



COMMONWEALTH OF VIRGINIA

Meeting of the Board of Pharmacy

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

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

December 15, 2010

9:00AM

TOPIC

PAGE(S)

Call to Order: Brandon Yi, Chairman

- Welcome and Introductions
- Reading of emergency evacuation script
- Approval of Agenda
- Approval of previous Board meeting minutes:
 - September 8, 2010, Full Board Meeting 1-9
 - September 8, 2010, Panel Formal Hearing 10-12
 - September 21, 2010, Special Conference Committee 13-16
 - September 28, 2010, Telephone Conference Call 17-18
 - October 28, 2010, Telephone Conference Call 19-20
 - November 10, 2010, Panel Formal Hearing 21-23
 - November 17, 2010, Special Conference Committee 24-25
 - December 2, 2010, Telephone Conference Call 26-27

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.

Legislation: Update - Elaine Yeatts

Regulations: Update - Elaine Yeatts

Update on Action Items: Caroline Juran

- Status of pharmacy routine inspection program – Sammy Johnson handout
- Consideration of pharmacy deficiencies listed in Guidance Document 110-9 28-34
- Research regarding the reporting of disciplinary action to NPDB-HIPDB 35-37
- Survey of other states' filing requirements regarding "on hold" prescriptions 38-39

Miscellaneous:

- Sanctioning Reference Points Training – Kimberly Langston, VisualResearch, Inc. 40-54

Reports:

- Report on Collection of Data and Information about Utilization of the Prescription Monitoring Program pursuant to SJR 73 and SJR 75 (2010) – Ralph Orr 55-75
- Report on NABP member forum meeting – John Beckner
- Report on disciplinary matters – Cathy Reiniers-Day
- Acting Executive Director's Report - Caroline Juran
 - Update on current innovative (pilot)
 - Report on Board of Health Professions
 - Status of RFP for contract administrator of the Virginia Federal and State Drug Law Exam
 - Report on NABP District I & II meeting

New Business

Consideration of consent orders (if any)

Adjourn

***The Board will have a working lunch at approximately 12 noon, to include presentation of former board member plaques.**

(DRAFT/UNAPPROVED)

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

September 8, 2010
Second Floor
Board Room 2

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

CALL TO ORDER: The meeting was called to order at 9:10 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, Acting Executive Director
Cathy M. Reimiers-Day, Deputy Executive Director
Howard M. Casway, Senior Assistant Attorney General
Arne Owens, Chief Deputy Director, DHP
Elaine J. Yeatts, Senior Regulatory Analyst, DHP
Sharon Davenport, Administrative Assistant (business matters)
Eusebia Joyner, Administrative Assistant (disciplinary matters)

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

APPROVAL OF AGENDA: The agenda was approved as presented and amended by the Board to add minutes of the August 25, 2010, Special Conference Committee, and to add discussion of the formation of a committee to review hospital-related deficiencies and Regulation 18 VAC 110-20-490, in lieu of reviewing Guidance Document 110-9.

APPROVAL OF MINUTES: The Board reviewed draft minutes for June 2, 2010; June 17, 2010; June 30, 2010; July 13, 2010; and August 25, 2010. With no changes to the minutes, the minutes were approved as presented.

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

DHP DIRECTOR'S REPORT: Mr. Owens, on behalf of Dianne Reynolds-Cane, M.D., reported that the first National Drug Take-Back Day would be held on September 25, 2010, from 10 a.m. to 2.p.m. at participating drop-off sites throughout Virginia. This is a collaborative effort of state and local law enforcement agencies, coordinated by DEA, to collect

from the public any expired, unwanted, or unused pharmaceutical controlled substances and other medications for destruction. DHP has posted information on its website and intends to communicate this subject to its licensees to encourage participation. Additionally, Mr. Owens briefly stated that this agency is involved with discussions regarding healthcare reform, and reminded the Board members of an orientation meeting to be held on October 27, 2010, for all new board members of this agency.

LEGISLATION:

- 2011 Legislative Proposal

Ms. Yeatts stated that a draft bill adding tramadol and carisoprodol to Schedule IV and immediate precursors of amphetamine, methamphetamine, phencyclidine, and fentanyl to Schedule II had been submitted for the Governor's consideration. She then explained that the two legislative proposals discussed at the June 2010 Board meeting regarding compounding and an allowance for multiple prescriptions per order form were not submitted for administrative review, due to conflicts with the language.

REGULATIONS:

- Regulation update

Ms. Yeatts reported that the permanent replacement of regulations for drug donation programs remains under administrative review and that the current emergency regulations will expire on October 6, 2010. Additionally, Ms. Yeatts stated regulations on the following subjects are under administrative review: emergency regulations for repackaging in community service boards and behavioral health authorities; signing of delivery record for automated dispensing devices in hospitals; and the addition of administrative fees and elimination of alarm system for certain emergency medical service agencies. Further, she reported that regulations regarding the following subjects became effective August 4, 2010: incorrect citation in 18 VAC 110-20-690; conformity with statute regarding maintenance of CE documentation; and conformity with DEA rules on e-prescribing.

- Response to petition for rulemaking regarding filing of prescriptions

Ms. Yeatts provided information on the petition received from Eric Haas requesting an amendment to 18 VAC 110-20-240 to allow prescriptions to be "filed chronologically by date of initial dispensing or initial entry into pharmacy electronic record keeping system if such a system is employed for use in the pharmacy." This proposed amendment would allow a prescription placed "on-hold", to be dispensed at a later time, to be filed by date of initial entry into the pharmacy's automated dispensing system, in lieu of filing chronologically by date of initial dispensing. The Board discussed the common practice of placing prescriptions "on-hold"; comment

was made that the practice may increase drug compliance and reduce the probability of a patient losing the prescription(s). Members expressed an interest in learning the requirements in other states. Ms. Juran stated that Ohio's regulations require the "on-hold" prescription to be entered into the pharmacy's automated data processing system when received, assigned a serial number, and permanently filed chronologically. Additionally, she stated that staff had received an email in the past from DEA with an informal opinion that while not directly prohibited by federal regulation, the practice of a pharmacy "holding" a patient's prescription(s) for dispensing at a later time was not recommended due to concerns for diversion. There was discussion to delay the decision-making process until more research could be performed regarding other states' requirements.

Motion:

The Board voted unanimously to deny the petition for rulemaking to amend Regulation 18 VAC 110-20-240, but agreed to query other states to determine their policies and/or rules for the filing of "on-hold" prescriptions and to revisit the request in December after additional information is obtained. (motion by Kozera, second by Beckner)

**UPDATE ON ACTION
ITEMS:**

- Pharmacy coupons

In response to the letter received by Jonathan Carter, a pharmacy student at VCU School of Pharmacy, requesting a prohibition on the use of pharmacy coupons and as requested by the Board at the June 2, 2010 board meeting, a survey of other states' restrictions on the use of pharmacy coupons was performed by NABP. Of the states that responded to the survey, Ms. Juran stated that she could only confirm that New York had current restrictions in place. New York restricts coupons to be used only for a discount or reduction of co-pay and not for other merchandise. Additionally, Mr. Yi stated that New Jersey's regulation regarding unprofessional conduct includes the distribution of premiums or rebates in connection with the sale of drugs, with some exception for trading stamps and discounts for seniors. Board counsel stated a prohibition of coupons may be a possible restraint of trade and that the Federal Trade Commission previously required the Board of Funeral Directors and Embalmers to reverse a prohibition of coupons/fee reductions. After further discussion, the Board decided to take no action at this time and to monitor future use of pharmacy coupons.

Motion:

The Board voted unanimously to take no action at this time regarding the request to prohibit the use of pharmacy coupons and to monitor the future use of these coupons. (motion by

Beckner, second by Kozera)

- Discussion regarding need for sending guidance document 110-27 to a new PIC now that attestation is included on the pharmacy permit application

Ms. Juran reported that staff had added the attestation to the pharmacy permit application, as requested at the June 2, 2010 board meeting, which requires the new pharmacist-in-charge to acknowledge having read and understood Guidance Document 110-27 and associated information regarding the inspection process. As a result, Ms. Juran asked if the Board wanted staff to continue mailing Guidance Document 110-27 along with the frequently asked questions (FAQs) regarding the pharmacy technician registration process after processing these submitted applications. The consensus was that staff should continue mailing the Guidance Document and the FAQs to ensure another opportunity for the PIC to read and understand the importance of the information contained within the document.

MISCELLANEOUS:

- Request from Allergan to discuss requirements for physician dispensing of topical drugs for aesthetic purposes

Ms. Juran stated that she; Scotti Russell, former Executive Director of the Board of Pharmacy; Scott Johnson and Tyler Cox of Hancock, Daniel, Johnson & Nagle, P.C.; and Pat Cannon, RN, Allergan, Inc., met on July 12, 2010. The meeting was to discuss current requirements for a physician to dispense drugs for aesthetic purposes. A formal request was then submitted to include this item on the September board meeting agenda to request an exemption from the security system and square footage requirements when dispensing topical Schedule VI drugs for aesthetic purposes. Ms. Juran explained that Regulation 18 VAC 110-30-20 already allows for the issuance of a limited-use license and that the Board has previously provided waivers of the 60 square feet requirement for the controlled substances selling and storage area when the scope, degree or type of services provided to the patient is of a limited nature and the inspector deems the square footage is sufficient for performing the limited purposes. There was discussion as to whether a security system should be required for protecting public safety when dispensing only topical Schedule VI cosmetic drugs and whether a limitation should be imposed on the number of drugs that could be dispensed by a physician when exempted from the security system requirement. After discussion, the Board determined it would delegate to the executive director, in consultation with the board chairman, the authority to review and approve applications for limited-use practitioner of the healing arts to sell controlled substances licenses and a waiver of the square footage and security system may be provided when storing and selling multiple strengths and formulations of no more than 5 different topical Schedule VI drugs intended for cosmetic use.

Motion:

The Board voted unanimously to delegate to the executive

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director, in consultation with the board chairman, the authority to review and approve applications for limited-use practitioner of the healing arts to sell controlled substances licenses and a waiver of the square footage and security system may be provided when storing and selling multiple strengths and formulations of no more than 5 different topical Schedule VI drugs intended for cosmetic use. (motion by Ross, second by Kozera)

- Update on the inspection program

Ms. Juran provided an update on the new routine inspection program which went “live” with retail inspections in July 2010. In July and August 2010, 54 retail inspections were performed; 27% resulted in no deficiencies, 38% resulted in deficiencies but no monetary penalty, and 33% resulted in deficiencies with a monetary penalty. Ms. Juran explained that these statistics are similar to the statistics reported at the conclusion of the piloting phase of the retail inspections performed between January and June 2010. Additionally, she reported that, of the 18 deficiencies with a monetary penalty, five of the disciplinary cases have been closed through the signing of the pre-hearing consent order, payment of the monetary penalty and submission of corrective action; six were currently at the pending closure stage; one pharmacy requested an informal conference for further consideration of the matter; and six were pending a response from the pharmacy. Ms. Juran then reported that, as of July 2010, the new inspection program began the “pilot” phase in hospital/institutional pharmacies and three hospitals had been inspected to date. Each hospital inspection resulted in deficiencies with a monetary penalty.

- Formation of committee to review hospital pharmacy deficiencies listed in Guidance Document 110-9 and Regulation 18 VAC 110-20-490

Ms. Juran stated that some inspection areas and thresholds had been identified as needing clarification to ensure inspectors are properly inspecting hospital pharmacies for substantial compliance. One area of concern involves the inspections of the recordkeeping requirements for automated dispensing devices (ADDs) in hospitals as required in Regulation 18 VAC 110-20-490. Additionally, Ms. Abernathy had previously communicated with staff that this regulation may not be clearly written and that the monthly auditing process may be overly burdensome for hospitals with a large number of ADDs. The Board agreed that the formation of a committee to review hospital deficiencies listed in Guidance Document 110-9 and Regulation 18 VAC 110-20-490 for possible revision would be useful and the following board members volunteered to participate: Gill Abernathy, Jody Allen, Ellen Shinaberry, and Brandon Yi. The committee plans to meet in November and provide recommendations to the Board at the December 2010 Board Meeting

- Request from David Kozera

Mr. Kozera briefly expressed concern for opening disciplinary cases

to discuss opening disciplinary case against pharmacy permit or PIC

resulting from the new inspection program against the pharmacy permit instead of the pharmacist-in-charge. Discussions surrounded the requirement to report disciplinary action to NABP and the National Practitioner Data Bank - Healthcare Integrity and Protection Data Bank (NPDB-HIPDB).

Action Item:

Mr. Kozera requested that staff research whether other states were reporting disciplinary action taken against a facility permit and Ms. Abernathy requested staff to contact the Centers for Medicare & Medicaid Services (CMS) or other appropriate persons to research whether reported disciplinary action taken against a facility permit would jeopardize a contract to receive government funds. Ms. Juran will report her findings at the December board meeting.

- Use of agency subordinates to hear disciplinary matters resulting from the new routine inspection process

Ms. Juran recommended the Board consider using an agency subordinate to expedite disciplinary matters resulting from the new routine inspection program as allowed in § 54.1-2400 and Regulation 18 VAC 110-20-15. Ms. Juran stated that Board of Nursing ("BON") has used agency subordinates for several years due to its high volume of cases and that BON staff has agreed to present information and offer training to the board members at the December 2010 Board Meeting. Also, BON staff has agreed to offer training to Board of Pharmacy staff for handling the administrative processes involved in using agency subordinates. Ms. Juran explained that the agency subordinate hears the matter and makes a recommendation to a panel or quorum of the Board who would then vote to approve or deny the subordinate's recommendation. She further reported that possible advantages to using an agency subordinate include: decreased cost and travel time associated with requiring two Board members to attend an informal conference committee meeting; increased consistency with recommendations when using a dedicated person to hear these matters; and faster scheduling of date for conferences since this requires only one person to participate. After discussion, the Board determined it would approve the use of an agency subordinate to hear disciplinary matters resulting from the new routine inspection process.

Motion:

The Board voted unanimously to approve the use of an agency subordinate to hear disciplinary matters resulting from the new routine inspection process and the annual CE auditing process. ((motion by Beckner, second by Kozera))

- Possible legislation proposal from VDH

Ms. Juran reported that the Virginia Department of Health has notified that Board that it may recommend a legislative proposal to amend §54.1-3303 C to include an allowance for prescribing Schedule VI antibiotics to other persons in close contact with a

diagnosed patient with chlamydia or gonorrhea.

- Discussion of vacancy for Board of Health Professions
- Set board meeting dates for 2011

Ms. Juran explained that there is currently a vacancy in the Board of Pharmacy's representation on the Board of Health Professions as allowed in §54.1-2507. She then directed any member who is interested in being appointed to the Board of Health Professions to inform her of this interest and complete the required document(s) found on the Secretary of the Commonwealth's website.

The following dates were chosen for holding full board meetings in 2011:

- March 9
- June 8
- September 7
- December 14

REPORTS:

- Report on Board of Health Professions

Ms. Juran discussed the information that was provided to her by Elizabeth Carter, Executive Director for the Board of Health Professions (BHP). Ms. Carter reported that BHP last met on May 4, 2010, and that the majority of BHP's current activities involve research into the need to regulate several "emerging" professions. Healthcare is evolving rapidly and the number of health professions seeking regulation is exploding in Virginia and nationally. Discussed at the May 4th meeting were the reviews on polysomnographers, community health workers/grand aides, surgical assistants and technologists, and genetic counselors. The General Assembly also assigned three studies to the BHP this year, two sunrise reviews for kinesiotherapists and laboratory scientists and laboratory technicians, and a review into the advisability of expanding medication aides into nursing homes. The BHP has also begun a review into the need for a new Allied Health Board within the Department of Health Professions or other means to help alleviate the burden placed on the Board of Medicine and Board of Nursing in Virginia to regulate professions outside of their traditional roles. Also, BHP is performing a formal research evaluation of Sanctioning Reference effectiveness.

- Acting Executive Director's report

Ms. Juran stated that the deadline for submitting applications for the Board's Executive Director position is September 28, 2010. It is anticipated that interviews will be held in October with a decision made later that month or in November. Additionally, the Board has a vacancy for an administrative office specialist and intends to advertise and fill this position as soon as possible.

Renee Watson, DHP Procurement Manager, provided information regarding issuance of a RFP for a contract administrator of the

Virginia Federal and State Drug Law Exam. She will contact staff later this year to schedule a committee meeting of the Board for reviewing submitted proposals. Participants on this committee are David Kozera, Brandon Yi, Caroline Juran, and Sammy Johnson. Ms. Juran then announced that John Beckner will be attending an upcoming NABP member forum meeting to be held at NABP headquarters in Mount Prospect, Illinois, on September 22-23, 2010. Expenses for this meeting were provided by NABP. This new meeting format consists of a one-day meeting, and the target audience will rotate triennially among board of pharmacy members, executive officers, and compliance officers from each active member board. It provides the participant an opportunity to discuss with their colleagues important and timely issues as well as learn about the latest enhancements to NABP programs and services. Ms. Juran also reported that the NABP District II meeting will be held October 29-31, 2010 in Cooperstown, New York.

NEW BUSINESS

There was no new business discussed.

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 two Consent Orders. Additionally, it was moved that Cathy Reiniers-Day, Caroline Juran, Eusebia Joyner and Howard Casway attend the closed meeting because their presence was deemed necessary and would aid the Board in its deliberation. (motion by Beckner, second by Yi)

Motion to certify the purpose
of the closed meeting:

The Board voted unanimously that only public business matters lawfully exempted from open meeting requirements and only such public business matters as were identified in the motion for closed meeting were heard, discussed or considered during the closed meeting. (motion by Beckner, second by Yi)

Motion:

The Board voted unanimously to accept the consent orders as presented by Ms. Reiniers-Day in the matter of Rebekah H. Scott, pharmacy technician, and Robert B. Scott, pharmacist. (motion by Beckner, second by Kozera)

SUMMARY SUSPENSION:

Closed meeting:

Mr. Beckner moved, and the Board voted unanimously, to convene a closed meeting pursuant to § 2.2-3711 (A) (27) of the Code of Virginia for the purpose of deliberation to reach a decision in the matter of a possible summary suspension. Additionally, he moved that Cathy Reiniers-Day, Caroline

Juran, Eusebia Joyner, Sharon Davenport, Howard Casway, Wayne T. Halbleib and Mykl Egan attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Board in its deliberations. (motion by Beckner, second by Dabney)

TIA J. LATHON
Pharmacy Technician
Registration Number:
0230-014535

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

Reconvene:

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

Decision:

Upon a motion by Mr. Kozera, and duly seconded by Mr. Beckner, the Board voted unanimously in favor of the motion that, according to the evidence presented, the pharmacy technician practice by Tia J. Lathon poses a substantial danger to the public; and therefore, the registration of Tia J. Lathon to practice as a pharmacy technician be summarily suspended and that a Consent Order be offered to Ms. Lathon for the revocation of her registration in lieu of a hearing. (motion by Beckner, second by Kozera)

ADJOURN:

With all business concluded, the meeting adjourned at 1:30 p.m.

Caroline D. Juran
Acting Executive Director

Brandon Yi, Board Chairman

Date

Date

(DRAFT/UNAPPROVED)

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

Wednesday, September 8, 2010
Commonwealth Conference Center
Second Floor
Board Room 2

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

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

CALL TO ORDER: A meeting of a panel of the Board of Pharmacy ("Board") was called to order at 1:45 p.m.

PRESIDING: Brandon K. Yi, Chair

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

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

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

DORIAN A. DOWNHAM
Registration # 0230-003973

Ms. Downham did not appear at the formal hearing. The panel chose to proceed in her absence as the Notice was mailed to Ms. Downham's legal address of record, both by regular and certified mail. The panel discussed that she may have violated certain laws and regulations governing the practice of pharmacy technicians in Virginia as stated in the June 10, 2010, Notice.

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

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David Kouse, Loss Prevention Manager, Rite Aid Corporation, and Nan Dunaway, DHP Pharmacy Inspector, testified on behalf of the Commonwealth.

Closed Meeting:

Upon a motion by Mr. Beckner and duly seconded by Mr. Dabney, the panel voted 9-0, 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 Dorian A. Downham. Additionally, he moved that Caroline Juran, Cathy Reiniers-Day, 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. Beckner and duly seconded by Mr. Kozera, the panel voted 9-0 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 9-0 that Ms. Downham's pharmacy technician registration be suspended for a period of not less than two (2) years.

LADAWN M. BODRICK
License # 0230-010742

Ms. Bodrick did not appear at the formal hearing. The panel chose to proceed in her absence as the Notice was mailed to Ms. Bodrick's legal address of record, both by regular and certified mail. The panel discussed that she may have violated certain laws and regulations governing the practice of pharmacy technicians in Virginia as stated in the June 24, 2010, Notice.

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

Rusty Maney, Pharmacy Supervisor, Walgreen Corporation; Amy L. Burns-Schulz, Loss Prevention Supervisor, Walgreens Corporation; and Vicki G. Garrison, DHP Pharmacy Inspector, testified on behalf of the Commonwealth.

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- Closed Meeting: Upon a motion by Mr. Beckner and duly seconded by Mr. Kozera, the panel voted 9-0, 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 LaDawn M. Bodrick. Additionally, he moved that Caroline Juran, Cathy Reiniers-Day, 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. Beckner and duly seconded by Mr. Kozera, the panel voted 9-0 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 9-0 that Ms. Bodrick's registration be suspended for a period of not less than two (2) years.
- Adjourn: With all business concluded, the meeting adjourned at 3:10 p.m.

Cathy M. Reiniers-Day
Deputy Executive Director

Brandon K. Yi, Chair

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF SPECIAL CONFERENCE COMMITTEE

Tuesday, September 21, 2010
Commonwealth Conference Center
Second Floor
Board Room 1

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

- CALL TO ORDER: A meeting of a Special Conference Committee of the Board of Pharmacy was called to order at 9:15 a.m.
- PRESIDING: David C. Kozera, Committee Chair
- MEMBERS PRESENT: John O. Beckner, Committee Member
- STAFF PRESENT: Cathy M. Reiniers-Day, Deputy Executive Director
Mykl D. Egan, DHP Adjudication Specialist
- PSC MEDSUPPLY, LLC
Permit No. 0214-001195
Lynn More, the pharmacist-in-charge of PSC MedSupply, LLC, appeared to discuss allegations that he may have violated certain laws and regulations governing the conduct of pharmacy as stated in the August 25, 2010, Notice.
- Closed Meeting: Upon a motion by Mr. Beckner, and duly seconded by Mr. Kozera, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, ("Code"), for the purpose of deliberation to reach a decision in the matter of PSC MedSupply, LLC. Additionally, he moved that Cathy Reiniers-Day and Mykl Egan attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
- Reconvene: Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the Committee re-convened in open meeting and announced the decision.
- Decision: Upon a motion by Mr. Beckner, and duly seconded by Mr. Kozera, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to offer PSC MedSupply, LLC a Consent Order to impose a monetary penalty of Five Thousand Dollars (\$5,000).

RENITA GREENE
License No. 0202-010790

Renita Greene appeared with Myron Greene, her husband, to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy as stated in the July 21, 2010, Notice.

Closed Meeting:

Upon a motion by Mr. Beckner, and duly seconded by Mr. Kozera, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, ("Code"), for the purpose of deliberation to reach a decision in the matter of Renita Greene. Additionally, he moved that Cathy Reiniers-Day and Mykl Egan attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

Reconvene:

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

Decision:

Upon a motion by Mr. Beckner, and duly seconded by Mr. Kozera, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted that Ms. Greene's license be placed on probation with certain terms and conditions.

As provided by law, this decision shall become a final Order thirty (30) days after service of such Order on Ms. Greene, unless a written request is made to the Board requesting a formal hearing on the allegations made against her is received from Ms. Greene within such time. If service of the Order is made by mail, three (3) additional days shall be added to that period. Upon such timely request for a formal hearing, the decision of this Special Conference Committee shall be vacated.

KIMBERLI T. HOGAN
Registration No. 0230-011669

Kimberli T. Hogan appeared to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the July 9, 2010, Notice.

Closed Meeting:

Upon a motion by Mr. Beckner, and duly seconded by Mr. Kozera, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of

the Code of Virginia, ("Code"), for the purpose of deliberation to reach a decision in the matter of Kimberli T. Hogan. Additionally, he moved that Cathy Reiniers-Day and Mykl Egan attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

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

Decision: Upon a motion by Mr. Beckner, and duly seconded by Mr. Kozera, the Committee closed the case with no violations noted.

MICHAEL S. MILLER
License No. 0202-010416
Michael S. Miller appeared to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the August 25, 2010, Notice.

Closed Meeting: Upon a motion by Mr. Beckner, and duly seconded by Mr. Kozera, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, ("Code"), for the purpose of deliberation to reach a decision in the matter of Michael S. Miller. Additionally, he moved that Cathy Reiniers-Day and Mykl Egan attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

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

Decision: Upon a motion by Mr. Beckner, and duly seconded by Mr. Kozera, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to issue an Order to Mr. Miller for a reprimand and to impose a monetary penalty and require that he successfully pass the Virginia Drug Law Examination.

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As provided by law, this decision shall become a final Order thirty (30) days after service of such Order on Mr. Miller, unless a written request is made to the Board requesting a formal hearing on the allegations made against him is received from Mr. Miller within such time. If service of the Order is made by mail, three (3) additional days shall be added to that period. Upon such timely request for a formal hearing, the decision of this Special Conference Committee shall be vacated.

ADJOURN:

With all business concluded, the meeting adjourned at 4:16 p.m.

Cathy M. Reiniers-Day
Deputy Executive Director

David C. Kozera, Chair

Date

(DRAFT/UNAPPROVED)

**VIRGINIA BOARD OF PHARMACY
MINUTES OF TELEPHONE CONFERENCE CALL**

Tuesday, September 28, 2010

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 8:30 a.m., on September 28, 2010, to consider the summary suspension of the registration of Beth A. Ogden, to practice as a pharmacy technician in the Commonwealth of Virginia.

PRESIDING: John O. Beckner, Chair

MEMBERS PRESENT: Jody H. Allen
Gerard Dabney
David C. Kozera
Leo H. Ross
Ellen B. Shinaberry
Pratt P. Stelly

STAFF PRESENT: Cathy M. Reiniers-Day, Deputy Executive Director
Caroline D. Juran, Acting Executive Director
Eusebia L. Joyner, Disciplinary Program Specialist
Howard Casway, Senior Assistant Attorney General
Mykl Egan, DHP Adjudication Specialist
Wayne T. Halbleib, Senior Assistant 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 a possible summary suspension case. The Board members stated that they would not have been able to attend.

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

BETH A. OGDEN
Registration No. 0230-012257

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

Upon a motion by David Kozera and duly seconded by Gerard Dabney, the Board unanimously voted that with the evidence presented, the practice as a pharmacy technician by Beth A. Ogden poses a substantial danger to the public; and therefore, said registration shall be summarily suspended; and that a Consent Order be offered to Ms. Ogden for the revocation of her registration in lieu of a hearing.

ADJOURN:

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

Cathy M. Reiniers-Day
Deputy Executive Director

Eusebia L. Joyner
Disciplinary Program Specialist

John O. Beckner, TCC Chair

Date

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(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF TELEPHONE CONFERENCE CALL

Thursday, October 28, 2010

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 9:00 a.m., on October 28, 2010, to consider the summary suspension of the registration of Kelly N. Hayes to practice as a pharmacy technician in the Commonwealth of Virginia.

PRESIDING:

Brandon K. Yi, Chair

MEMBERS PRESENT:

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

STAFF PRESENT:

Cathy M. Reiniers-Day, Deputy Executive Director
Caroline D. Juran, Acting Executive Director
Eusebia L. Joyner, Disciplinary Program Specialist
Howard Casway, Senior Assistant Attorney General
Mykl Egan, DHP Adjudication Specialist
Wayne T. Halbleib, Senior Assistant 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 a possible summary suspension case. The Board members stated that they would not have been able to attend.

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

KELLY N. HAYES
Registration No. 0230-009090

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

Upon a motion by Mr. Dabney and duly seconded by Mr. Beckner, the Board unanimously voted that, with the evidence presented, the practice as a pharmacy technician by Kelly N. Hayes poses a substantial danger to the public; and therefore, said registration shall be summarily suspended; and that a Consent Order be offered to Ms. Hayes for the revocation of her registration in lieu of a hearing.

ADJOURN:

With all business concluded, the conference call adjourned at 9:15 a.m.

Cathy M. Reiniers-Day
Deputy Executive Director

Eusebia L. Joyner
Disciplinary Program Specialist

Brandon K. Yi, Chair

Date

VIRGINIA BOARD OF PHARMACY
MINUTES OF A PANEL OF THE BOARD

Wednesday, November 10, 2010
Commonwealth Conference Center
Second Floor
Board Room 1

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

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

CALL TO ORDER: A meeting of a panel of the Board of Pharmacy ("Board") was called to order at 2:00 p.m.

PRESIDING: John O. Beckner, Vice Chair

MEMBERS PRESENT: Gerard Dabney
David C. Kozera
Robert M. Rhodes
Leo H. Ross
Pratt P. Stelly

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

QUORUM: With six (6) members of the Board present, a panel was established.

BETH A. OGDEN
Registration # 0230-012257

Ms. Ogden did not appear at the formal hearing. The panel proceeded in Ms. Ogden's absence as the Notice was mailed to Ms. Ogden's legal address of record, both by regular and certified mail. The panel discussed that she may have violated certain laws and regulations governing the practice of pharmacy technicians in Virginia as stated in the October 6, 2010, Notice.

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

Denise Sexton, DHP Senior Investigator, testified on behalf of the Commonwealth.

Jeff Hager, Loss Prevention District Manager, K-Mart testified on behalf of the Commonwealth.

Closed Meeting:

Upon a motion by Mr. Kozera and duly seconded by Mr. Dabney, the panel voted 6-0, 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 Beth A. Ogden. Additionally, he moved that Caroline Juran, Cathy Reiniers-Day, 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 6-0 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 6-0 that Ms. Ogden's pharmacy technician registration be revoked.

GWENDOLYN K. FOWLER
License # 0202-206951

Ms. Fowler did not appear at the formal hearing. The panel chose to proceed in her absence as the Notice was mailed to Ms. Fowler's legal address of record, both by regular and certified mail. The panel discussed that she may have violated certain laws and regulations governing the practice of pharmacy in Virginia as stated in the October 8, 2010, Notice.

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

Debra Hay-Pierce, DHP Senior Investigator, testified on behalf of the Commonwealth.

Susan A. Beasecker, BOP Compliance Case Manager, testified on behalf of the Commonwealth.

- Closed Meeting: Upon a motion by Mr. Kozera and duly seconded by Mr. Dabney, the panel voted 6-0, 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 Gwendolyn K. Fowler. Additionally, he moved that Caroline Juran, Cathy Reiniers-Day, 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 6-0 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. Rhodes, the panel voted 6-0 that Ms. Fowler's pharmacy license be indefinitely suspended for a period of not less than two (2) years.
- CHRISTY J. HART
Registration # 0230-006131
- Wayne Halbleib, Senior Assistant Attorney General, presented a signed facsimile copy of the consent order received from Christy J. Hart for the indefinite suspension of her pharmacy technician registration.
- Decision Upon a motion by Mr. Kozera, and duly seconded by Mr. Dabney, the panel voted unanimously in favor of the motion to accept the voluntary surrender of Ms. Hart's registration and that her registration be indefinitely suspended.
- Adjourn: With all business concluded, the meeting adjourned at 4:30 p.m.

Cathy M. Reiniers-Day
Deputy Executive Director

John O. Beckner, Vice Chair

Date

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(DRAFT/UNAPPROVED)

**VIRGINIA BOARD OF PHARMACY
MINUTES OF SPECIAL CONFERENCE COMMITTEE**

Wednesday, November 17, 2010
Commonwealth Conference Center
Second Floor
Training Room 2

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

- CALL TO ORDER: A meeting of a Special Conference Committee of the Board of Pharmacy was called to order at 9:00 a.m.
- PRESIDING: David C. Kozera, Committee Chair
- MEMBERS PRESENT: Brandon K. Yi, Committee Member
- STAFF PRESENT: Cathy M. Reiniers-Day, Deputy Executive Director
Mykl D. Egan, DHP Adjudication Specialist
- STEPHANIE R. CAMPBELL
Pharmacy Technician
Reinstatement Applicant
Stephanie R. Campbell appeared with Theodore M. Galanides, her attorney, to discuss her petition for reinstatement of her pharmacy technician registration and to review allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the October 8, 2010, Notice.
- Closed Meeting: Upon a motion by Mr. Yi, and duly seconded by Mr. Kozera, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, ("Code"), for the purpose of deliberation to reach a decision in the matter of Stephanie R. Campbell. Additionally, he moved that Cathy Reiniers-Day and Mykl Egan attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
- Reconvene: Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the Committee re-convened in open meeting and announced the decision.
- Decision: Upon a motion by Mr. Yi, and duly seconded by Mr. Kozera, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to reinstate Ms. Campbell's pharmacy technician registration with terms and conditions.

As provided by law, this decision shall become a final Order thirty (30) days after service of such Order on Ms. Campbell, unless a written request is made to the Board requesting a formal hearing on the allegations made against her is received from Ms. Campbell within such time. If service of the Order is made by mail, three (3) additional days shall be added to that period. Upon such timely request for a formal hearing, the decision of this Special Conference Committee shall be vacated.

BETHANY L. BOYD
Registration No. 0230-007836

This informal conference was scheduled, but not held and the matter was referred to a formal hearing.

ADJOURN:

With all business concluded, the meeting adjourned at 1:50 p.m.

Cathy M. Reiniers-Day
Deputy Executive Director

David C. Kozera, Chair

Date

(DRAFT/UNAPPROVED)

**VIRGINIA BOARD OF PHARMACY
MINUTES OF TELEPHONE CONFERENCE CALL**

Thursday, December 2, 2010

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 9:00 a.m., on December 2, 2010, to consider the summary suspension of the registration of Elisabeth A. Williams to practice as a pharmacy technician in the Commonwealth of Virginia.

PRESIDING: Brandon K. Yi, Chair

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

STAFF PRESENT: Cathy M. Reiniers-Day, Deputy Executive Director
Caroline D. Juran, Acting Executive Director
Eusebia L. Joyner, Disciplinary Program Specialist
Howard Casway, Senior Assistant Attorney General
Mykl Egan, DHP Adjudication Specialist
Corie Tillman-Wolf, Assistant 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 a 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.

ELISABETH A. WILLIAMS
Registration No. 0230-015687

Corie Tillman-Wolf presented a summary of the evidence in this case.

Upon a motion by Mr. Beckner and duly seconded by Ms. Abernathy, the Board unanimously voted that, with the evidence presented, the practice as a pharmacy technician by Elisabeth A. Williams poses a substantial danger to the public; and therefore, said registration shall be summarily suspended; and that a Consent Order be offered to Ms. Williams for the revocation of her registration in lieu of a hearing.

ADJOURN:

With all business concluded, the conference call adjourned at 9:15 a.m.

Cathy M. Reiniers-Day
Deputy Executive Director

Eusebia L. Joyner
Disciplinary Program Specialist

Brandon K. Yi, Chair

Date

**Virginia Board of Pharmacy
Pharmacy Inspection Deficiency Monetary Penalty Guide**

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Major Deficiency	Law/Reg Cite	Conditions	\$ Penalty
1. No PIC or PIC not fully engaged in practice at pharmacy location	54.1-3434 and 18VAC110-20-110	must have documentation	1000
2. PIC in place, inventory taken, but application not filed with Board	54.1-3434 and 18VAC110-20-110		100
3. Unregistered persons performing duties restricted to pharmacy technician when not enrolled in a Board-approved pharmacy technician training program or beyond 9 months	54.1-3321 and 18VAC110-20-111	per individual	250
4. Pharmacists/pharmacy technicians/pharmacy interns performing duties on an expired license/registration	18VAC110-20-80, 18VAC110-20-40, and 18VAC110-20-105	per individual	100
5. Pharmacy technicians, pharmacy interns without monitoring, or unlicensed persons engaging in acts restricted to pharmacists	54.1-3320		500
6. Exceeds pharmacist to pharmacy technician ratio	54.1-3320	per each technician over the ratio	100
7. COL or remodel without application or Board approval	18VAC110-20-140	must submit an application and fee	250
8. Refrigerator/freezer temperature out of range greater than +/- 4 degrees	18VAC110-20-150 and 18VAC110-20-10	determined using inspector's or pharmacy's calibrated thermometer	100 Drugs may be embargoed
9. Alarm not operational or not being set or incapable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational	18VAC110-20-180 and 18VAC110-20-190		1000
10. Unauthorized access to alarm or locking device for Rx department	18VAC110-20-180 and 18VAC110-20-190		1000

Major Deficiency	Law/Reg Cite	Conditions	\$ Penalty
11. Insufficient enclosures or locking devices	18VAC110-20-190		500
12. Storage of Rx drugs not in prescription department	18VAC110-20-190		500
13. No biennial inventory, or over 30 days late	54.1-3404 and 18VAC110-20-240		500
14. No incoming change of PIC inventory taken within 5 days or <i>substantially incomplete</i>	54.1-3434 and 18VAC110-20-240	will not be cited until 9/1/2010 <i>10% threshold</i>	500
15. Perpetual inventory not being maintained or monitored as required	18VAC110-20-240		250
16. Theft/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	54.1-3404 and 18VAC110-20-240 54.1-3404, 18VAC110-20-240, 18VAC110-20-250, 18VAC110-20-420 and 18VAC110-20-425		250
18. Records of dispensing not maintained as required	18VAC110-20-270, 18VAC110-20-420 and 18VAC110-20-425		250
19. Pharmacists not verifying or failing to document verification of accuracy of dispensed prescriptions	18VAC110-20-420 and 18VAC110-20-425	10% threshold for documentation	500
20. Pharmacist not checking and documenting repackaging, compounding, or bulk packaging	54.1-3410.2, 18VAC110-20-355 and 18VAC110-20-425	10% threshold	250
21. No clean room	54.1-3410.2		5000
22. Certification of the direct compounding area (DCA) for CSPs indicating ISO Class 5 over 60 days late (6mo + 60 days)	54.1-3410.2		3000 per DCA
23. Certification of the buffer or clean room and ante room indicating ISO Class 8 or better over 60 days late (6mo+60 days)	54.1-3410.2		1000 per area

Major Deficiency	Law /Reg Cite	Conditions	\$ Penalty
24. Sterile compounding of hazardous drugs performed in an area not physically separated from other preparation areas	54.1-3410.2		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
26. Training documentation involving media-fill tests for low and medium-risk levels not maintained for > 30% of individuals preparing CSPs, or no documentation maintained of a passing media-fill test for any individual preparing low and medium-risk CSPs >45 days after receipt of a failed media-fill test	54.1-3410.2		500
27. Compounding using ingredients in violation	54.1-3410.2		1000
28. Compounding copies of commercially available products	54.1-3410.2	per Rx dispensed up to maximum of 100 RX or \$5000	50
29. Unlawful compounding for further distribution by other entities	54.1-3410.2		500
30. Security of after-hours stock not in compliance	18VAC110-20-450		500
31. For LTC, ADD being accessed for orders prior to pharmacist review and release	18VAC110-20-555		250
32. No monthly audits performed of ADDs	18VAC110-20-490		250
33. Have clean room, but not all physical standards in compliance, e.g., flooring, ceiling	54.1-3410.2		2000

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Minor Deficiencies

If ~~three (3)~~ *five (5)* or more minor deficiencies are cited, a \$250 monetary penalty shall be imposed. Another \$100 monetary penalty will be added for each additional minor deficiency over the initial ~~three~~ *five*.

Minor Deficiency	Law/Regulation Cite	Conditions
General Requirements:		
1. Site specific training documentation not maintained as required	18VAC110-20-111	
2. Special/limited-use scope being exceeded without approval	18VAC110-20-120	
3. Decreased hours of operation without public/Board notice	18VAC110-20-135	
4. No hot/cold running water	18VAC110-20-150	
5. No thermometer or non-functioning thermometer in refrigerator/freezer, but within range of 4 degrees	18VAC110-20-150 and 18VAC110-20-110	determined using inspector's calibrated thermometer
6. Rx department substantially not clean and sanitary and in good repair	18VAC110-20-160	must have picture documentation
7. Current dispensing reference not maintained	18VAC110-20-170	
8. Emergency access alarm code/key not maintained in compliance	18VAC110-20-190	
9. Expired drugs in working stock or dispensed drugs being returned to stock not in compliance	18VAC110-20-200 18VAC110-20-355	10% threshold
10. Storage of paraphernalia/Rx devices not in compliance	18VAC110-20-200	

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Guidance Document 110-9

Minor Deficiency	Law/Regulation Cite	Conditions
11. Storage of will-call not in compliance	18VAC110-20-200	
12. Biennial taken late but within 30 days	54.1-3404 and 18VAC110-20-240	
13. Inventories taken on time, but not in compliance, i.e., no signature, date, opening or close, CII not separate	54.1-3404 and 18VAC110-20-240	
14. Records of receipt (invoices) not on site or retrievable	54.1-3404 and 18VAC110-20-240	
15. Other records of distributions not maintained as required	54.1-3404 and 18VAC110-20-240	
16. Prescriptions do not include required information	54.1-3408.01 and 54.1-3410	10% threshold
17. Prescriptions not transmitted as required (written, oral, fax, electronic, etc.)	54.1-3408.02, 54.1-3410, 18VAC110-20-280 and 18VAC110-20-285	10% threshold
18. CII emergency oral prescriptions not dispensed in compliance	54.1-3410 and 18VAC110-20-290	>3
19. Not properly documenting partial filling	54.1-3412, 18VAC110-20-255, and 18VAC110-20-320	
20. Offer to counsel not made as required	54.1-3319	
21. Prospective drug review not performed as required	54.1-3319	
22. Engaging in alternate delivery not in compliance	18VAC110-20-275	
23. Engaging in remote processing not in compliance	18VAC110-20-276 and 18VAC110-20-515	

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Minor Deficiency	Law/Regulation Cite	Conditions
24. Labels do not include all required information	54.1-3410, 54.1-3411 and 18VAC110-20-330	
25. Compliance packaging or labeling does not conform to USP requirements	18VAC110-20-340	
26. Special packaging not used or no documentation of request for non-special packaging	54.1-3426, 54.1-3427 and 18VAC110-20-350	10% threshold
Repackaging, specialty dispensing, compounding:		
27. Repackaging records and labeling not kept as required or in compliance	18VAC110-20-355	10% threshold
28. Unit dose procedures or records not in compliance	18VAC110-20-420	
29. Robotic pharmacy systems not in compliance	18VAC110-20-425	
30. Required compounding/dispensing/distribution records not complete and properly maintained; compounded products not properly labeled or assigned appropriate expiration date	54.1-3410.2	
31. Required "other documents" for USP 797 listed or inspection report are not appropriately maintained	54.1-3410.2	30% threshold
32. Personnel performing CSPs do not comply with cleansing and garbing requirements	54.1-3410.2	30% threshold
33. Compounding facilities and equipment used in performing non-sterile compounds not in compliance	54.1-3410.2	

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Minor Deficiency

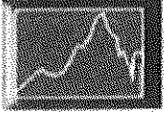
Law/Regulation Cite

Conditions

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Hospital specific or long-term care specific:

<p>34. Policies and procedures for proper storage, security and dispensing of drugs in hospital not established or assured</p>	<p>18VAC110-20-440</p>	
<p>35. Policies and procedures for drug therapy reviews not maintained or followed</p>	<p>18VAC110-20-440</p>	
<p>36. After hours access or records not in compliance</p>	<p>18VAC110-20-450</p>	<p>10% threshold</p>
<p>37. Floor stock records not in compliance, pharmacist not checking, required reconciliations not being done</p>	<p>18VAC110-20-460</p>	<p>10% threshold</p>
<p>38. ADD loading, records, and monitoring/reconciliation not in compliance</p>	<p>54-1-3434.02, 18VAC110-20-490 and 18VAC110-20-555</p>	<p>10% threshold</p>
<p>39. EMS procedures or records not in compliance</p>	<p>18VAC110-20-500</p>	<p>10% threshold</p>
<p>40. Emergency kit or stat-drug box procedures or records not in compliance</p>	<p>18VAC110-20-540 and 18VAC110-20-550</p>	<p>10 % threshold</p>
<p>41. Maintaining floor stock in LTCF not authorized</p>	<p>18VAC110-20-520 and 18VAC110-20-560</p>	



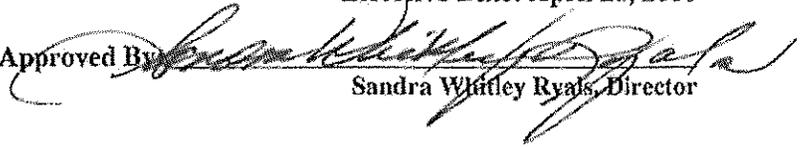
Department of Health Professions

DIRECTOR'S POLICY # 76-4.3

Reporting to NPDB, HIPDB and Section 1921 Data Banks

Effective Date: April 26, 2010

Approved By



Sandra Whitley Ryals, Director

76-4.3 Reports to Reports to The National Practitioner Data Bank, The Healthcare Integrity & Protection Data Bank and Section 1921

Purpose:

To establish policy for receipt and transmittal of adverse action reports to the National Practitioner Data Bank (NPDB), the Healthcare Integrity & Protection Data Bank (HIPDB), and to Section 1921 data bank of the Social Security Act, which require licensing boards to report disciplinary actions within thirty (30) days.

Policy:

All publicly available disciplinary actions taken by the health regulatory boards ("boards") within the Department will be transmitted to the NPDB, the HIPDB and Section 1921 within thirty (30) days of the entry of the final action.

Procedures:

A. Health Regulatory Board's Responsibility:

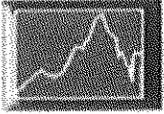
Within three days of the entry of a disciplinary action ("order") the board will:

1. Close the case in the Department's case management database-License 2000 ("L2K").
2. Enter the closure, disposition and effective dates in L2K.
3. Enter the actions and basis for action codes in L2K.
4. Forward a copy of the order to the Administrative Proceedings Division ("APD") Office Manger.

B. Administrative Proceedings Division's Responsibility:

Upon notice from the Data Division that the NPDB/HIPDB Initial Action Draft file has been updated, APD will:

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Department of Health Professions

DIRECTOR'S POLICY # 76-4.3

Reporting to NPDB, HIPDB and Section 1921 Data Banks

Effective Date: April 26, 2010

Approved By:



Sandra Whitley Ryals, Director

1. Print the Action table which lists all unreported cases closed with a violation by board, respondent and case number.
2. Verify that each case listed has a copy of the board order.
3. Review the Board order, and for all initial reports, enter the appropriate Length of Action ("LOA") code in L2K and the Competency and Conduct ("CCB") code in the CCB table. Review the Basis For Action (BFA) codes and all dates entered by the boards, and when necessary, notify the designated board staff as to what corrections are recommended.
4. For all revision to previous action reports, enter the Databank Control Number ("DCN") and the LOA in L2K, enter the CCB in the Revision-M-User table, and the case number in the Revision-M table.
5. Remove from the Action table any cases that need to have corrections completed or any cases that do not have the copy of the Order available to allow them to be reported at a later date when the corrections have been completed by the boards and/or the order is made available to the APD Office Manager.
6. Review with the division director all initial cases that will be reported weekly to the Databanks.
7. Via e-mail to the Data division release the Action table for reporting to HIPDB/NPDB.
8. APD will maintain hard copies of all initial reports for six (6) months.

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SURVEY OF STATE BOARDS OF PHARMACY REGARDING REPORTING TO HIPDB

Do you report actions to HIPDB?	YES	NO	DONT REGISTER	NO ANSWER
Pharmacists	25	0		0
Pharmacies	19	6		0
Pharmacy Technicians	20	4	1	0
Types of actions reported.	YES	NO	DONT IMPOSE	NO ANSWER
Revocation	25	0	0	0
Suspension	24	0	1	0
Probated Suspension	19	0	3	3
Fine/Administrative Penalty	20	1	4	0
Reprimand	19	4	2	0
Censure	1			
Citation & Warning	1			
Continuing Education	2			
Conditional License	1			
Deferred Action		1		
Letter of Admonition	1			
Letter of Warning	1			
Limitation	1			
Probation	7			
Voluntary Surrender	1			
Warning	1			
Your Success Rx	1			
Are you seeing any reluctance on the part of licensees/registrants to agree to settlement/agreed orders because of:	YES	NO	NO ANSWER	
a concern that an individual licensee/registrant may denied employment or certification, if they have an action reported to HIPDB.	6	18	1	
a concern that a pharmacy may be denied a contract or certification, if they have an action reported to HIPDB.	5	17	3	
NUMBER OF STATES REPORTING				
25				
Arizona, California, Colorado, Connecticut, Delaware, Idaho, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Michigan, Minnesota, Nevada, New Hampshire, North Carolina, North Dakota, Rhode Island, South Carolina, South Dakota, Texas, Utah, Virginia, and Wyoming				

STATE	Question 1	Question 2	Question 3	Question 4	Question 5	Comments
Alabama	N/A	N/A	N/A	N/A	N/A	Alabama has no statutes or rules that specifically address. The fact that the patient or the pharmacy has custody of the "unfilled" prescription would not alter the issue date. Alabama has not passed legislation to permit electronic only storage of original prescriptions.
Colorado	N/A	N/A	N/A	N/A	N/A	Colorado does not have laws or rules for "on-hold" prescriptions.
Idaho	N/A	N/A	N/A	N/A	N/A	Idaho does not address this issue in rule or statute.
Louisiana	N/A	N/A	N/A	N/A	N/A	Louisiana does not have any laws or rules relative to 'on-hold' prescriptions
Maine	Yes	No	No	No	No	See Board Rule Chapter 19, Sec 2 (2)(B) "No pharmacist may fill a prescription drug order for a controlled substance that is presented to the pharmacist more than 90 days after the date of the prescription."
Minnesota	Yes	No	No	Yes	No	Treated as any other prescription.
Mississippi	Yes	No	No	No	No	Mississippi's regulations do not specifically address "on hold" prescriptions. We do have facilities that place them in the computer on hold, and when they do the facility is required to follow ARTICLE XIII of our regulations. However, we also have facilities that keep these prescriptions filed manually and do not enter them into their computer systems till needed. There is no filing requirement until the prescriptions are placed in the computer.
North Dakota	Yes	No	No	No	No	Essentially we treat them the same as any other prescription, except the quantity dispensed says zero, until it is filled. A few computer systems will not accept a quantity of zero, so one gets entered and a not made that none was dispensed. Of course the pharmacy must make separate documentation to be sure their controlled records are correct.
Ohio	Yes	No	See comment	Yes	No	Question 1 - Rule 4729-5-27 Paragraph N (http://www.pharmacy.ohio.gov/rules/4729-5-27.pdf) Question 3 - Rule 4729-5-27(N)(4) and Rule 4729-5-09 (http://www.pharmacy.ohio.gov/rules/4729-5-09.pdf)
Oregon	Yes	No	No	No	No	The Oregon Board does allow pharmacies to place prescriptions on hold to be filled at a later date. Oregon does not have rule specific to placing prescriptions on hold.

STATE	Question 1	Question 2	Question 3	Question 4	Question 5	Comments
Oklahoma	N/A	N/A	N/A	N/A	N/A	Oklahoma does not have any rules/regulations addressing "on-hold" prescriptions.
Texas	Yes	No	No	No	No	The only place in our rules that we talk about "hold" prescriptions is the following language that requires a pharmacist to verify the accuracy of data entry for a "hold" prescription. The reason we adopted this rule is that we had some problems with dispensing errors when "hold" prescriptions were data entered into the system but not dispensed (i.e. placed on "hold"). These prescriptions were being data entered just like all prescriptions, but because they were placed on "hold" the store policy for these prescriptions did not require the pharmacist to verify that the "hold" prescription was data entered correctly. This step in the process was supposed to be conducted when the patient actually requested that the hold prescription be filled. We had several cases where dispensing errors occurring because the data entry was not occurring at this fill step. To complete this process the pharmacist was required to pull the original hard copy of the prescription then verify data entry; however, this was not occurring. Therefore, we changed the rules to specify that any prescription entered into the data processing system has to be verified for accurate entry by the pharmacist at the time of data entry. 1
Wyoming	Yes	N/A	N/A	N/A	N/A	We have had some bad medication errors after prescriptions were put "on hold" and one was a fatal warfarin dose that never got checked. I would be interested in any good rules that you receive if you can share them
Canada	Yes	No	No	No	No	-Since the order has not been filled it does not have legal status as a prescription. All that's been done is the order has been filed for use in the future. We permit pharmacies to put these orders on hold using best practices and the knowledge that filling at later date is not the same as a refill rather that it is a new prescription. - They are treated the same as a new prescription and access to the original is left to the pharmacist's discretion.

Survey Questions:

1. Does your state permit a pharmacy to maintain prescriptions "on-hold" for a patient who does not intend to fill the prescription until some later date?
2. Are there restrictions for placing a prescription written for drugs in Schedule II-V "on-hold"?
3. Are "on-hold" prescriptions required to be filed in a specific manner? Please reference and provide links to any applicable laws or regulations.
4. Are "on-hold" prescriptions required to be assigned a serial number and filed accordingly at the time the pharmacy receives the prescription for the patient?
5. Are "on-hold" prescriptions permitted or required to be filed differently once dispensed?

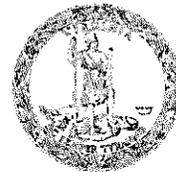
SANCTIONING REFERENCE POINTS

INSTRUCTION
MANUAL

Board of Pharmacy

Virginia Department
of Health Professions

Board of Pharmacy
Guidance Document 110-21
Adopted September 12, 2007



SANCTIONING REFERENCE POINTS

INSTRUCTION MANUAL

Board of Pharmacy

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Board of Pharmacy
Guidance Document 110-21
Adopted September 12, 2007



COMMONWEALTH OF VIRGINIA

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September 2007

Dear Interested Parties:

In the spring of 2001, the Virginia Department of Health Professions approved a workplan to study sanctioning in disciplinary cases for Virginia's 13 health regulatory boards. The purpose of the study was to "...provide an empirical, systematic analysis of board sanctions for offenses and, based on this analysis, to derive reference points for board members..." The purposes and goals of this study are consistent with state statutes which specify that the Board of Health Professions periodically review the investigatory and disciplinary processes to ensure the protection of the public and the fair and equitable treatment of health professionals.

Each health regulatory board hears different types of cases, and as a result, considers different factors when determining an appropriate sanction. After interviewing Board of Pharmacy members and staff, a committee of Board members, staff, and research consultants assembled a research agenda involving one of the most exhaustive statistical studies of sanctioned Pharmacists in the United States. The analysis included collecting over 100 factors on all Board of Pharmacy sanctioned cases in Virginia over a 6-year period. These factors measured case seriousness, respondent characteristics, and prior disciplinary history. After identifying the factors that were consistently associated with sanctioning, it was decided that the results provided a solid foundation for the creation of sanction reference points. Using both the data and collective input from the Board of Pharmacy and staff, analysts then developed a usable sanctioning worksheet as a way to implement the reference system.

By design, future sanction recommendations will encompass, on average, about 79% of past historical sanctioning decisions; an estimated 21% of future sanctions will fall above or below the sanction point recommendations. This allows considerable flexibility when sanctioning cases that are particularly egregious or less serious in nature. Consequently, one of the most important features of this system is its voluntary nature; that is, the Board is encouraged to depart from the reference point recommendation when aggravating or mitigating circumstances exist.

Equally important to recommending a sanction, the system allows each respondent to be evaluated against a common set of factors—making sanctioning more predictable, providing an educational tool for new Board members, and neutralizing the possible influence of "inappropriate" factors (e.g., race, sex, attorney presence, identity of Board members). As a result, the following reference instrument should greatly benefit Board members, health professionals and the general public.

Sincerely yours,

Sandra Whitley Ryals
Director

Cordially,

Elizabeth A. Carter, Ph.D.
Executive Director
Virginia Board of Health Professions

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Overview

The Virginia Board of Health Professions has spent the last 4 years studying sanctioning in disciplinary cases. The study is examining all 13 health regulatory boards, with the greatest focus most recently on the Board of Pharmacy. The Board of Pharmacy is now in a position to implement the results of the research by using a set of voluntary *Sanctioning Reference Points*. This manual contains some background on the project, the goals and purposes of the system, and the offense-based sanction worksheet that will be used to help Board members determine how a similarly situated respondent has been treated in the past. This sanctioning system is based on a specific sample of cases, and thus only applies to those persons sanctioned by the Virginia Board of Pharmacy. Moreover, the worksheet has not been tested or validated on any other groups of persons. Therefore, they should not be used at this point to sanction respondents coming before other health regulatory boards, other states, or other disciplinary bodies.

The Sanctioning Reference system is comprised of a single worksheet which scores case type, prior history and offense factors identified using statistical analysis. These factors have been isolated and tested in order to determine their influence on sanctioning outcomes. Sanctioning thresholds found on the offense worksheet recommend a range of sanctions from which the Board may select in a particular case.

In addition to this instruction booklet, separate coversheets and worksheets are available to record the respondent's score, recommended sanction, actual sanction and any reasons for departure (if applicable). The completed coversheets and worksheets will be evaluated as part of an on-going effort to monitor and refine the Sanctioning Reference Points. These instructions and the use of the Sanctioning Reference Points system fall within current Department of Health Professions and Board of Pharmacy policies and procedures. Furthermore, all sanctioning recommendations are those currently available to and used by the Board and are specified within existing Virginia statutes.

Background In April of 2001, the Virginia Board of Health Professions (BHP) approved a work plan to conduct an analysis of health regulatory board sanctioning and to consider the appropriateness of developing historically-based sanctioning reference points for health regulatory boards, including the Board of Pharmacy (BOP). The Board of Health Professions and project staff recognize the complexity and difficulty in sanction decision-making and have indicated that for any sanction reference system to be successful, it must be “*developed with complete Board oversight, be value-neutral, be grounded in sound data analysis, and be totally voluntary*”—that is, the system is viewed strictly as a Board decision tool.

Goals The Board of Health Professions and the Board of Pharmacy cite the following purposes and goals for establishing Sanctioning Reference Points:

- Making sanctioning decisions more predictable
- Providing an education tool for new Board members
- Adding an empirical element to a system that is inherently subjective
- Providing a resource for BOP and those involved in proceedings.
- “Neutralizing” sanctioning inconsistencies
- Validating Board member or staff recall of past cases
- Constraining the influence of undesirable factors—e.g., Board member ID, overall Board makeup, race or ethnic origin, etc.
- Helping predict future caseloads and need for probation services and terms

Methodology The fundamental question when developing a sanctioning reference system is deciding whether the supporting analysis should be grounded in historical data (a *descriptive approach*) or whether it should be developed normatively (a *prescriptive approach*). A normative approach reflects what policymakers feel sanction recommendations *should be*, as opposed to what they *have been*. Sanctioning reference points can also be developed using historical data analysis with normative adjustments to follow. This approach combines information from past practice with policy adjustments, in order to achieve some desired outcome. The Board of Pharmacy chose a descriptive approach with a limited number of normative adjustments.

■ Qualitative Analysis

Researchers conducted in-depth personal interviews of some past and all current BOP members, Board staff, and representatives from the Attorney General’s office. The interview results were used to build consensus regarding the purpose and utility of sanctioning reference points and to further frame the analysis. Additionally, interviews helped ensure the factors that Board members consider when sanctioning were included during the quantitative phase of the study. A literature review of sanctioning practice across the United States was also conducted.

Methodology, continued**■ Quantitative Analysis**

Researchers analyzed detailed information on BOP disciplinary cases ending in a violation between 1997 and 2002; approximately 361 sanctioning “events” covering close to 450 cases. Over 100 different factors were collected on each case in order to describe the case attributes Board members identified as potentially impacting sanction decisions. Researchers used data available through the DHP case management system combined with primary data collected from hard copy files. The hard copy files contained investigative reports, Board notices, Board orders, and all other documentation that is made available to Board members when deciding a case sanction.

A comprehensive database was created to analyze the offense and respondent factors which were identified as potentially influencing sanctioning decisions. Using statistical analysis to construct a “historical portrait” of past sanctioning decisions, the significant factors along with their relative weights were derived. These factors and weights were formulated into a sanctioning worksheet with three thresholds, which are the basis of the Sanctioning Reference Points.

Offense factors such as patient injury, financial gain and case severity (priority level) were analyzed as well as prior history factors such as substance abuse, and previous Board orders. Some factors were deemed inappropriate for use in a structured sanctioning reference system. For example, respondent gender and presence of an attorney are considered “extra-legal” factors, and were explicitly excluded from the sanction reference points. Although many factors, both “legal” and “extra-legal” can help explain sanction variation, only those “legal” factors the Board felt should consistently play a role in a sanction decision were included in the final product. By using this method, the hope is to achieve more neutrality in sanctioning, by making sure the Board considers the same set of “legal” factors in every case.

Wide Sanctioning Ranges

The Sanctioning Reference Points consider and weigh the circumstances of an offense and the relevant characteristics of the respondent, providing the Board with a sanction range that encompasses roughly 79% of historical practice. This means that 21% of past cases had received sanctions either higher or lower than what the reference points indicate, acknowledging that aggravating and mitigating factors play a role in sanctioning. The wide sanctioning ranges recognize that the Board will sometimes reasonably disagree on a particular sanction outcome, but that a broad selection of sanctions fall within the recommended range.

Any sanction recommendation the Board derives from the Sanctioning Reference Points worksheets must fall within Virginia law and regulations. If a Sanctioning Reference Point worksheet recommendation is more or less severe than a Virginia statute or DHP regulation, the existing laws or policies supercede any worksheet recommendation.

Three Sets of Sanctioning Factors

The Board indicated early in the study that sanctioning is influenced by variety of circumstances beyond the instant offense. The empirical analysis supported the notion that not only case type but offense factors and prior history impacted sanction outcomes. To this end, the Sanction Reference Points system, as designed for the Board of Pharmacy, makes use of three factors that combine for a sanctioning outcome that lies within one of three thresholds. The first dimension assesses factors related to case type, the second assesses factors related to the offense, and the third dimension relates to prior history.

So a respondent before the Board for an records/inspections/audits case may also receive points for having had substance abuse problems, or for having a history of disciplinary violations for other types of cases. In the first dimension points are assigned for the type of case the Board is currently considering. The second dimension assigns points for factors related to the offense. For example, the respondent may receive points if they were impaired at the time of the offense. The last dimension assigns points for prior history. In this category, a respondent's prior Board orders and/or any past substance abuse are considered.

Voluntary Nature

The Sanctioning Reference Points system is a tool to be utilized by the Board of Pharmacy. Compliance with the Sanctioning Reference Points is voluntary. The Board will use the system as a reference tool and may choose to sanction outside the recommendation. The Board maintains complete discretion in determining the sanction handed down. However, a structured sanctioning system is of little value if the Board is not provided with the appropriate coversheet and worksheet in every case eligible for scoring. A coversheet and worksheet should be completed in cases resolved by Informal Conferences and Consent Orders that come before Informal Conference committees. The coversheet and worksheets will be referenced by Board members during Closed Session.

**Worksheets Not Used
in Certain Cases**

The Sanctioning Reference Points will not be applied in any of the following circumstances:

- Formal Hearings — Sanction Reference Points will not be used in cases that reach a Formal Hearing level.
- Mandatory suspensions – Virginia law requires that under certain circumstances (conviction of a felony, declaration of legal incompetence or incapacitation, license revocation in another jurisdiction) the license of a pharmacist must be suspended. The sanction is defined by law and is therefore excluded from the Sanctioning Reference Point system.
- Compliance/reinstatements – The Sanctioning Reference Points should be applied to new cases only.
- Action by another Board – When a case which has already been adjudicated by a Board from another state appears before the Virginia Board of Pharmacy, the Board often attempts to mirror the sanction handed down by the other Board. The Virginia Board of Pharmacy usually requires that all conditions set by the other Board are completed or complied with in Virginia. The Sanctioning Reference Points do not apply as the case has already been heard and adjudicated by another Board.
- Confidential Consent Agreements (CCA) - Sanction Reference Points will not be used in cases settled by CCA.

Case Selection When Multiple Cases Exist

When multiple cases have been combined into one "event" (one order) for disposition by the Board, only one coversheet and worksheet should be completed and it should encompass the entire event. If a case (or set of cases) has more than one offense type, one case type is selected for scoring according to the offense group which appears highest on the following table and receives the highest point value. For example, a pharmacist found in violation of both a wrong drug error and personal drug use would receive fifty points, since Inability to Safely Practice is above Prescription Error on the list and receives the most points. If an offense type is not listed, find the most analogous offense type and use the appropriate score. The case type that has been selected from the list below is the only case type that receives points on the sanctioning worksheet.

Sanctioning Reference Points Case Type Table

Case Type	Included Categories	Points Assignment
Inability to Safely Practice	Incapacitation – mental/physical Impairment – drugs/alcohol Inability to Safely Practice - other Drug Related - Excessive Dispensing Drug Related – Security Drug Related - Obtaining Drugs by Fraud Drug Related – Personal Use Drug Related – Other	50
Professional Practice Issues	Criminal Activity Business Practice Issues Fraud Unlicensed Activity Records/Inspections/Audits Unprofessional Conduct	35
Prescription Error	Strength/Quantity Error Directions/Expired Medications Error Wrong Drug Error Wrong Patient/Physician Name Error Generic/Brand Error	10

Completing the Coversheet and Worksheet

Ultimately, it is the responsibility of the BOP to complete the Sanction Reference Point coversheet and worksheet in all applicable cases.

The information relied upon to complete a coversheet and worksheet is derived from the case packet provided to the Board and respondent. It is also possible that information discovered at the time of the informal conference may impact worksheet scoring. The Sanction Reference Point coversheet and worksheet, once completed, are confidential under the Code of Virginia. However, complete copies of the Sanction Reference Point Manual, including blank coversheets and worksheets, can be found on the Department of Health Professions web site: www.dhp.state.va.us (paper copy also available on request).

Sanctioning Worksheet

Instructions for case scoring are contained adjacent to each worksheet in subsequent sections of this manual. Instructions are provided for each line item of each worksheet and should be referenced to ensure accurate scoring for a specific factor. When scoring a worksheet, the scoring weights assigned to a factor on the worksheet *cannot be adjusted*. The scoring weights can only be applied as 'yes or no' with all or none of the points applied. In instances where a scoring factor is difficult to interpret, the Board has final say in how a case is scored.

Coversheet

The coversheet is completed to ensure a uniform record of each case and to facilitate recodation of other pertinent information critical for system monitoring and evaluation.

If the Board feels the sanctioning threshold does not recommend an appropriate sanction, the Board is encouraged to depart either high or low when handing down a sanction. If the Board disagrees with the sanction recommendation and imposes a sanction greater or less than the recommended sanction, a short explanation can be recorded on the coversheet. The explanation could identify the factors and the reasons for departure. This process will ensure worksheets are revised appropriately to reflect current Board practice. If a particular reason is continually cited, the Board can examine the issue more closely to determine if the worksheets should be modified to better reflect Board practice.

Aggravating and mitigating circumstances that may influence Board decisions can include, but should not be limited to, such things as:

- Prior record
- Dishonesty/Obstruction
- Motivation
- Remorse
- Victim vulnerability
- Restitution/Self-corrective action
- Multiple offenses/Isolated incident

A space is provided on the coversheet to record the reason(s) for departure. Due to the uniqueness of each case, the reason(s) for departure may be wide-ranging. Sample scenarios are provided on the following page.

Coversheet, continued

Departure Example #1

Sanction Grid Result: Remove from practice.

Imposed Sanction: Probation with terms – practice restriction.

Reason(s) for Departure: Respondent was particularly remorseful and had already begun corrective action.

Departure Example #2

Sanction Grid Result: Reprimand.

Imposed Sanction: Probation – practice monitoring.

Reason(s) for Departure: Respondent may be trending towards future violations, implement oversight now to avoid future problems.

Determining a Specific Sanction

The Sanction thresholds have three separate sanctioning outcomes: Monitoring/Treatment/Refer to Formal, Reprimand/Monetary Penalty, and Knowledge Based. The table below lists the most frequently cited sanctions under the three sanctioning outcomes that are part of the sanction threshold. After considering the sanction recommendation, the Board should fashion a more detailed sanction(s) based on the individual case circumstances.

Sanctioning Reference Points Threshold Table

Worksheet Threshold	Available Sanctions
Monitoring/ Treatment/ Refer to Formal	Recommend Formal (revocation or suspension may result) Suspension Stayed Suspension Probation Terms Quarterly performance evaluations from employer Written notification to pharmacist in charge Quarterly self reports/DEA forms Inform board of any changes in employment Random drug screenings Begin/continue AA/NA, caduceus, etc. Inform board upon resuming practice Continue in therapy and therapist provides quarterly reports Aftercare/peer assistance group contract – continue Chemical dependency/psych/mental/phys/ evaluation Quarterly reports from probation/parole officer Provide board with court order
Reprimand/ Monetary Penalty	Monetary Penalty Reprimand Terms Shall not be Pharmacist in Charge Abstain from alcohol and controlled substances
Knowledge Based	No Sanction Terms Continuing Education – general Drug Diversion Awareness Program

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Sanctioning Reference Points - Coversheet for Board of Pharmacy

- Complete *Case Type Score* section on the Sanctioning Reference Point Worksheet.
- Complete the *Offense Factor* section on the Sanctioning Reference Point Worksheet.
- Complete the *Prior History* section on the Sanctioning Reference Point Worksheet.
- Determine the *Recommended Sanction* using the scoring results and the *Sanction Thresholds*.
- Complete this Coversheet.

Case Number(s)

Respondent Name _____
Last First Title

License Number _____

Case type Inability to Safely Practice
 Professional Practice Issues
 Prescription Error

Sanction Threshold Result Knowledge Based
 Reprimand/Monetary
 Monitoring/Treatment/Refer to Formal

Imposed Sanction Revocation
 Suspension
 Stayed Revocation - Immediate
 Stayed Suspension - Immediate
 Probation - duration in months _____
 Monetary Penalty - enter amount \$ _____
 Reprimand
 No Sanction
 Terms: _____

Reasons for Departure from Sanction Threshold Result _____

Worksheet Prepared by: _____ Date completed: _____

Confidential pursuant to §54.1-2400.2 of the Code of Virginia.

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Board of Pharmacy - Sanctioning Reference Points WORKSHEET INSTRUCTIONS

Case Type

(score only one, see list on page 5)

- A. Enter "50" if case involves an Inability to Safely Practice. These cases include:
- Incapacitation—mental/physical
 - Impairment—drugs/alcohol
 - Inability to Safely Practice—other
 - Drug Related—excessive dispensing
 - Drug Related—security
 - Drug Related—obtaining drugs by fraud
 - Drug Related – personal use
 - Drug Related – other
- B. Enter "35" if the case involves Professional Practice Issues. These cases include:
- Criminal Activity
 - Business Practice Issues
 - Fraud
 - Unlicensed Activity
 - Records/Inspections/Audits
 - Unprofessional Conduct
- C. Enter "10" if the case involves a Prescription Error. These cases include:
- Strength/Quantity
 - Directions/Expired Medications
 - Wrong Drug
 - Wrong Patient/Physician Name
 - Generic/Brand

Offense Factors Scoring

(score all that apply)

- B. Enter "70" in cases where an individual may have committed an act or is highly likely to commit an act that constitutes significant and substantial danger to the health and safety of any person (Priority A) or in cases where an individual may have committed a harmful act to another person but does not pose an imminent threat to public safety (Priority B).

B. Enter "50" if there was financial or other material gain from the offense.

C. Enter "50" if there was an act of commission. An act of "commission" is interpreted as purposeful, intentional, or clearly not accidental.

D. Enter "50" if the respondent was impaired at the time of the incident. Impairment can include drugs, alcohol, mental and/or physical.

E. Enter "10" if the patient was injured. Patient injury includes any injury reported by the consumer regardless of follow up treatment.

Prior History Scoring

(score all that apply)

- A. Enter "30" if the respondent has had any past difficulties or treatment in any of the following areas: drugs, alcohol, mental health and/or physical health. Difficulties in these areas must be relevant to the current case and treatment must have been provided by a bono fide health care practitioner.
- B. Enter "10" if the respondent has had one or more prior Board violations.
- C. Enter "10" if the respondent has had a prior violation similar to the current case. Cases are considered similar when they fall within the same category.

Inability to Safely Practice:

- Incapacitation – mental/physical
- Impairment – drugs/alcohol
- Inability to Safely Practice - other
- Drug Related - excessive dispensing
- Drug Related – security

- Drug Related - obtaining drugs by fraud
- Drug Related – personal use
- Drug Related – other

Professional Practice Issues

- Criminal Activity
- Business Practice Issues
- Fraud
- Unlicensed Activity
- Records/Inspections/Audits
- Unprofessional Conduct

Prescription Error

- Strength/Quantity
- Directions/Expired Medications
- Wrong Drug
- Wrong Patient/Physician Name
- Generic/Brand

Total Score

Sum all points on the worksheet and locate the sanction recommendation on the threshold table provided.

Scoring Outcome

The use of the Sanction Reference Points is voluntary. In addition, the worksheet sanction result may be combined with sanctions from lower sanction thresholds. For example, should a respondent fall within the "Reprimand/Monetary" area with a score of 40, the Board may choose a sanction package that includes a "Monetary Penalty" and a "Knowledge Based" sanction.

Board of Pharmacy - Sanctioning Reference Points WORKSHEET

Case Type (score only one)	Points	Score
Inability to safely practice	50	_____
Professional Practice Issues	35	_____
Prescription Error.....	10	_____

score
only
one

Offense Factors (score all that apply)

Priority A or B	70	_____
Financial/Material gain.....	50	_____
Act of commission	50	_____
Respondent impaired during incident	50	_____
Patient injured	10	_____

score
all
that
apply

Prior History (score all that apply)

Any past substance abuse or treatment	30	_____
One or more prior Board violations	10	_____
Any prior similar Board violations	10	_____

score
all
that
apply

Total Respondent Score

THRESHOLDS

Knowledge Based	0-30
Reprimand/Monetary	31-120
Monitoring/Treatment/Refer to Formal	121 or more

Respondent Name: _____

Date: _____

**REPORT OF THE VIRGINIA
DEPARTMENT OF HEALTH PROFESSIONS**

**Report on the Collection of
Data and Information about
Utilization of the Prescription
Monitoring Program pursuant
to SJR 73 and SJR 75 (2010)**

**TO THE GOVERNOR AND
THE GENERAL ASSEMBLY OF VIRGINIA**



SENATE DOCUMENT NO. 13

**COMMONWEALTH OF VIRGINIA
RICHMOND
2010**

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COMMONWEALTH of VIRGINIA

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October 15, 2010

MEMORANDUM

TO: The Honorable Robert F. McDonnell, Governor of Virginia
Members of the General Assembly

FROM: Dianne L. Reynolds-Cane, M.D., Director *DLC*
Department of Health Professions

RE: **Report on the Collection of Data and Information about utilization of the Prescription Monitoring Program pursuant to SJR73 and SJR75 (2010)**

Pursuant to Senate Joint Resolutions 73 and 75 (2010), the Department of Health Professions has collected data and information on the utilization of the Virginia Prescription Monitoring Program by prescribers and dispensers of controlled substances.

The resolution also requests specific and related data to be provided for each month of 2010 and the provision of any recommendations for changes to the Prescription Monitoring Program for the 2011 General Assembly.

We offer sincere thanks and gratitude to the individuals who serve on the Virginia Prescription Monitoring Program Advisory Panel, the staff of the Program and the Department, as well as other interested parties for their participation and assistance in reviewing data concerning the program and developing recommendations to improve the efficiency and efficacy of the program.

**VIRGINIA PRESCRIPTION MONITORING PROGRAM
ADVISORY PANEL**

Members

Dr. Kenneth Walker, Chairman

Randell Clouse, Medicaid Fraud Unit, Office of the Attorney General, Vice Chair

Carola Bruflat, Family Nurse Practitioner

Mellie Randall, Department of Behavioral Health and Developmental Services

First Sergeant Harvey Smith, Virginia State Police

Dr. Amy Tharp, Office of the Chief Medical Examiner

Holly Morris, Pharmacist

Dr. John Barsanti, Pain Management Specialist

Brenda Mitchell, Virginia Association for Hospices

Department Staff

Dianne Reynolds-Cane, M.D., Director, Department of Health Professions

Arne Owens, Chief Deputy Director

Howard Casway, Senior Assistant Attorney General

Ralph A. Orr, Program Director, Virginia Prescription Monitoring Program

Executive Summary

The Virginia Prescription Monitoring Program (VPMP) was created due to grave concerns related to a prescription drug abuse epidemic primarily located in Southwest Virginia. The program is primarily a tool to assist prescribers and dispensers in making more informed treatment and dispensing decisions. It is also designed to be a tool for authorized law enforcement and regulatory personnel to assist them in investigations related to prescription drug abuse and diversion.

The VPMP started operations in September 2003 as a fax-based system covering Schedule II prescriptions dispensed by pharmacies located in southwest Virginia. Information was available only to prescribers licensed in Virginia and to authorized agents of the State Police as well as limited access to Department of Health Professions personnel. In June 2006, the VPMP went statewide covering Schedule II-IV controlled substances prescriptions dispensed by resident and non-resident pharmacies as well as dispensing physicians. At this time, the program began using web-based software to facilitate the submission of requests and the provision of requests and access was expanded to all prescribers and to pharmacists with a current active license regardless of licensing state, as were other categories of users such as authorized personnel of the Office of the Chief Medical Examiner. This generated further growth of the program but did not meet the needs of those healthcare professionals who needed quick access to prescription information during evenings, nights and weekends.

On October 1, 2009 the VPMP turned on 24/7 access, automated response software in response to requests to make the program more accessible, timely, and efficient. The response to this improvement to the program has been astounding with the number of registered users doubling over the past year and the program processing more than 4 times the number of requests from January through September as were processed in all of 2009. Healthcare professionals comment frequently that the speed of response is amazing as approximately 95% of all requests are processed and sent back to the requestor within one minute. Emergency room providers and other healthcare professionals who did not register for the program previously are now using the program with almost one-third of all requests made during evening, nights, and weekend hours.

The VPMP recognizes that providing education about the program and the issues impacting prescription drug abuse and diversion is critical to making an impact on this public health and safety issue. The program has been very involved in co-sponsoring educational conferences such as one held at the University of Virginia in May 2010. Program staff frequently gives presentations at other educational events and have been exhibitors at various state healthcare professional association meetings. In February of 2010 a mass mailing to approximately 39,000 prescribers and pharmacists licensed in Virginia, providing information specific to the program and other resources, resulted in a surge in registrations and use of the program. The VPMP continues to support, in collaboration with the Virginia Commonwealth University School of Medicine, an online chronic pain management course that licensees of the Department of Health Professions may take at no cost and receive continuing education credit through their respective licensing board.

The VPMP is making several recommendations for the enhancement of the program. While some of the recommendations will ensure the program meets certain minimum eligibility requirements for federal grants, the greater overall impact of the recommendations will allow for more meaningful information being provided to users and ensure compatibility for interoperability with other state prescription monitoring programs.

RECOMMENDATIONS
Add tramadol and carisoprodol to Schedule IV in the Drug Control Act
Add authority to add additional drugs of concern as covered substances utilizing the regulatory process of the Virginia Board of Pharmacy
Expand access to include additional federal law enforcement to include authorized agents of FBI, FDA, and HHS with the requirement of having an open investigation. (Based on NASPER)
Expand access to include authority for medical reviewers for workman's compensation programs (Reviewer would be a prescriber)
Add authority to provide unsolicited reports to law enforcement and regulatory agencies.
Change reporting requirement to "within 7 days of dispensing"
Change reporting format to ASAP version 2007, provide mechanism for Director to change reporting format by providing timeframe to come into compliance.
Add requirement of notarized application for prescribers, dispensers, and delegates
Add requirement of notarized application for Law Enforcement and Regulatory personnel
Add method of payment to reporting requirements (Cash, Medicaid, other)
Require dispensers to report the DEA registration of the dispenser (Note: change from NCPDP#, cost savings for program, align with other state programs)
Require dispensers to report the number of refills ordered
Require dispensers to report whether the prescription was a new or refill
Require the dispenser to report the date the prescription was written
Require estimated number of days for which prescription should last (Days Supply)

Authority for the Prescription Monitoring Program

The law governing the Virginia Prescription Monitoring Program is found in Chapter 25.2 of Title 54.1 of the Code of Virginia. Regulations governing the program are found at 18 VAC 76-20-10 et seq.

Information requested by Senate Joint Resolutions 73 and 75

Senate Joint Resolutions 73 and 75 of the 2010 General Assembly requested certain information to be collected and reported to the 2011 General Assembly. The requested information was:

- (i) *The number of registered agents/users eligible to receive reports from the Prescription Monitoring Program*
- (ii) *The number of reports of dispensing of covered medications submitted to the Prescription Monitoring Program*
- (iii) *The number of exemptions from reporting requirements authorized.*
- (iv) *The number of requests for information from registered agents/users made and responded to*
- (v) *The number of notifications of substantial or unusual prescribing or dispensing activity or indications of potential misuse or abuse of covered substances sent to prescribers and dispensers, and the number and nature of responses to such notifications*
- (vi) *The number of responses to requests for information relevant to an investigation of a specific recipient, prescriber, or dispenser made, and the agency or entity to which such information was released*
- (vii) *The number of disciplinary proceedings initiated by a health regulatory board against a person required to report dispensing of a covered substance to the Prescription Monitoring Program for failure to report as required.*

Response to SJR 73 and 75

- (i) *The number of registered agents/users eligible to receive reports from the Prescription Monitoring Program*

The VPMP started operations in September 2003 as a fax-based system covering Schedule II prescriptions dispensed by pharmacies located in southwest Virginia. Information was available only to prescribers licensed in Virginia. In June 2006, the VPMP went statewide covering Schedule II-IV controlled substances prescriptions dispensed by resident and non-resident pharmacies as well as dispensing physicians. At this time the program began using web-based software to facilitate requests and the provision of requests and access was expanded to all prescribers and to pharmacists with a current active license regardless of licensing state.

At this time requests input via the VPMP WebCenter still required a staff member to manually select the patient information that matched the request and then process the request. Since these requests were only processed during normal business hours and users had to wait 30-

60 minutes for a report, many prescribers and pharmacists did not feel the program would be useful in their specific practices.

On October 1, 2009 the VPMP turned on 24/7 access, automated response software in response to requests to make the program more accessible, timely, and efficient. In February of 2010, VPMP mailed approximately 39,000 brochures describing the VPMP to all prescribers and pharmacists licensed in Virginia resulting in 959 new users being added in March. The response to the software upgrade and the accompanying marketing has been extremely positive. On October 1, 2009 there were 2,990 total registered users, at the end of September there are 7,906 with an average of 432 registered users added each month since October (Figure 1). There were 2,178 registered prescribers a year ago; at the end of September 2010 there were 6,231.

The VPMP is continually working to expand the usage of the program and does this by sponsoring conferences like the event co-sponsored by the University of Virginia Continuing Medical Education Office held in May of this year. Program staff has been exhibitors at annual meetings for the Virginia Council of Nurse Practitioners and the Virginia Pharmacists Association and have given presentations at conferences sponsored by the Appalachian College of Pharmacy held in Lebanon, Virginia in May and a conference sponsored by the Virginia Association of Medication Assisted Recovery Programs in September. Articles about the VPMP have appeared in the Board of Pharmacy Newsletter and Board of Medicine Board Brief. These activities are crucial to promoting the use of the program as well as educating healthcare professionals about the corresponding issues surrounding the legitimate medical use of controlled substances.

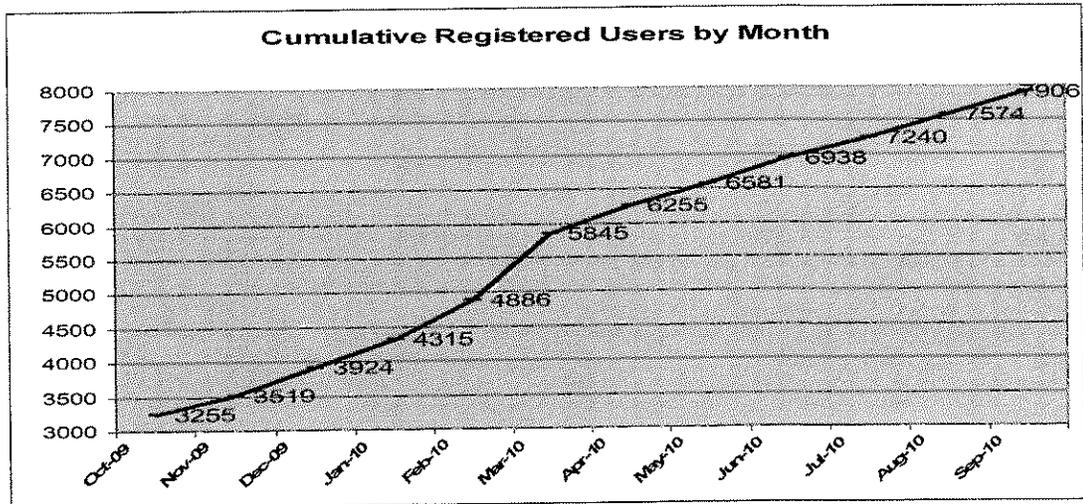


Figure 1.

(ii) *The number of reports of dispensing of covered medications submitted to the Prescription Monitoring Program.*

The VPMP requires pharmacies and physicians licensed to dispense controlled substances to report their records of dispensed medications twice monthly. All data from the 1st through the 15th of each month is due to VPMP by the 25th of the same month and all data from the 16th through the 31st of each month is due by the 10th of the following month.

The number of prescriptions reported to the VPMP each month has historically been, and continues to be, approximately one million records per month.

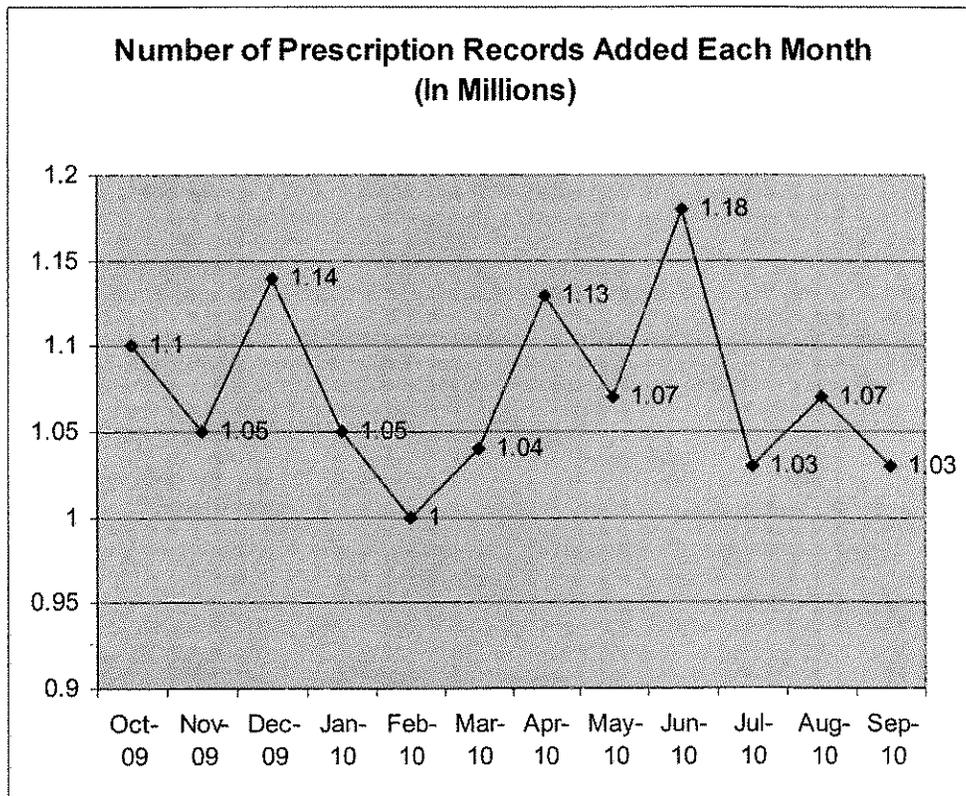


Figure 2.

Another way of looking at the dispensed prescription data is to determine the total number of individuals receiving (a) Class II, (b) Class II and/or III and (c) Class II, Class III and/or Class IV prescriptions in 6-month time blocks to look at trends over time (Figure 3). This data seems to demonstrate that the existence of VPMP does not prevent individuals from receiving controlled substances for legitimate medical purposes, nor does its existence appear to have a “chilling effect” on the prescribing habits of physicians treating those individuals. The increases may reflect population growth in Virginia over the past few years.

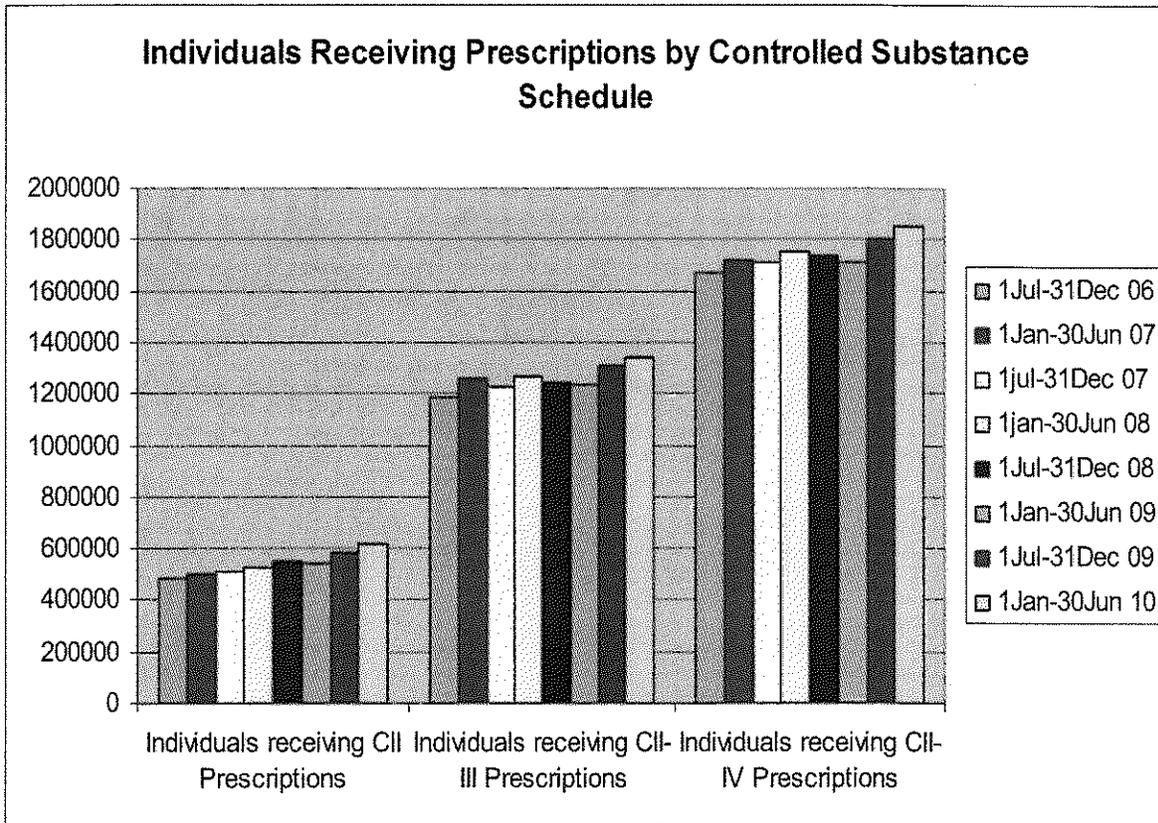


Figure 3.

(iii) The number of exemptions from reporting requirements authorized.

On a monthly basis, the VPMP exempts or waives a small number of pharmacies or physicians licensed (dispensers) to dispense controlled substances (Figure 4). Dispensers that are waived have attested that they dispense no Schedule II-IV prescriptions. Some physicians licensed to dispense controlled substances who are waived may be members of a large group practice whereby the entity submits the dispensed controlled substances to VPMP on their behalf.

Pharmacies that are exempt from reporting are exempt due to the fact that they fall into one of the categories listed in the Virginia Code. Exemptions include dispensing exclusively to inpatients in hospices, dispensing to inpatients in hospitals and nursing homes, and dispensing covered substances within an appropriately licensed narcotic maintenance treatment program, among others.

As of September 2010, there were 1707 resident pharmacies, 397 non-resident pharmacies and 343 physicians licensed to sell controlled substances licensed or permitted by the Board of Pharmacy. Currently, 140 of the resident pharmacies are waived or exempted from reporting (8.2%); 145 of the non-resident pharmacies are waived or exempted from reporting (36.5%); and 249 physicians licensed to sell controlled substances are waived.

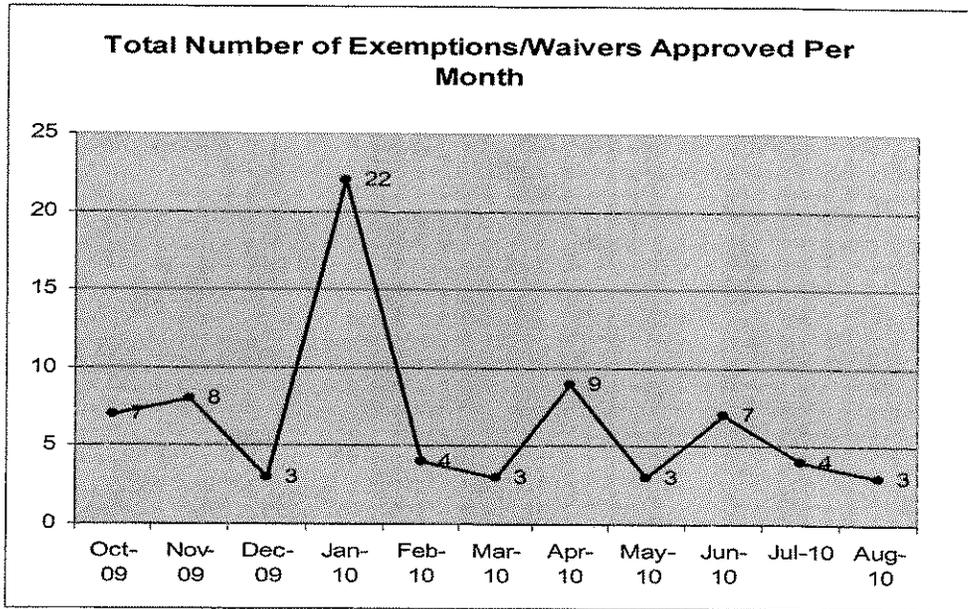


Figure 4. Note: The significant increase in January was due to several physicians receiving their license to sell and the employing entity stipulating that it would submit reports of dispensing on their behalf. These dispensers received a waiver from reporting their dispensing information on an individual basis.

(iv) The number of requests for information from registered users made and responded to

Patient profile requests from registered users have increased dramatically on a monthly basis since the introduction of 24/7 access--automated response software on October 1, 2009 (Figure 5). A dramatic surge of requests followed the distribution of VPMP brochures in February of 2010 to all prescribers and pharmacists licensed in Virginia. The VPMP processed 75,000 requests in 2009; over 300,000 requests have been processed through September 2010.

Prescribers submit the majority of requests for patient information, submitting 90.2% of all requests submitted in 2010. Pharmacists submitted 7.6% of the total volume while authorized medical examiners and the drug diversion agents of the Virginia State Police submitted slightly less than 1% of the total each. Combined, these four categories of users accounted for 99.5% of all requests submitted in 2010.

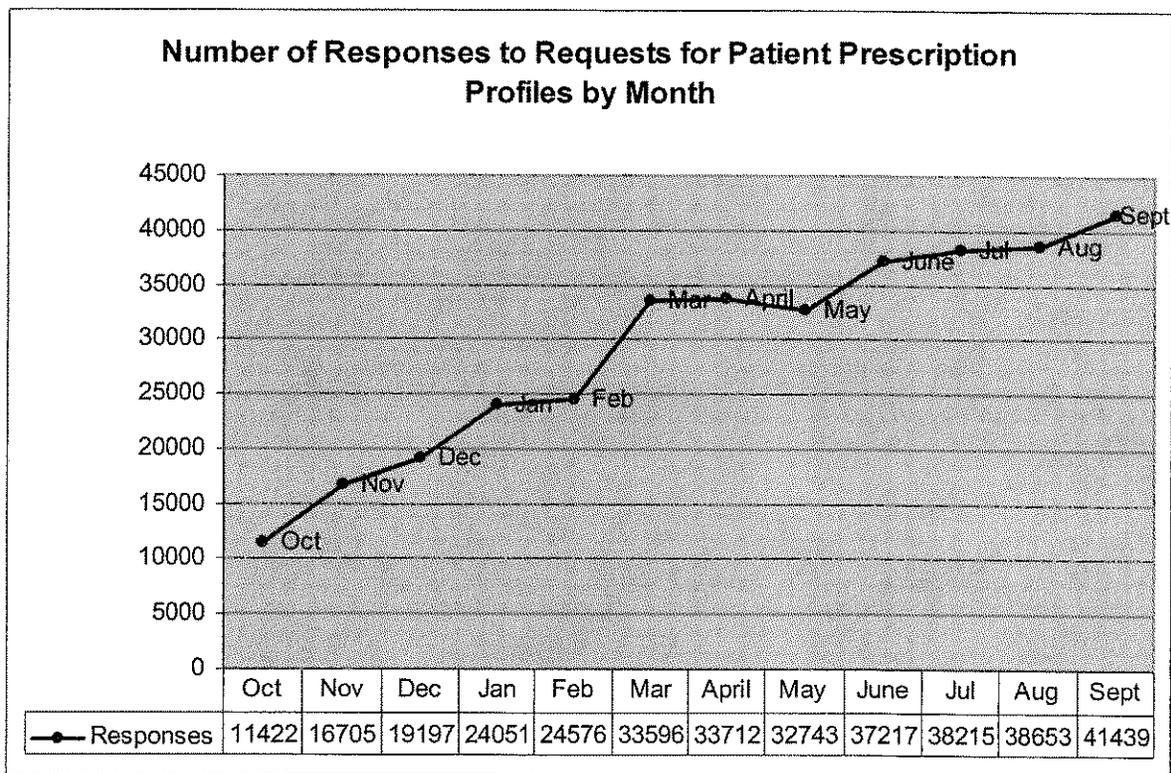


Figure 5.

- (v) *The number of notifications of indications of potential misuse [or abuse] of covered substances sent to prescribers and the number and nature of responses to such notifications*

Beginning in February of 2010, VPMP staff began evaluation of the 2010 prescription data for indicators of potential misuse, abuse or diversion. Queries were completed requesting the names of individuals who had received prescriptions from at least seven prescribers and dispensed from at least three pharmacies in a one month period. This search criterion is not intended to capture all incidents of possible abuse or diversion rather only the most egregious examples. Processing these reports is a very labor-intensive endeavor and must be done with great care to ensure patients are not incorrectly identified as meeting the criteria. After this careful review, the reports are then generated for each of those patients for the month in question and sent to each prescriber on the patient's report to alert the prescriber that he or she does not appear to be the only practitioner from whom the patient is seeking medical treatment or evaluation.

The types of responses from prescribers receiving the notification reports generally fall into 2 broad categories: the person listed in the report is not a patient of the prescriber or the patient is no longer a patient of the prescriber. VPMP does not generally receive a great number of comments and for this reason is developing a survey mechanism that will ask registered prescribers the following: 1. Did you receive the report? 2. If you received the report how did this impact your treatment? a. no change, b. discharged patient, c. counseled patient and made

referral for substance abuse treatment, d. counseled patient and made referral to pain management, e. other. 3. Did you report matter to law enforcement? This information will be used to further enhance the unsolicited report process.

Figure 6 shows the total number of patients identified in a specific month as a result of the VPMP's threshold search. During the first six months of 2010, an average of 83 patients met the designated thresholds of at least seven physicians consulted and at least three pharmacies dispensing their medications in a one month period. These individuals utilized on average per month; 7 (seven) pharmacies and 9 (nine) prescribers to obtain 12 (twelve) prescriptions.

It is not clear why there was a significant increase in the number of patients identified in March 2010. However, in looking back at previous years' data, it appears that there is a yearly spike in what appears to doctor shopping activity during this time period. Whether this is related to spring vacations or some other phenomenon is not clear.

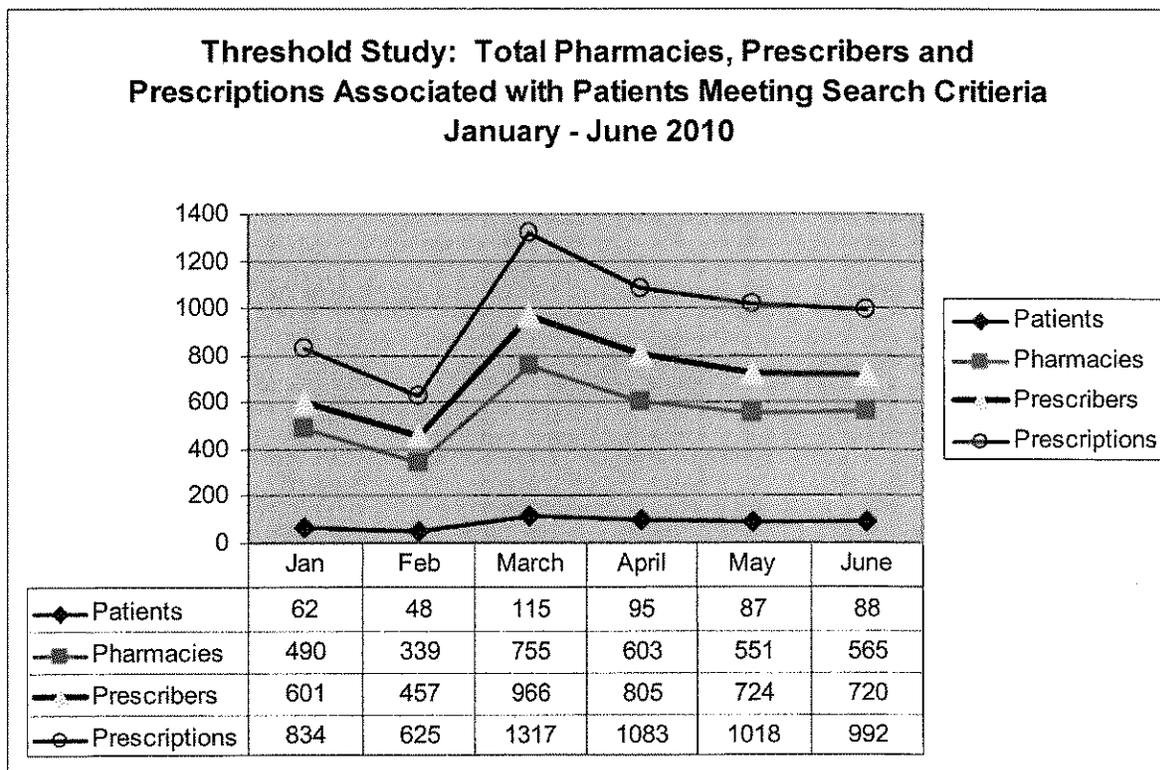


Figure 6.

The VPMP also tracked the distribution of patients by zip code to provide a further analysis of the notifications sent to prescribers (Figures 7 & 8). While the pilot project of the program was initiated in 2003 as a result of the epidemic of prescription drug abuse in Southwest Virginia (SW V); in the first half of 2010 only 7% of the 491 patients identified appeared to have a primary residence in that region which comprises approximately 20% of the population of the Commonwealth. This could be due to the proximity of several border states in this area which encourages cross border traffic.

The majority of patients identified (exactly 50% of the total) identified their primary residence as located in Northern Virginia (N VA) which comprises approximately 40% of the population. Central Southeast Virginia (C-SE VA) had 43% of patients identified during this time period.

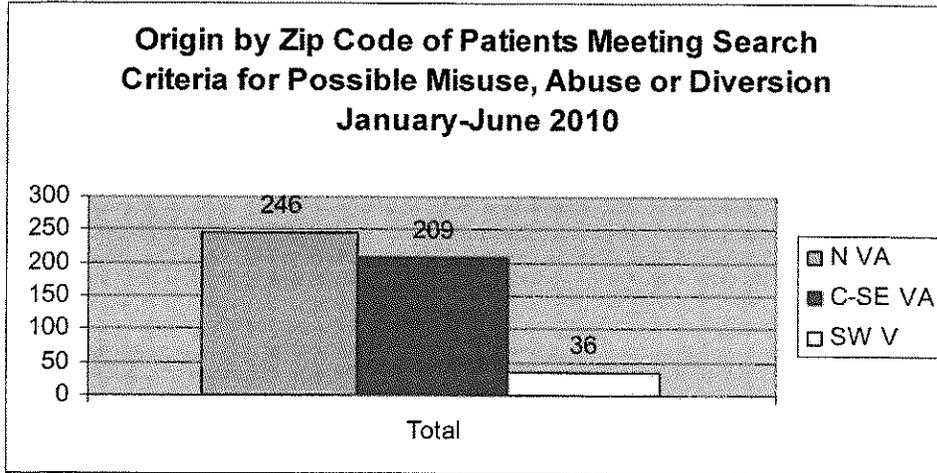


Figure 7.

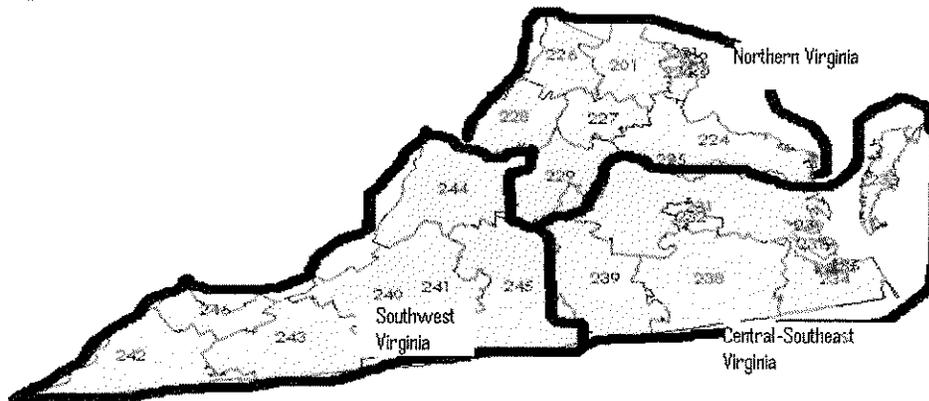


Figure 8.

The VPMP also looks at broader data to determine impact of the overall program on “doctor shopping” indicators. The following tables show the number of persons in the VPMP who have utilized pharmacies and prescribers in the following numbers: 5 & 5; 10 & 10; 15 & 15 during six-month periods dating back to the second half of 2006. This information is generated as part of the federal grant performance measures that are mandated for inclusion in grant progress reports.

Figure 9 represents persons utilizing five prescribers and five pharmacies during the most recent six month period. It is important to note that the utilization of five prescribers and five pharmacies in a six-month period is not necessarily an indication of prescription misuse, abuse or diversion, but may be a reflection of individuals either seeking care from several specialists or receiving care from different prescribers within the same practice.

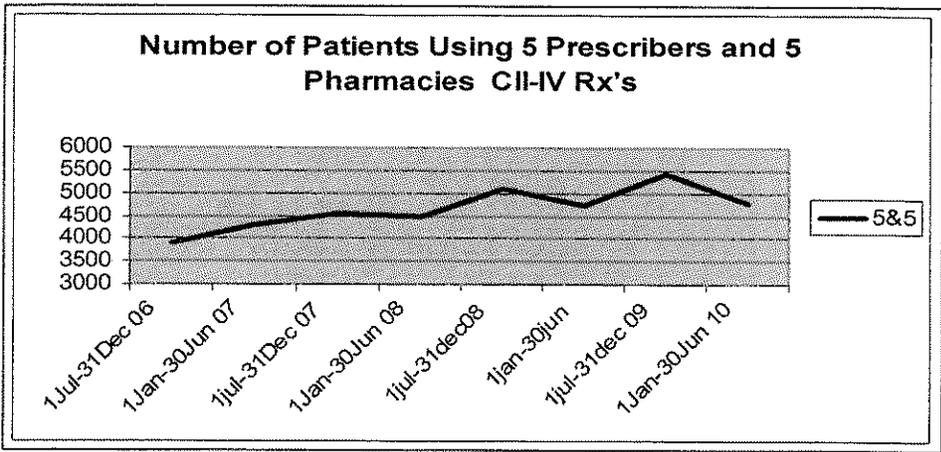


Figure 9.

Figure 10 demonstrates that 24/7 access to VPMP appears to have had a significant impact on those persons seeking care from greater numbers of prescribers and pharmacists. Utilization of prescribers and pharmacies at these levels is more likely to be an indicator of prescription drug misuse, abuse or diversion.

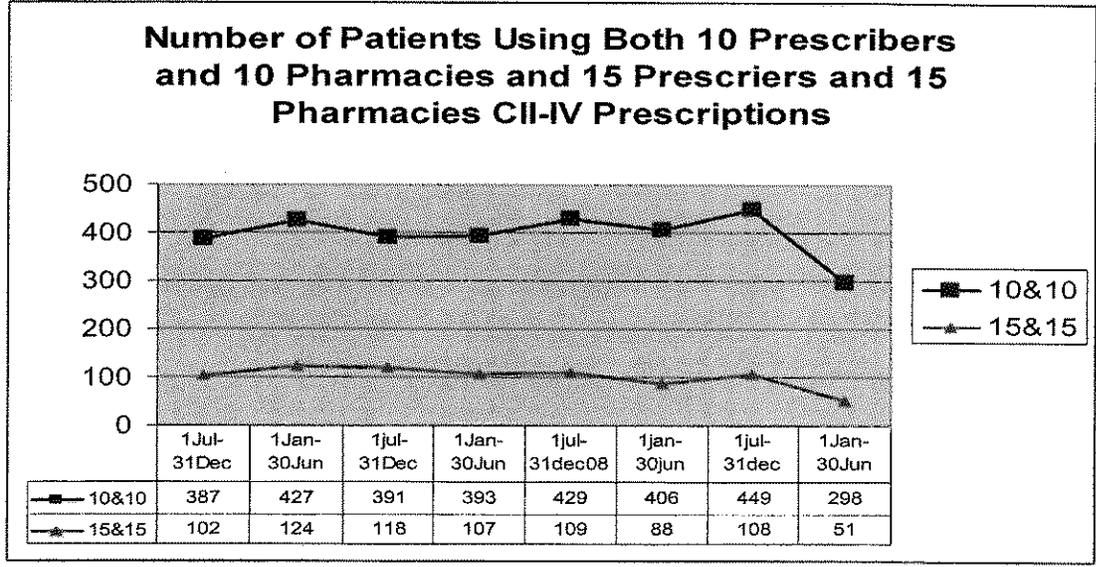


Figure10.

(vi) *The number of responses to requests for information relevant to an investigation of a specific recipient, prescriber, or dispenser made, and the agency or entity to which such information was released*

Registered users of the VPMP who utilize the program for purposes other than to make treatment decisions may only receive prescription data based on specific authority and the presence of an open investigation. The Department of Health Professions (DHP) investigates complaints on licensees related to abuse, diversion, and indiscriminate prescribing or dispensing.

Drug Diversion Agents of the Virginia State Police (VSP DDU) investigates complaints related to abuse, diversion, and indiscriminate prescribing or dispensing and Drug Enforcement Administration (DEA) investigate cases related to indiscriminate prescribing or dispensing. Medical Examiners (ME) request VPMP reports on deceased individuals according to protocol in order to assist them in specifying the types of drug screens to order and assist in making cause of death determinations. The Health Practitioners' Monitoring Program (HPMP) monitors for drug utilization compliance as specified in a Board Order. Details are found in Figure 11.

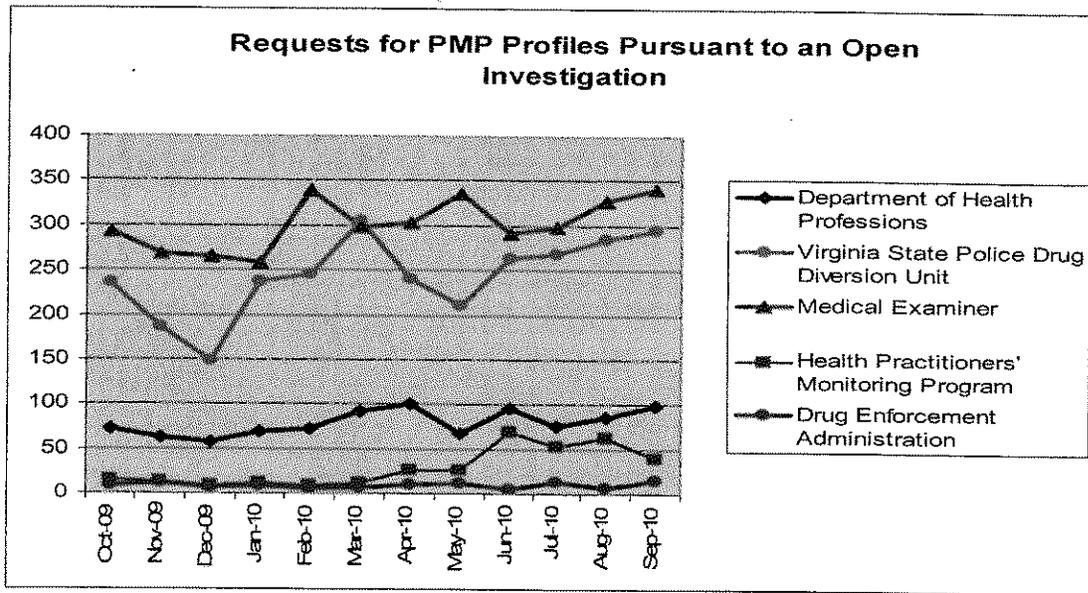


Figure 11.

- (vii) *The number of disciplinary proceedings initiated by a health regulatory board against a person required to report dispensing of a covered substance to the Prescription Monitoring Program for failure to report as required.*

Timely reporting of prescription data to the VPMP is crucial, especially when reporting is required just twice a month. Anecdotally, many other state programs have reported issues with obtaining compliance with reporting requirements. Federal grants providing funding to PMPs now require as part of required quarterly progress reports information on the number of dispensers delinquent in the reporting of prescription data.

VPMP utilizes a process whereby any dispenser delinquent in reporting data in a reporting period receives a letter with instructions and requesting that the data be reported immediately but not later than the deadline for the next reporting period. Letters of notification are sent to the specific dispensers not in compliance two days following the deadline reporting date for a report period, during which time a delinquent report is generated from the data collection site. The delinquent lists for each category of dispenser is checked daily for compliance and the compliance date is recorded when data is received.

Dispensers delinquent for two or more reporting periods receive a certified letter in addition to the notification letter that is sent by regular mail. A copy of the certified letter is

forwarded to the appropriate Board of Pharmacy licensing the dispenser. Consistent tracking and the sending of the regular and certified letters have been very successful in encouraging the timely reporting of controlled substance data to the VPMP.

The Board of Pharmacy has published a guidance document (110-06) which details under what circumstances and the specific actions the Board may take for failure to submit timely required reports to the program. The Board has not taken any disciplinary action to date on a dispenser being non-compliant with the reporting requirements of the VPMP.

Figure 12 indicates the total number of certified letters sent each month to pharmacies that have failed to report prescription data as required. Dispensers report software issues and non-availability of the person responsible for submitting reports as the main causes for being delinquent.

CERTIFIED LETTERS SENT	
October 2009	0
November 2009	3
December 2009	12
January 2009	22
February 2009	8
March 2009	17
April 2009	4
May 2009	1
June 2010	2
July 2010	6
August 2010	15
September 2010	16

Figure 12.

Recommendations for Enhancement of the Prescription Monitoring Program

The Director of the Virginia Department of Health Professions respectfully submits the following recommendations for enhancing the Virginia Prescription Monitoring Program (VPMP) with guidance from the Advisory Committee of the VPMP. The recommendations will enable the program to meet minimum eligibility requirements for the federal grant funding as well as provide more complete information to registered users of the program to assist them in making treatment and dispensing decisions. The recommendations also assist in aligning the program with other state programs to ensure compatibility enabling interoperability between state programs.

RECOMMENDATIONS
Add tramadol and carisoprodol to Schedule IV in the Drug Control Act
Add authority to add additional drugs of concern as covered substances utilizing the regulatory process of the Virginia Board of Pharmacy
Expand access to include additional federal law enforcement to include authorized agents of FBI, FDA, and HHS with the requirement of having an open investigation. (Based on NASPER)
Expand access to include authority for medical reviewers for workman's compensation programs (Reviewer would be a prescriber)
Add authority to provide unsolicited reports to law enforcement and regulatory agencies
Change reporting requirement to "within 7 days of dispensing"
Change reporting format to ASAP version 2007, provide mechanism for Director to change reporting format by providing timeframe to come into compliance
Add requirement of notarized application for prescribers, dispensers, and delegates
Add requirement of notarized application for Law Enforcement and Regulatory personnel
Add method of payment to reporting requirements (Cash, Medicaid, other)
Require dispensers to report the DEA registration of the dispenser (Note: change from NCPDP#, cost savings for program, align with other state programs)
Require dispensers to report the number of refills ordered
Require dispensers to report whether the prescription was a new or refill
Require the dispenser to report the date the prescription was written
Require estimated number of days for which prescription should last (Days Supply)

SENATE JOINT RESOLUTION NO. 73

Continuing the Joint Subcommittee to Study Strategies and Models for Substance Abuse Prevention and Treatment. Report.

Agreed to by the Senate, March 10, 2010
Agreed to by the House of Delegates, March 9, 2010

WHEREAS, Senate Joint Resolution No. 77 (2008) established the Joint Subcommittee to Study Strategies and Models for Substance Abuse Prevention and Treatment; and

WHEREAS, Senate Joint Resolution No. 318 (2009) last continued the study for one year to continue to identify and characterize the nature of substance abuse in the Commonwealth; identify current state policies and programs targeting substance abuse prevention and treatment; examine the cost of such policies and programs to the Commonwealth; identify and examine policies and prevention programs from other leading states in the field of substance abuse and prevention; and benchmark the Commonwealth's substance abuse prevention and treatment programs and policies against those of the leading states; and

WHEREAS, a number of meetings with stakeholders were held throughout the state, the work groups established pursuant to Senate Joint Resolution No. 318 to assist the joint subcommittee each met three times, and the full joint subcommittee met four times during the 2009 interim to collect information and carry out its work; and

WHEREAS, substance abuse treatment insurance parity requirements increase access to medically necessary services for insured persons in need of substance abuse treatment services and may reduce the cost of substance abuse and substance abuse treatment services to the Commonwealth; and

WHEREAS, the Bureau of Insurance of the State Corporation Commission is the state agency charged with ensuring that citizens of the Commonwealth are provided with access to adequate and reliable insurance protection and that insurance companies conduct their business according to statutory and regulatory requirements and acceptable standards of conduct; and

WHEREAS, the Office of the Chief Medical Examiner reports that between 2003 and 2007, the last year for which data is currently available, the number of drug-caused deaths in the Commonwealth rose from 564 deaths in 2003 to 717 deaths, or 8.9 deaths per 100,000 people, in 2007, with a substantial majority of such deaths linked to the use or abuse of prescription medications; and

WHEREAS, the Department of Health Professions' Prescription Monitoring Program provides a valuable tool that prescribers and dispensers of prescription medications can use to identify individuals who may be misusing or abusing prescription drugs, reduce rates of prescription drug misuse and abuse, and protect the health and safety of Virginians; and

WHEREAS, the work groups recommended and the full Joint Subcommittee to Study Strategies and Models for Substance Abuse Prevention and Treatment concurred that the joint subcommittee be continued for one more year to continue to process and evaluate the information received by the work groups and strategies and models identified during the 2009 interim and to develop a more comprehensive list of recommendations for treating and preventing substance abuse and reducing the costs of substance abuse in the Commonwealth; now, therefore, be it

RESOLVED by the Senate, the House of Delegates concurring, That the Joint Subcommittee to Study Strategies and Models for Substance Abuse Prevention and Treatment be continued. The joint subcommittee shall have a total membership of 11 members that shall consist of two members of the Senate appointed by the Senate Committee on Rules; three members of the House of Delegates appointed by the Speaker of the House of Delegates in accordance with the principles of proportional representation contained in the Rules of the House of Delegates; one nonlegislative citizen member representing a private or nonprofit organization dedicated to substance abuse prevention or treatment programs to be appointed by the Senate Committee on Rules; two nonlegislative citizen members representing private or nonprofit organizations dedicated to substance abuse prevention or treatment to be appointed by the Speaker of the House of Delegates; and the Commissioner of Social Services, the Commissioner of the Department of Behavioral Health and Developmental Services, and the Director of the Department of Corrections or their designees to serve ex officio with nonvoting privileges. Nonlegislative citizen members of the joint subcommittee shall be citizens of the Commonwealth of Virginia. The current members appointed by the Senate Committee on Rules shall continue to serve until replaced. The current members appointed by the Speaker of the House of Delegates shall be subject to reappointment. Vacancies shall be filled by the original appointing authority. Unless otherwise approved in writing by the chairman of the joint subcommittee and the respective Clerk, nonlegislative citizen members shall only be reimbursed for travel originating and ending within the Commonwealth of

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Virginia for the purpose of attending meetings. If a companion joint resolution of the other chamber is agreed to, written authorization of both Clerks shall be required. The joint subcommittee shall elect a chairman and vice-chairman from among its membership, who shall be members of the General Assembly.

In conducting its study, the joint subcommittee shall continue to process information received and models and strategies identified by the joint subcommittee during the 2009 interim, in order to (i) identify and characterize the nature of substance abuse in the Commonwealth; (ii) identify current state policies and programs targeting substance abuse prevention and treatment; (iii) examine the cost of such policies and programs to the Commonwealth; (iv) identify and examine policies and prevention programs from other leading states in the field of substance abuse and prevention; and (v) compare the Commonwealth's substance abuse prevention and treatment programs and policies with those of the leading states. The joint subcommittee shall also continue the work groups established during the 2009 interim to explore issues related to substance abuse treatment, substance abuse prevention, and special issues related to the abuse of prescription medication.

In addition, as a part of the joint subcommittee's study, the Bureau of Insurance of the State Corporation Commission shall collect data on and information about the coverage provided by health insurers, health services plans, and health maintenance organizations for substance abuse treatment services. The Bureau of Insurance shall collect such data and information as specified in the Senate Amendment in the Nature of a Substitute for Senate Joint Resolution No. 74 (2010).

To further assist the joint subcommittee in its work, the Department of Health Professions shall collect data on and information about utilization of the Prescription Monitoring Program by prescribers and dispensers of controlled substances and responses to notifications sent by the Department to prescribers. The Department of Health Professions shall collect such data and information as specified in Senate Joint Resolution No. 75 (2010), as amended by the Senate.

Administrative staff support shall continue to be provided by the Office of the Clerk of the Senate. Legal, research, policy analysis, and other services as requested by the joint subcommittee shall continue to be provided by the Division of Legislative Services. All agencies of the Commonwealth shall provide assistance to the joint subcommittee for this study, upon request.

The joint subcommittee shall be limited to four meetings for the 2010 interim, and the direct costs of this study shall not exceed \$6,200 without approval as set out in this resolution. Approval for unbudgeted nonmember-related expenses shall require the written authorization of the chairman of the joint subcommittee and the respective Clerk. If a companion joint resolution of the other chamber is agreed to, written authorization of both Clerks shall be required.

No recommendation of the joint subcommittee shall be adopted if a majority of the Senate members or a majority of the House members appointed to the joint subcommittee (i) vote against the recommendation and (ii) vote for the recommendation to fail notwithstanding the majority vote of the joint subcommittee.

The Bureau of Insurance of the State Corporation Commission and the Department of Health Professions shall submit such data and information as requested to be collected, respectively, to the Joint Subcommittee to Study Strategies and Models for Substance Abuse Prevention and Treatment, which shall include the findings of each agency in its report to the Governor and 2011 Regular Session of the General Assembly.

The joint subcommittee shall complete its meetings by November 30, 2010, and the chairman shall submit to the Division of Legislative Automated Systems an executive summary of its findings and recommendations no later than the first day of the 2011 Regular Session of the General Assembly. The executive summary shall state whether the joint subcommittee intends to submit to the General Assembly and the Governor a report of its findings and recommendations for publication as a House or Senate document. The executive summary and report shall be submitted as provided in the procedures of the Division of Legislative Automated Systems for the processing of legislative documents and reports and shall be posted on the General Assembly's website.

Implementation of this resolution is subject to subsequent approval and certification by the Joint Rules Committee. The Committee may approve or disapprove expenditures for this study, extend or delay the period for the conduct of the study, or authorize additional meetings during the 2010 interim.

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SENATE JOINT RESOLUTION NO. 75

Senate Amendments in [] — February 16, 2010

Requesting the Department of Health Professions to collect data and information about utilization of the Prescription Monitoring Program by prescribers and dispensers of controlled substances and responses to notifications sent by the Department to prescribers and dispensers. Report.

Patron Prior to Engrossment—Senator Hanger

Referred to Committee on Rules

WHEREAS, prescription medications such as pain relievers, tranquilizers, stimulants, and sedatives have substantial benefits when used appropriately but can result in serious negative consequences to the individual and society when used in an inappropriate or illegal manner; and

WHEREAS, while most people use prescription medications lawfully and as directed by the prescriber, a growing number of persons are engaging in the inappropriate, illegal, nonmedical use and abuse of prescription medications; and

WHEREAS, the Office of the Chief Medical Examiner reports that between 2003 and 2007, the last year for which data is currently available, the number of drug-caused deaths in the Commonwealth rose from 564 deaths in 2003 to 717 deaths, or 8.9 deaths per 100,000 people, in 2007, with a substantial majority of such deaths linked to the use or abuse of prescription medications; and

WHEREAS, the Department of Health Profession's Prescription Monitoring Program provides a valuable tool that prescribers and dispensers of prescription medications can use to identify individuals who may be misusing or abusing prescription drugs, reduce rates of prescription drug misuse and abuse, and protect the health and safety of Virginians; now, therefore, be it

RESOLVED by the Senate, the House of Delegates concurring, That the Department of Health Professions be requested to collect data on and information about utilization of the Prescription Monitoring Program by prescribers and dispensers of controlled substances and responses to notifications sent by the Department to prescribers [and dispensers] .

Data and information about use of the Prescription Monitoring Program and responses to notifications collected and reported by the Department of Health Professions shall include, for each month of 2010: (i) the number of registered [agents users] eligible to receive reports from the Prescription Monitoring Program; (ii) the number of reports of dispensing of covered medications submitted to the Prescription Monitoring Program; (iii) the number of exemptions from reporting requirements authorized; (iv) the number of requests for information from registered [agents users] made and responded to; (v) the number of notifications of [substantial or unusual prescribing or dispensing activity or] indications of potential misuse [or abuse] of covered substances sent to prescribers [and dispensers,] and the number and nature of responses to such notifications; (vi) the number of responses to requests for information relevant to an investigation of a specific recipient, prescriber, or dispenser made, and the agency or entity to which such information was released; and (vii) the number of disciplinary proceedings initiated by a health regulatory board against a person required to report dispensing of a covered substance to the Prescription Monitoring Program for failure to report as required. The Department shall also include any recommendations for changes to the Prescription Monitoring Program and any other information relevant to the use of the Prescription Monitoring Program as the Department shall deem appropriate.

All agencies of the Commonwealth shall provide assistance to the Department of Health Professions in collecting the information, upon request.

The Department of Health Professions shall submit to the Division of Legislative Automated Systems an executive summary and a report of the data on and information about utilization of the Prescription Monitoring Program by prescribers and dispensers of controlled substances and responses to notifications sent by the Department to prescribers and dispensers no later than the first day of the 2011 Regular Session of the General Assembly. The executive summary and report of data and information shall be submitted for publication as a report document as provided in the procedures of the Division of Legislative Automated Systems for the processing of legislative documents and reports and shall be posted on the General Assembly's website.

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