the MIC.**

The airborne concentration of the surrogate marker inside the MIC ranged from Less than 7 to 405 nanograms per meter cube depending on location. This was measured during the preparation of eighty 50ml piggybacks. The surrogate was prepared in 10ml vials at a concentration of 150 mg per ml. A 20 gauge needle was used.

There was no detection of the surrogate outside the main chamber of the MIC

There was no detection of the surrogate inside the airlock.

There was no detection of the surrogate in the preparation area.

Note: Background level of Naproxen Sodium was 11 nanograms per cubic meter
Airborne concentration

Conclusion:

There was no detectable surrogate inside the airlock or in the preparation area based on a detection level of the surrogate of 2.0 nanograms per cubic meter using HPLC analytical method of analysis.

- 2. Determine the surface concentration of surrogate marker inside the MIC.**

Surface concentration:

Left side near inlet HEPA filter >10 nanograms per cubic meter

Right side near exhaust HEPA filter . >101 nanograms per cubic meter

Work area >137 nanograms per cubic meter

Note: > Indicates less than

Conclusion:

The MIC air handling system is working to capture airborne particulates.

- 3. Determine the surface concentration of surrogate marker present on piggybacks prepared according to protocols normally used for preparation of IV admixtures (no protection of the piggyback inside the MIC).**

Surface concentration:

Using the "standard" method of no protection of piggyback surface – 0.02

Note: Concentrations are expressed in nanograms per cubic centimeter

Standard – $0.02 \times 100 / 10 = 0.2$ nanogram per cubic meter

- 4. Determine the surface concentration of surrogate marker present on piggybacks prepared according to protocols, which covered the piggyback with a zip lock bag during preparation (protection of the piggy back inside the MIC).**

Surface concentration:

Using the method of protecting the piggybacks with a zip lock bag - 0.01

Note: Concentrations are expressed in nanograms per cubic centimeter

Best Practice – $0.01 \times 100 / 10 = 0.1$ nanogram per cubic meter

Conclusions number 3 and number 4

Both the standard method of not covering the piggyback and best practice, method of covering the piggyback with a zip lock bag shows surface produced results of 0.2 nanograms per cubic meter airborne equivalent. The best practice method of covering the piggyback with a zip lock bag resulted in a 100% improvement of the surface concentration over the standard method.

Surface contamination for purposes of evaluating potential exposures has a conversion factor of 10x less than airborne concentrations that means that it takes approximated ten times the amount of surface concentration as compared the airborne concentration. One hundred square centimeters is considered the area of a human hand and is used to calculate potential exposures concentration of surface samples compared to airborne concentrations. Based on this standard Industrial Hygiene practice of calculating exposure potential the results of the surface concentration levels can be converted to airborne concentration equivalent.

Summary of Airborne and Surface Sampling of the MIC

There was no detectable surrogate inside the airlock or in the preparation area based on a detection level of the surrogate of 2.0 nanograms per cubic meter using HPLC analytical method of analysis.

Surface sampling indicates using best practices that the surfaces of piggybacks prepared in the MIC show trace concentrations of 0.1 nanograms of the surrogate material

5. Determine the airborne concentration that occurs during the "spiking" of a pre primed set with a piggyback contained the surrogate.

Air monitoring

Twenty-five administration sets were pre primed and then a 50ml piggyback was "spiked" to the set on an open counter.

Pharmacist breathing zone spiking twenty-five (25) sets ->14 nanograms per cubic meter

Area samples:

Upper work surface within 12" of "spiking"	- 21.4 nanograms per cubic meter
Left work surface within 12" of "spiking"	- >14 nanograms per cubic meter
Right side surface within 12" of "spiking"	- >14 nanograms per cubic meter
Ambient area approximately 20' from "Spiking"	- >14 nanograms per cubic meter

Note: > Indicates less than

Note: Background of Naproxen Sodium was >14 nanograms per cubic meter

6. Determine the surface contamination created during the "spiking" of a pre primed set with a piggyback containing the surrogate.

Surface sampling

Twenty-five administration sets were pre primed and then a 50ml piggyback was "spiked" to the set on an open counter. Wipe samples of the primary work surface before and after operations.

Results showed a net concentration of surrogate was 0.047 nanograms per centimeter square or equivalent airborne concentration of 0.47 nanograms per cubic meter.

Summary of "spiking" pre primed sets airborne and surface sample results

Data indicates that with pre priming of the sets the concentration the concentration of the surrogate materials was:

Airborne less than 22.0 nanograms per cubic meter.
Surface less than 0.47 nanograms per cubic meter equivalent

Results of other data gathered during testing

Concentration of surrogate materials detected during pre priming of sets both in airborne sampling and surface sampling are significantly below pharmaceutical companies exposure levels used to monitor the manufacturing workplace.

Conclusions

The MIC provides protection levels that exceed pharmaceutical manufacturers recommendations for protection of their employees producing the cytotoxic drugs both in airborne and surface concentrations.

Major Deficiency	Law/Reg Cite	Conditions	\$ Penalty
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
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
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 or as defined by USP. Review 2 months records.	2000
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



Guidance requested by staff regarding perpetual inventories

Staff is requesting guidance for how to inspect for compliance with the requirement of performing "reconciliation" during a perpetual inventory of all Schedule II drugs received and dispensed, i.e., what documentation, if any, must be maintained as proof of performing reconciliation, is a verbal explanation of a discrepancy sufficient, should the quantity recorded on the inventory be corrected to accurately reflect the quantity on-hand? If guidance is offered, staff recommends including this information in guidance document 110-16 to educate the licensees of the expectation and amending Major Deficiency #15 in guidance document 110-9 to include language regarding reconciliation.

In Board agenda packet:

- Copy of relevant sections from Regulations 18VAC110-20-10 and 18VAC110-20-240
- Copy of guidance document 110-16 entitled *Performing Inventories*
- Copy of relevant section of guidance document 110-9

Board action:

- Amend guidance document 110-16 to include guidance for performing reconciliation during a perpetual inventory of all Schedule II drugs received and dispensed **AND**
- Amend Major Deficiency #15 in guidance document 110-9 to include language regarding reconciliation

Regulation 18VAC110-20-10

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

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.

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.

Guidance Document 110-16

Performing Inventories

Virginia Board of Pharmacy

Performing Inventories

Various sections of law or regulation, to include §§ 54.1-3404 and 54.1-3434 of the Code of Virginia and 18 VAC 110-20-240 of the Regulations of the Board of Pharmacy, address requirements for performing an inventory of drugs in Schedules I-V. However, it is unclear whether certain individuals are required to perform a physical count of the drugs when performing the inventories. Recently, the Board concluded the following:

- Those persons required in law to perform an inventory of drugs shall physically count the drugs in Schedules I-V when a theft or any other unusual loss has occurred, and he is unable to determine the exact kind and quantity of the drug loss;
- Dispensers, researchers, and reverse distributors may otherwise perform the inventory in a manner consistent with federal allowances, as listed in 21 CFR 1304.11 (attached to this document), which require a physical count of drugs in Schedules I and II, but allow for an estimation of drugs in Schedules III-V unless the container contains greater than 1,000 tablets/capsules; and
- Nothing shall prohibit a person from choosing to perform a physical count of all drugs listed in Schedules I-V when performing an inventory.

from 21 CFR 1304.11

Section 1304.11 Inventory Requirements

(a)*General requirements.* Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken, and shall be maintained in written, typewritten, or printed form at the registered location. An inventory taken by use of an oral recording device must be promptly transcribed. Controlled substances shall be deemed to be "on hand" if they are in the possession of or under the control of the registrant, including substances returned by a customer, ordered by a customer but not yet invoiced, stored in a warehouse on behalf of the registrant, and substances in the possession of employees of the registrant and intended for distribution as complimentary samples. A separate inventory shall be made for each registered location and each independent activity registered, except as provided in paragraph (e)(4) of this section. In the event controlled substances in the possession or under the control of the registrant are stored at a location for which he/she is not registered, the substances shall be included in the inventory of the registered location to which they are subject to control or to which the person possessing the substance is responsible. The inventory may be taken either as of opening of business or as of the close of business on the inventory date and it shall be indicated on the inventory.

(b)*Initial inventory date.* Every person required to keep records shall take an inventory of all stocks of controlled substances on hand on the date he/she first engages in the manufacture, distribution, or dispensing of controlled substances, in accordance with paragraph (e) of this section as applicable. In the event a person commences business with no controlled substances on hand, he/she shall record this fact as the initial inventory.

(c) *Biennial inventory date.* After the initial inventory is taken, the registrant shall take a new inventory of all stocks of controlled substances on hand at least every two years. The biennial inventory may be taken on any date which is within two years of the previous biennial inventory date.

(d)*Inventory date for newly controlled substances.* On the effective date of a rule by the Administrator pursuant to §§1308.45, 1308.46, or 1308.47 of this chapter adding a substance to any schedule of controlled substances, which substance was, immediately prior to that date, not listed on any such schedule, every registrant required to keep records who possesses that substance shall take an inventory of all stocks of the substance on hand. Thereafter, such substance shall be included in each inventory made by the registrant pursuant to paragraph (c) of this section.

(e)*Inventories of manufacturers, distributors, dispensers, researchers, importers, exporters and chemical analysts.* Each person registered or authorized (by §1301.13 or §§1307.11–1307.13 of this chapter) to manufacture, distribute, dispense, import, export, conduct research or chemical analysis with controlled substances and required to keep records pursuant to §1304.03 shall include in the inventory the information listed below.

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(1) *Inventories of manufacturers.* Each person registered or authorized to manufacture controlled substances shall include the following information in the inventory:

(i) For each controlled substance in bulk form to be used in (or capable of use in) the manufacture of the same or other controlled or non-controlled substances in finished form, the inventory shall include:

(A) The name of the substance and

(B) The total quantity of the substance to the nearest metric unit weight consistent with unit size.

(ii) For each controlled substance in the process of manufacture on the inventory date, the inventory shall include:

(A) The name of the substance;

(B) The quantity of the substance in each batch and/or stage of manufacture, identified by the batch number or other appropriate identifying number; and

(C) The physical form which the substance is to take upon completion of the manufacturing process (e.g., granulations, tablets, capsules, or solutions), identified by the batch number or other appropriate identifying number, and if possible the finished form of the substance (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter) and the number or volume thereof.

(iii) For each controlled substance in finished form the inventory shall include:

(A) The name of the substance;

(B) Each finished form of the substance (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter);

(C) The number of units or volume of each finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial); and

(D) The number of commercial containers of each such finished form (e.g. four 100-tablet bottles or six 3-milliliter vials).

(iv) For each controlled substance not included in paragraphs (e)(1)

(i), (ii) or (iii) of this section (e.g., damaged, defective or impure substances awaiting disposal, substances held for quality control purposes, or substances maintained for extemporaneous compoundings) the inventories shall include:

(A) The name of the substance;

(B) The total quantity of the substance to the nearest metric unit weight or the total number of units of finished form; and

(C) The reason for the substance being maintained by the registrant and whether such substance is capable of use in the manufacture of any controlled substance in finished form.

(2) *Inventories of distributors.* Except for reverse distributors covered by paragraph (e)(3) of this section, each person registered or authorized to distribute controlled substances shall include in the inventory the same information required of manufacturers pursuant to paragraphs (e)(1)(iii) and (iv) of this section.

(3) *Inventories of dispensers, researchers, and reverse distributors.* Each person registered or authorized to dispense, conduct research, or act as a reverse distributor with controlled substances shall include in the inventory the same information required of manufacturers pursuant to paragraphs (e)(1)(iii) and (iv) of this section. In determining the number of units of each finished form of a controlled substance in a commercial container which has been opened, the dispenser, researcher, or reverse distributor shall do as follows:

(i) If the substance is listed in Schedule I or II, make an exact count or measure of the contents, or

(ii) If the substance is listed in Schedule III, IV or V, make an estimated count or measure of the contents, unless the container holds more than 1,000 tablets or capsules in which case he/she must make an exact count of the contents.

(4) *Inventories of importers and exporters.* Each person registered or authorized to import or export controlled substances shall include in the inventory the same information required of manufacturers pursuant to paragraphs (e)(1) (iii) and (iv) of this section. Each such person who is also registered as a manufacturer or as a distributor shall include in his/her inventory as an importer or exporter only those stocks of controlled substances that are actually separated from his stocks as a manufacturer or as a distributor (e.g., in transit or in storage for shipment).

(5) *Inventories of chemical analysts.* Each person registered or authorized to conduct chemical analysis with controlled substances shall include in his inventory the same information required of manufacturers pursuant to paragraphs (e)(1) (iii) and (iv) of this section as to substances which have been manufactured, imported, or received by such person. If less than 1 kilogram of any controlled substance (other than a hallucinogenic controlled substance listed in Schedule I), or less than 20 grams of a hallucinogenic substance listed in Schedule I (other than lysergic acid diethylamide), or less than 0.5 gram of lysergic acid diethylamide, is on hand at the time of inventory, that substance need not be included in the inventory. Laboratories of the Administration may possess up to 150 grams of any hallucinogenic substance in Schedule I without regard to a need for an inventory of those substances. No inventory is required of known or suspected controlled substances received as evidentiary materials for analysis.

Major Deficiency	Law/Reg Cite	Conditions	\$ Penalty
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
17. Hard copy prescriptions not maintained or retrievable as required (i.e. hard copy of fax for Schedule II, III, IV & V drugs and refill authorizations)	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

Discuss ISMP and pharmacist's concerns regarding 15-minute prescription guarantee dispensing policy

In Board agenda packet:

- Copy of letter to Board from pharmacist regarding Harris Teeter Pharmacy
- Copy of letter from ISMP to NABP

Board action:

- Determine appropriate response to letter
- Determine if action is needed to address policy

To: Virginia Board of Pharmacy

I am a licensed VA pharmacist who is quite concerned about the safety of my patients. Currently, my employer—Harris Teeter Pharmacy, is following in the misguided footsteps of Rite Aid and intends to implement the “15-minute Prescription Guarantee” in mid-August 2011. This process guarantees that if a patient brings up to 3 prescriptions, they will be ready in 15 minutes or less. If the pharmacy fails to meet this mark, the customer receives a gift card.

The pressure on pharmacists today continues to mount with increased third-party demands requiring countless time spent on the phone, the addition of immunizations, increased prescription volumes due to free 14-day supplies of certain antibiotics, and cuts in technician hours. All of which pull a pharmacist in several different directions at once. Couple all of these factors with the reality that *each* prescription must be checked for complete accuracy, making sure the *correct* patient is getting the *correct* drug, dose, and directions. The profile must be verified to assure there are no therapeutic duplications or drug interactions. Often, the pharmacist must call the physicians’ office for clarification or to alert the physician of an allergy issue. In addition, patients are constantly approaching the pharmacist with over-the-counter questions and concerns.

With all of the demands on pharmacists, it seems grossly inappropriate to add a speed requirement. Patient safety is the pharmacist’s primary concern, but when a company’s driving motivation is volume and profits, there will be consequences. Unfortunately, those consequences will be medication errors that could ultimately compromise patient safety and result in harm to the patient. Just ask yourself this: would it be suitable to require a surgeon to perform a surgery in 1 hour or less, or the patient gets reduction in the price of his or her procedure? How has it become acceptable to place an unrealistic timeframe on healthcare?

The Institute for Safe Medication Practices (ISMP) has already received reports of serious medication errors wherein the pharmacist was so rushed that he/she could not appropriately verify their work. The ISMP has gone on in a letter to the NABP to state that “The problem with these [guarantees] is that they can jeopardize public health by putting pressure on pharmacists to work as quickly as possible and discouraging them from checking the patient’s history and drug profile...”

I realize that Board of Pharmacy’s primary objective is to protect the public. So as a practicing pharmacist, I urge you to examine this trend of “fast-food pharmacy” and put a stop to a practice that could compromise patient safety.

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INSTITUTE FOR SAFE MEDICATION PRACTICES

A NONPROFIT ORGANIZATION

200 Lakeside Drive, Suite 200 • Horsham, PA 19044-2321
Tel. 215.947.7797 • www.consumermedsafety.org • www.ismp.org

June 6, 2011

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Gordian Health Solutions

Malcolm J. Broussard, RPh
President
National Association of Boards of Pharmacy
1600 Feehanville Drive
Mount Prospect, IL 60056

Dear Mr. Broussard:

As the only national nonprofit organization focused entirely on efforts to prevent medication errors, we are writing on behalf of the Institute for Safe Medication Practices (ISMP) Board of Trustees to voice our concern about a safety issue that has been illustrated by a wave of recent national advertising—promoting and rewarding the speed at which community pharmacies dispense prescriptions for patients. The National Association of Boards of Pharmacy (NABP) and its members should play a key role in discouraging speed as a primary marketing tool for pharmacy services.

One of the largest pharmacy chains, Rite Aid Corporation, now advertises a “15-Minute Prescription Guarantee,” where up to three new prescriptions will be dispensed within 15 minutes (average of about 5 minutes) or less. If a pharmacy fails to meet the mark, the customer receives a \$5 gift card. Although there are some caveats mentioned in the fine print, the message is clear that speed should be a primary motivator in choosing a pharmacy. This trend is not limited to just one pharmacy corporation; other chains as well as independent community pharmacies have, from time to time, initiated advertising campaigns that insinuate or offer similar prescription time guarantees to their customers.

We have heard from pharmacists who claim that their pharmacy’s management actually tracks pharmacist productivity based on the number of prescriptions they dispense and whether or not they meet time promises. A 15-minute dispensing claim for up to three prescriptions can jeopardize public health by putting pressure on pharmacists to work as quickly as possible and discouraging them from checking the patient’s history and drug profile; looking for possible drug interactions or duplications and other drug use evaluation concerns; calling physicians’ offices for clarification; and educating patients about the proper use of prescriptions (e.g., meeting patient counseling regulations).

It is unacceptable to hold pharmacists to specific timeframes for preparing and dispensing medications, since any mistakes that occur can have devastating effects on patients. Time limits also help promote the idea that the dispensing of medications is a ‘quick in and out process’ that only involves counting tablets.

ISMP frequently receives reports from consumers about medication errors resulting in harm to them or a family member. All too often they observe that the pharmacist seemed so rushed that work could not be thoroughly checked. Examples of serious errors due to volume and workplace distractions have been published in the *ISMP Medication Safety Alert! Community/Ambulatory Care Edition* newsletter.

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Malcolm J. Broussard, RPh, President, National Association of Boards of Pharmacy
June 6, 2011
Page 2

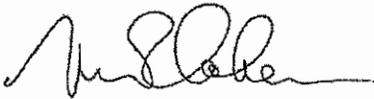
We realize that there are many issues that need to be addressed to encourage greater adoption of pharmaceutical care and improve safety in community pharmacy practice, such as reimbursement for counseling. But the reality is that community pharmacy prescription programs and inducements for such (e.g., discount coupons) are detrimental to safety and the practice of pharmacy. We should not be educating consumers that the primary determining factor about where they should have prescriptions dispensed is speed.

Since NABP's mission is to support state boards of pharmacy in protecting public health, ISMP requests that NABP explore and assist members in employing methods to eliminate inducements to consumers that insinuate or promise prescriptions will be dispensed within timeframes that may compromise patient safety.

Sincerely,



Lou Martinelli, PhD, PharmD
Chair, ISMP Board of Trustees



Michael R. Cohen, RPh, MS, ScD, FASHP
President, ISMP

Cc: ISMP Board of Trustees
Carmen Catizone, Executive Director, NABP
William T. Winsley, MS, RPh, Immediate Past President, NABP

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Tentative Dates for the 2012 Full Board Meetings

March Dates:

Tuesday, March 13th

June Dates:

Monday, June 11th

Tuesday, June 12th

September Dates:

Tuesday, September 11th

Wednesday, September 12th

Thursday, September 13th

December Dates:

Monday, December 10th

Wednesday, December 12th

**Virginia Department of Health Professions
2012 Session of the General Assembly**

Draft Legislation

A bill to amend and reenact §§ 54.1-2521, 54.1-2523, 54.1-2523.1 and 54.1-2523.2 of the Code of Virginia, relating to reporting and disclosure requirements for the Prescription Monitoring Program.

Be it enacted by the General Assembly of Virginia:

1. That §§ 54.1-2521, 54.1-2523, 54.1-2523.1 and 54.1-2523.2 of the Code of Virginia are amended and reenacted as follows:

§ 54.1-2521. Reporting requirements.

A. The failure by any person subject to the reporting requirements set forth in this section and the Department's regulations to report the dispensing of covered substances shall constitute grounds for disciplinary action by the relevant health regulatory board.

B. Upon dispensing a covered substance, a dispenser of such covered substance shall report the following information:

1. The recipient's name and address.
2. The recipient's date of birth.
3. The covered substance that was dispensed to the recipient.
4. The quantity of the covered substance that was dispensed.
5. The date of the dispensing.
6. The prescriber's identifier number.
7. The dispenser's identifier number.
8. Method of payment for prescription

~~§. 9.~~ Any other non-clinical information that is designated by the Director as necessary for the implementation of this chapter in accordance with the Department's regulations.

9- 10. Any other information specified in regulations promulgated by the Director as required in order for the Prescription Monitoring Program to be eligible to receive federal funds.

C. The reports required herein shall be made and transmitted in such manner and format and according to the standards and schedule established in the Department's regulations.

§ 54.1-2523. Confidentiality of data; disclosure of information; discretionary authority of Director.

A. All data, records, and reports relating to the prescribing and dispensing of covered substances to recipients and any abstracts from such data, records, and reports that are in the possession of the Prescription Monitoring program pursuant to this chapter and any material relating to the operation or security of the program shall be confidential and shall be exempt from the Virginia Freedom of Information Act (§ 2.2-3700 et seq.) pursuant to subdivision 15 of § 2.2-3705.5. Further, the Director shall only have discretion to disclose any such information as provided in subsections B and C.

B. Upon receiving a request for information in accordance with the Department's regulations and in compliance with applicable federal law and regulations, the Director shall disclose the following:

1. Information relevant to a specific investigation of a specific recipient or of a specific dispenser or prescriber to an agent designated by the superintendent of the Department of State Police to conduct drug diversion investigations pursuant to § 54.1-3405.

2. Information relevant to an investigation or inspection of or allegation of misconduct by a specific person licensed, certified, or registered by or an applicant for licensure, certification, or registration by a health regulatory board; information relevant to a disciplinary proceeding before a health regulatory board or in any subsequent trial or appeal of an action or board order to designated employees of the Department of Health Professions; or to designated persons operating the Health Practitioners' Monitoring Program pursuant to Chapter 25.1 (§ 54.1-2515 et seq.) of this title.

3. Information relevant to the proceedings of any investigatory grand jury or special grand jury that has been properly impaneled in accordance with the provisions of Chapter 13 (§ 19.2-191 et seq.) of Title 19.2.

4. Information relevant to a specific investigation of a specific recipient, dispenser or specific prescriber to an agent of ~~the United States Drug Enforcement Administration~~ a federal law enforcement agency with authority to conduct drug diversion investigations.

C. In accordance with the Department's regulations and applicable federal law and regulations, the Director may, in his discretion, disclose:

1. Information in the possession of the program concerning a recipient who is over the age of 18 to that recipient.

2. Information on a specific recipient to a prescriber, as defined in this chapter, for the purpose of establishing the treatment history of the specific recipient when such recipient is either under care and treatment by the prescriber or the prescriber is initiating treatment of such recipient. In a manner specified by the Director in regulation, notice shall be given to patients that information may be requested by the prescriber from the Prescription Monitoring Program.

3. Information on a specific recipient to a dispenser for the purpose of establishing a prescription history to assist the dispenser in determining the validity of a prescription in accordance with § 54.1-3303 when the recipient is seeking a covered substance from the dispenser or the facility in which the dispenser practices. In a manner specified by the Director in regulation, notice shall be given to patients that information may be requested by the dispenser from the Prescription Monitoring Program.

4. Information relevant to an investigation or regulatory proceeding of a specific dispenser or prescriber to other regulatory authorities concerned with granting, limiting or denying licenses, certificates or registrations to practice a health profession when such regulatory authority licenses such dispenser or prescriber or such dispenser or prescriber is seeking licensure by such other regulatory authority.

5. Information relevant to an investigation relating to a specific dispenser or prescriber who is a participating provider in the Virginia Medicaid program or information relevant to an investigation relating to a specific recipient who is currently eligible for and receiving or who has been eligible for and has received medical assistance services to the Medicaid Fraud Control Unit of the Office of the Attorney General or to designated employees of the Department of Medical Assistance Services, as appropriate.

6. Information relevant to determination of the cause of death of a specific recipient to the designated employees of the Office of the Chief Medical Examiner.

7. Information for the purpose of bona fide research or education to qualified personnel; however, data elements that would reasonably identify a specific recipient, prescriber, or dispenser shall be deleted or redacted from such information prior to disclosure. Further, release of the information shall only be made pursuant to a written agreement between such qualified personnel and the Director in order to ensure compliance with this subdivision.

D. The Director may enter into agreements for mutual exchange of information among prescription monitoring programs in other jurisdictions, which shall use the information only for purposes allowed by this chapter.

E. This section shall not be construed to supersede the provisions of § 54.1-3406 concerning the divulging of confidential records relating to investigative information.

F. Confidential information that has been received, maintained or developed by any board or disclosed by the board pursuant to subsection A shall not, under any circumstances, be available for discovery or court subpoena or introduced into evidence in any medical malpractice suit or other action for damages arising out of the provision of or failure to provide services. However,

this subsection shall not be construed to inhibit any investigation or prosecution conducted pursuant to Article 1 (§ 18.2-247 et seq.) of Chapter 7 of Title 18.2.

§ 54.1-2523.1. Criteria for indicators of misuse; Director's authority to disclose information; intervention.

The Director shall develop, in consultation with an advisory panel, criteria for indicators of misuse and a method for analysis of data collected by the Prescription Monitoring Program using the criteria for indicators of misuse. Upon the development of such criteria and data analysis, the Director may, in addition to the discretionary disclosure of information pursuant to § 54.1-2523, disclose information using the criteria that indicates potential misuse by recipients of covered substances to: a) their specific prescribers for the purpose of intervention to prevent such misuse or abuse; or b) to an agent designated by the superintendent of the Department of State Police for the purpose of an investigation into possible drug diversion.

§ 54.1-2523.2. Authority to access database.

Any prescriber authorized to access the information in the possession of the Prescription Monitoring Program pursuant to this chapter may, pursuant to regulations promulgated by the Director to implement the provisions of this section, delegate such authority to ~~up to two~~ health care professionals who are (i) licensed, registered, or certified by a health regulatory board under the Department of Health Professions, and (ii) employed at the same facility and under the direct supervision of the prescriber.

Effective October 1, 2011

DEPARTMENT OF HEALTH PROFESSIONS

Elements required for federal funds

18VAC76-20-40. Standards for the manner and format of reports and a schedule for reporting.

A. Data shall be transmitted to the department or its agent ~~on a semi-monthly basis within seven days of dispensing~~ in the ~~Telecommunication Format for Controlled Substances~~ (~~, May 1995,~~) Electronic Reporting Standard for Prescription Monitoring Programs, Version 4.1 (November 2009) of the American Society of Automation in Pharmacy (ASAP), which are hereby incorporated by reference into this chapter.

B. Data shall be transmitted in a file layout provided by the department and shall be transmitted by a media acceptable to the vendor contracted by the director for the program. Such transmission shall begin on a date specified by the director, no less than 30 days from notification by the director to dispensers required to report.

C. Under extraordinary circumstances, an alternative means of reporting may be approved by the director.

D. Data not accepted by the vendor due to a substantial number of errors or omissions shall be corrected and resubmitted to the vendor within five business days of receiving notification that the submitted data had an unacceptable number of errors or problems.

E. Required data elements shall include those listed in subsection B of § 54.1-2521 of the Code of Virginia and the following:

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.

VIRGINIA BOARD OF PHARMACY
2011-2012

STANDING COMMITTEES

REGULATION	EXAMINATION	ITEM REVIEW	PILOT PROGRAM	SPECIAL CONFERENCE
Gill Abernathy, Chair Dave Kozera Jody Allen Empsy Munden Robbie Rhodes Alternates: Citizen: Pratt Stelly Gerard Dabney Licensee: Crady Adams Any other Board member	Gill Abernathy Dave Kozera Crady Adams Brandon Yi Caroline Juran	Rick Baxter David Creecy Latonya Hairston Michelle Lincoln Jennifer Nguyen Leo Ross Bob Stoneburner Scott Arnott Don Jackson Nan Dunaway Vicki Garrison Sammy Johnson Caroline Juran	Gill Abernathy, Chair Brandon Yi Alternates: Dave Kozera Jody Allen	Dave Kozera Jody Allen Alternates: Robbie Rhodes Any other board member Pratt Stelly Brandon Yi Alternates: Ellen Shinaberry Any other board member

AD HOC COMMITTEES

INSPECTIONS	COI			
Gill Abernathy, Chair Crady Adams Dave Kozera Ellen Shinaberry Pratt Stelly	Gill Abernathy, Chair John Beckner Rick Baxter Michelle Lincoln Tim Musselman Ellen Shinaberry Anila Xhixho Brandon Yi Sammy Johnson Caroline Juran			

VIRGINIA:

BEFORE THE BOARD OF PHARMACY

IN RE: BRIAN P. MUSGROVE, PHARMACIST REINSTATEMENT APPLICANT
License No. 0202-009540

NOTICE OF HEARING

Pursuant to § 2.2-4020, § 2.2-4021, § 54.1-110 and § 54.1-2400(11) of the Code of Virginia (1950), as amended ("Code"), Brian P. Musgrove is hereby given notice that in accordance with § 2.2-4024 of the Code, a formal administrative hearing will be held before the Board of Pharmacy ("Board"). The hearing will be held on September 20, 2011, at 1:00 p.m., at the Department of Health Professions, Perimeter Center, 9960 Mayland Drive, Suite 201, Henrico, Virginia, at which time Mr. Musgrove will be afforded the opportunity to be heard in person or by counsel.

At the hearing, Mr. Musgrove has the following rights, among others: the right to representation by counsel, the right to have witnesses subpoenaed and to present witnesses on his behalf, the right to present documentary evidence, and the right to cross-examine adverse witnesses. Should Mr. Musgrove want any witnesses to be subpoenaed to appear on his behalf, he must notify the Director of the Administrative Proceedings Division, Perimeter Center, 9960 Mayland Drive, Suite 300, Henrico, Virginia 23233, giving the names and addresses of the witnesses, at least fifteen (15) days prior to the date of the hearing in order that subpoenas may be issued.

The purpose of the hearing is to act upon the application of Brian P. Musgrove for reinstatement of his license to practice pharmacy in the Commonwealth of Virginia that expired on December 31, 2004, and to receive and act upon evidence that Mr. Musgrove may have violated certain laws governing the practice of pharmacy, as more fully set forth in the statement of particulars below.

As the applicant, the burden of proof shall be upon Mr. Musgrove to provide evidence satisfactory to the Board that he is prepared to resume the competent practice of pharmacy. Further, Mr. Musgrove has waived his right to an informal conference.

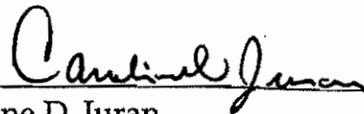
STATEMENT OF PARTICULARS

The Board alleges that:

1. Mr. Musgrove may have violated § 54.1-3316(7) and (11) of the Code in that on February 13, 2004, he was convicted in the United States District Court of the District of South Carolina of healthcare fraud, a felony.

2. Mr. Musgrove may have violated § 54.1-3316(7) and (10) of the Code in that on September 23, 2004, his license to practice as a pharmacist in South Carolina was suspended for two years by the South Carolina Board of Pharmacy.

FOR THE BOARD



Caroline D. Juran
Executive Director

Entered: August 5, 2011

VIRGINIA:

BEFORE THE BOARD OF PHARMACY

IN RE: PHILIP D. RICHARD, PHARMACIST REINSTATEMENT APPLICANT
License No. 0202-004237

NOTICE OF HEARING

Pursuant to § 2.2-4020, § 2.2-4021, § 54.1-110 and § 54.1-2400(11) of the Code of Virginia (1950), as amended ("Code"), Philip D. Richard is hereby given notice that in accordance with § 2.2-4024 of the Code, a formal administrative hearing will be held before a panel of the Board of Pharmacy ("Board"). The hearing will be held on September 20, 2011, at 2:00 p.m., at the offices of the Department of Health Professions, Perimeter Center, 9960 Mayland Drive, Suite 201, Henrico, Virginia, at which time Mr. Richard will be afforded the opportunity to be heard in person or by counsel.

At the hearing, Mr. Richard has the following rights among others: the right to representation by counsel, the right to have witnesses subpoenaed and to present witnesses on his behalf; the right to present documentary evidence, and the right to cross-examine adverse witnesses. If Mr. Richard wants any witnesses to be subpoenaed to appear on his behalf, he must notify the Director of Administrative Proceedings, 9960 Mayland Drive, Suite 300, Henrico, Virginia 23233, giving the names and addresses of the witnesses, at least fifteen (15) days prior to the date of the hearing in order that subpoenas may be issued.

The purpose of the hearing is to act upon the application of Mr. Richard for reinstatement of his license to practice pharmacy in the Commonwealth of Virginia, which was mandatorily suspended by Order of the Department of Health Professions entered May 23, 2011, pursuant to § 54.1-2409(A) of the Code, due to the revocation of Mr. Richard's license to practice pharmacy in the State of Colorado.

As the applicant, the burden of proof shall be upon Mr. Richard to provide evidence satisfactory to the Board that he is prepared to resume the competent practice of pharmacy. Pursuant to § 54.1-2409(D)

of the Code, reinstatement of Mr. Richard's license requires the affirmative vote of three-fourths of the members of the Board in attendance at the hearing.

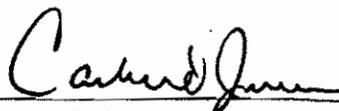
STATEMENT OF PARTICULARS

The Board alleges that:

1. Mr. Richard may have violated § 54.1-3316(10) of the Code, in that on May 7, 2002, he surrendered his license to practice pharmacy in the state of Colorado which had the full force and effect as revocation due to his dispensing numerous medications, including controlled substances, to two patients without valid prescription orders on file, and failing to maintain proper dispensing records and prescription orders.

2. Mr. Richard may have violated § 54.1-3316(5), (6), and (7) of the Code in that from on or about January 2009, to on or about January 2011, during the course of his employment as a pharmacist at Rite Aid Pharmacy #1900 Exmore, Virginia, he created and data entered prescriptions for medications into the pharmacy computer system in his name and his family's names so that he could obtain rebate coupons. Mr. Richard then printed out the necessary paperwork to redeem the coupons with the various drug manufacturers and submitted the information for cash reimbursement. Mr. Richard then changed the names on the prescription profiles maintained on the pharmacy computer system to one of three false names and never filled or dispensed the prescriptions.

FOR THE BOARD



Caroline D. Juran
Executive Director

Entered : August 30, 2011