



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 Public Hearing and Full Board Meeting

March 25, 2016

9:00AM

TOPIC

PAGES

Call to Order of Public Hearing for Scheduling Certain Substances: Cynthia Warriner, Chairman

- Welcome & Introductions
- Reading of Emergency Evacuation Script

Call for Public Comment:

- Possible scheduling of the following substances:
 - N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-butanamide (Other name: butyryl fentanyl)
 - Flubromazolam
 - 5-methoxy-N,N-methylisopropyltryptamine (Other name: 5-MeO-MIPT)
 - N-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-[(4-fluorophenyl)methyl]-1H-indazole-3-carboxamide (Other name: ADB-FUBINACA)
 - Methyl 2-[1-[(4-fluorophenyl)methyl]-1H-indazole-3-carboxamido]-3,3-dimethylbutanoate (Other name: MDMB-FUBINACA)
 - Methyl 2-[1-(5-fluoropentyl)-1H-indazole-3-carboxamido]-3,3-dimethylbutanoate (Other names: 5-fluoro-ADB, 5-Fluoro-MDMB-PINACA)

Adjournment of Public Hearing

Call to Order of Full Board Meeting: Cynthia Warriner, Chairman

- Approval of Agenda
- Approval of Previous Board Meeting Minutes:
 - November 23, 2015, Special Conference Committee 1-2
 - December 1, 2015, Full Board Meeting 3-10
 - December 1, 2015, Public Hearing for Hours of Continuous Work by Pharmacists 11-12
 - December 15, 2015, Special Conference Committee 13-14
 - December 29, 2015, Pilot Informal Conference Committee 15-19
 - January 5, 2016, Regulation Committee 20-25

Call for Public Comment: The Board will receive public comment at this time. The Board will not receive comment on any regulation process for which a public comment period has closed or any pending disciplinary matters.

DHP Director's Report: David Brown, DC

- Report on Pharmacy Benefit Manager Workgroup 26-35

Regulatory Actions:

- Legislative Update - Elaine Yeatts 36-41
- Regulatory Update - Elaine Yeatts 42

- Report from Regulation Committee – Ellen Shinaberry/Elaine Yeatts
 - Committee Recommendation regarding Adoption of NOIRA for Periodic Review of *Regulations Governing the Practice of Pharmacy*, chapter 20, and *Regulations Governing Wholesale Distributors, Manufacturers, and Warehousemen*, chapter 50 42A-48
- Consideration of Any Scheduling Action from Public Hearing - Elaine Yeatts 49-53
- Petitions for Rulemaking: Elaine Yeatts 54
 - Allow long term care facility to provide prescription information for Schedule VI drugs to a “back-up” pharmacy located near the facility 55-61
 - Allow pharmacists in hospitals or free-standing emergency departments to adjust or order medications according to clinically accepted guidelines 62-67
 - Allow bar code and RFID scanning to extend the pharmacist check, once bar code or RFID scan has been verified 68-79
- Adoption of Proposed Regulations to Replace Emergency Regulations for Permitted Facilities used by Practitioners of the Healing Arts to Sell Controlled Substances - Elaine Yeatts 80-90
- Adoption of Proposed Regulations to Replace Emergency Regulations for Outsourcing Facilities- Elaine Yeatts 91-106
- Adoption of Proposed Regulations for a Prohibition on Incentives to Transfer Prescriptions- Elaine Yeatts 107-116
- Adoption of Final Regulations on Setting Certain Conditions on Work Hours for Pharmacists- Elaine Yeatts 117-126
- Adoption of Fast-Track Amendment for 18VAC110-20-540, Emergency Drug Kit 127A-C
- Possible Topics for 2017 Legislative Proposals- Elaine Yeatts/Caroline Juran

Old Business:

- Guidance for Whether Nurses May Prepare Methadone Take-home Bottles - Jim Rutkowski 6, 127-129

New Business: Caroline D. Juran

- Amend Healthcare Workforce Pharmacist Survey – Elizabeth Carter, Ph.D., Director, HWDC 130-146
- Amend *Protocol for the Prescribing and Dispensing of Naloxone* 147-149
- Consideration for “white bagging, brown bagging” and “specialty drugs” 31,35
- Amend Guidance Document 110-9 Pharmacy Inspection Deficiency Monetary Penalty Guide 150-162
- Amend Guidance Document 110-29 *Physicians Dispensing Drugs* 163-169

Reports:

- Chairman’s Report – Cynthia Warriner
- Report on Board of Health Professions – Ryan Logan
- Report on Licensure Program – J. Samuel Johnson, Jr.
- Report on Disciplinary Program – Cathy M. Reiniers-Day Handout
- Executive Director’s Report –Caroline D. Juran Handout

Consideration of consent orders & possible summary restrictions/suspensions, if any**Adjourn**

****The Board will have a working lunch at approximately 12pm and recognize former board members Dinny Li and Empsy Munden. ****

VIRGINIA BOARD OF PHARMACY
SPECIAL CONFERENCE COMMITTEE MINUTES *(Draft/Unapproved)*

Monday, November 23, 2015
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 ("Board") was called to order at 9:30 a.m.

PRESIDING: Jody Allen, Committee Chair

MEMBERS PRESENT: Melvin Boone, Sr., Committee Member

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

SAMANTHA WARREN
Registration No. 0230-015146

Samantha Warren did not appear to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the September 18, 2015 Notice. The Chair of the Committee chose to proceed with the informal conference as the Notice had been sent to Ms. Warren's legal address of record.

Closed Meeting: Upon a motion by Mr. Boone, and duly seconded by Ms. Allen, 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 Samantha Warren. Additionally, he moved that Cathy Reiniers-Day, Mykl Egan, and Loni Dickerson 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. Boone, and duly seconded by Ms. Allen, the Committee made certain Findings of Fact and Conclusions of Law and unanimously voted to offer an Order for the suspension of Ms. Warren's pharmacy technician registration.

KWATU TUFFOUR
Registration No: 0230-017150

Kwatu Tuffour did not appear to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the October 19, 2015 Notice. The Chair of the Committee chose to proceed with the informal conference as the Notice had been sent to Mr. Tuffour's legal address of record.

Closed Meeting:

Upon a motion by Mr. Boone, and duly seconded by Ms. Allen, 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 Kwatu Tuffour. Additionally, he moved that Cathy Reiniers-Day, Mykl Egan, and Loni Dickerson 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. Boone, and duly seconded by Ms. Allen, the Committee made certain Findings of Fact and Conclusions of Law and unanimously voted to offer an Order for the suspension of Mr. Tuffour's pharmacy technician registration.

Adjourn:

With all business concluded, the meeting adjourned at 1:25 p.m.

Jody H. Allen, Chair

Cathy M. Reiniers-Day
Deputy Executive Director

Date

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DRAFT/UNAPPROVED

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

December 1, 2015
Second Floor
Board Room 2

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

- CALL TO ORDER:** The meeting was called to order at 9:15 a.m.
- PRESIDING:** Cynthia Warriner, Chairman
- MEMBERS PRESENT:** Melvin L. Boone, Sr. (arrived 9:18 a.m.)
Michael I. Elliott
Freeda Cathcart
Ryan K. Logan
Rafael Saenz
Rebecca Thornbury
Ellen B. Shinaberry
Jody H. Allen
Sheila K. W. Elliott (arrived 9:18 a.m.)
- STAFF PRESENT:** Caroline D. Juran, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
Lisa Hahn, Chief Deputy Director, DHP
James Rutkowski, Assistant Attorney General
Elaine J. Yeatts, Senior Policy Analyst, DHP
Beth O'Halloran, Individual Licensing Manager
Sharon Davenport, Administrative Assistant
- STAFF ABSENT:** J. Samuel Johnson, Jr., Deputy Executive Director
- QUORUM:** With eight members present initially, a quorum was established.
- APPROVAL OF AGENDA:** An amended agenda was provided as a handout for the members, staff, and the public. The following two topics were included on the amended agenda: under Old Business, a request from VPhA to amend guidance document 110-36 *Compliance with USP Standards for Compounding* and under new Business, consideration for mandatory continuing education for pharmacists on a specific topic in 2016.
- MOTION:** **The Board voted unanimously to approve the amended agenda as presented in the handout. (motion by Shinaberry, second by Saenz)**
- APPROVAL OF MINUTES:** The Board reviewed draft minutes in the agenda packet for:
- September 29, 2015, Public Hearing for Scheduling Certain Chemicals
 - September 29, 2015, Full Board Meeting

- September 29, 2015, Panel Formal Hearings
- September 30, 2015, Inspection Special Conference Committee
- November 3, 2015, Regulation Committee

MOTION: **The Board voted unanimously to approve the minutes as presented for the meetings held between September 29, 2015 and November 3, 2015. (motion by Allen, second by Logan)**

PUBLIC COMMENTS: No comment was provided to the Board.

DHP DIRECTOR'S REPORT: Cynthia Warriner introduced the newly-appointed Chief Deputy Director of DHP, Lisa Hahn, who provided the Director's report in place of David Brown, D.C who was attending another meeting outside of the office. Ms. Hahn provided comment that the new board member training as well as board member development day went very well. Ms. Hahn elaborated on the additional training that DHP has been providing staff regarding employee hiring, employee work performance reviews, and supervisor training. Ms. Hahn also spoke of the Healthcare Workforce Data Center and the surveys conducted mainly during renewal of licensure and how they will be used in an aggregate manner in the near future to educate high school students about careers in healthcare.

REPORT ON APPALACHIAN COLLEGE OF PHARMACY: Susan Mayhew, Dean of Appalachian College of Pharmacy provided a report via Polycom to the board on recent school activities. A handout summarizing her report was also provided to the members, staff, and public. The College has graduated over 500 students who are practicing throughout the United States. Dean Mayhew indicated that between 40-50% of the graduates remain in the Appalachian region. In 2014 the College had Virginia's highest pass rate on the NAPLEX examination. The College has Virginia's only three-year accelerated Doctor of Pharmacy program.

The College recently opened its Mountain Care Center delivering pharmaceutical care to the indigent in the region. The College has begun a global health elective, started a community residency program as well as a post doctorate program. The school also just completed a re-accreditation through ACPE and has an upcoming accreditation visit from the Southern Association of Colleges of Pharmacy.

REPORT ON HAMPTON UNIVERSITY COLLEGE OF PHARMACY: Wayne Harris, Dean, and Anand Iyer, Assistant Dean of Academic and Student Affairs from Hampton University College of Pharmacy appeared in-person and provided a report to the board on recent school activities. Dean Harris reported that the College admitted its first class in 1998 and has graduated over 600 PharmD candidates. Current enrollment is approximately 250 students with possible growth in the future. The site visit for ACPE in November 2014 went well and the accreditation was continued for a time period of eight years. The school has an ongoing curriculum review to build for the future and includes establishing the Hampton University center of excellence which will focus on providing medication therapy management to medically underserved clinics.

Four faculty members at The College currently have research grants through the National Institutes of Health (NIH). He reported there is an interest in increasing the school's involvement in research. Dean Harris is currently a co-director of a minority men's health initiative, funded NIH to address minority health disparities.

REGULATORY ACTIONS:

- REGULATORY UPDATE:

Ms. Yeatts provided a chart of regulatory actions as a handout. Emergency regulations for outsourcing facilities and Practitioner of the Healing Arts are currently at the Governor's office. There are two actions that are at the Department of Budget and Planning and those are the collection sites for disposal of unused drugs and the repackaging at PACE sites. In addition there are two actions that are in a public comment period, one of which the public hearing was held just prior to this Board meeting. Those public comment period for the prohibition against incentives to transfer prescriptions ends 12/16/15 and the comment period for addressing hours of continuous work by pharmacists ends 1/29/16.

- REGULATION COMMITTEE REPORT ON ISSUANCE OF CSR TO MEDICAL OFFICE BUILDING:

Ms. Shinaberry reported that the Regulation Committee determined at its November 3, 2015 meeting to recommend that the board not issue one controlled substances registration certificate (CSR) to authorize multiple medical clinics located in the same medical office building with shared ownership to stock drugs in multiple locations throughout the building. Based on concerns for oversight, it recommended that board staff continue to issue CSRs to individual clinics that maintain their own stock of drugs for their own use. Mr. Saenz recused himself from the discussion and voting since the request for a single CSR came from his employer.

VOTE

The Board voted unanimously to accept the recommendation of the Regulation Committee and not authorize staff to issue one controlled substances registration certificate (CSR) to authorize multiple medical clinics located in the same medical office building with shared ownership to stock drugs in multiple locations throughout the building. (Saenz recused)

- REQUEST FOR RULEMAKING TO ALLOW "BACK-UP" PHARMACY TO DISPENSE FIRST FILL OF PRESCRIPTION WITHOUT NECESSITATING TRANSFER OF PRESCRIPTION:

Ms. Yeatts advised that this request should be treated as a petition for rulemaking which requires a publication of the request and a 21-day public comment period prior to the Board considering the matter. Therefore, this matter will be deferred to a later date.

OLD BUSINESS:

- **REQUEST FROM VPHA TO AMEND GUIDANCE DOCUMENT 110-36:**

Ms. Juran provided a handout on the issue and reminded the board members that this issue was discussed at the September board meeting and staff was tasked with researching the issue further. Ms. Juran contacted USP experts who confirmed that USP allows for alternative methods of sterility testing. Since Virginia law allows compliance with USP, alternative methods of sterility testing are allowable. Ms. Shinaberry pointed out that the first two sentences in the draft answer to #39 in the guidance document may need to be adjusted in the future based on proposed revisions to USP <797>. Ms. Allen agreed and pointed out that proposed revisions may take up to two years or longer to be adopted by USP.

MOTION:

The Board voted unanimously to amend Guidance Document 110-36 as presented in the handout which provides guidance in a new question #39 regarding the use of a microbiological method alternative to compendial methods used. (motion by Cathcart, second by S. Elliott)

NEW BUSINESS:

- **NEED GUIDANCE FOR NURSES PUMPING METHADONE TAKE HOME BOTTLES:**

Ms. Juran referenced the request from a narcotic treatment program (NTP) in the agenda packet. The NTP would like to know if nurses can pump, i.e., prepare methadone take home bottles for patients under pharmacist supervision. Board counsel advised he would need to research the statute regarding duties of a pharmacy technician and if these duties could be performed by a nurse in a NTP under pharmacist supervision.

ACTION ITEM:

The Board recommended that the matter regarding a need for guidance for nurses pumping methadone take home bottles be deferred to the March board meeting to allow counsel time for researching the issue.

- **REQUEST TO AMEND GUIDANCE DOCUMENT 110-8, PRESCRIPTIVE AUTHORITY IN VIRGINIA:**

Ms. Yeatts stated that there are two changes to this document on prescriptive authority. The first change is that optometrists may now prescribe hydrocodone in combination with acetaminophen products which are now Schedule II and a regulatory change for physician assistants regarding the co-signature of prescriptions in certain schedules. Since the change for optometrists is a legislative change that has already been passed and the second change for PA's prescribing rules is a regulatory change that is likely to be effective on January 15, 2016, Ms. Yeatts suggested that the Board either have two separate motions or one motion with two parts. The Board agreed to have two separate motions as this would be clearer in the event the regulatory change did not occur on January 15, 2016.

MOTION:

The Board voted unanimously to amend Guidance Document 110-8 as presented to reflect the legislative change in 2015 that permits optometrists to prescribe hydrocodone in combination with

acetaminophen products. (motion by S. Elliott, second by Cathcart)

MOTION:

Contingent upon the Board of Medicine regulatory amendment becoming final January 15, 2016, the Board voted unanimously to amend Guidance Document 110-8 as presented which would advise that the name of the supervising physician be included on a Schedule II-V prescription written by a physician assistant. (motion by Allen, second by Boone)

- AMEND GUIDANCE DOCUMENT 110-4, CONTINUING PHARMACY EDUCATION GUIDE:

Ms. Juran indicated that there are some exceptions in law that appear to create confusion for licensees as to when they must renew their license or registration and if they must obtain hours of continuing education. Staff has recently answered numerous questions on this subject and recommends that the board amend Guidance Document 110-4 to provide clarity on the subject. A handout was provided with staff's suggested amendments for the guidance document. Ms. Shinaberry recommended the question and answer on page 3 of the handout be changed to read, "Q. I've taken a course near the end of the year and didn't get my certificate until the next calendar year. How are the hours applied? A. CE credit is awarded based on the date the certificate is issued or the date the hours are awarded. Live courses are counted on the date of attending the course." Prior to voting, a corrected version of the handout was also provided which included staff's draft language for two additional frequently asked questions.

MOTION:

The Board voted unanimously to amend the question and answer on page 3 of the corrected handout to read, "Q. I've taken a course near the end of the year and didn't get my certificate until the next calendar year. How are the hours applied? A. CE credit is awarded based on the date the certificate is issued or the date the hours are awarded. Live courses are counted on the date of attending the course." and to otherwise amend the guidance document as presented in the corrected handout provided during the meeting. (motion by Saenz, second by Shinaberry)

- CONSIDER MANDATORY CE FOR PHARMACISTS ON A SPECIFIC TOPIC IN 2016:

Ms. Warriner discussed the possibility of continuing the opioid use and abuse CE topic or possibly choosing another pertinent topic for mandatory continuing education for pharmacists based on the allowance in §54.1-3314.1 J. Mr. Saenz asked the possibility of reaching out to the Department of Health or other agency to determine if there are other public health issues that may be problematic. Ms. Allen commented that we may want to see results from a continuing education audit from 2015 prior to choosing another mandatory topic for continuing education. Mr. Elliott agreed with Ms. Allen. Ms. Shinaberry stated that this one time mandatory CE was intended to educate on this specific topic and did not see a need to continue it in 2016.

MOTION:

The Board voted unanimously to not have a mandatory topic of continuing education for pharmacists in 2016.

- AMEND GUIDANCE DOCUMENT 110-27, PHARMACIST-IN-CHARGE RESPONSIBILITIES

Ms. Juran reported that staff occasionally receives questions on PIC responsibilities and recommends the board consider amending Guidance Document 110-27 to provide clarity on the subject.

MOTION:

The Board voted unanimously to amend Guidance Document 110-27 as presented in the agenda packet which clarifies on page two of the document that the pharmacy permit application must indicate the effective date the pharmacist intends to assume the role as PIC, strikes the sentence regarding board approval of the signed application, and clarifies that the incoming PIC inventory must be taken prior to opening for business on the date the pharmacist first assumes the role as PIC. (motion by Logan, second by Saenz).

- PRESENTATION ON THE HEALTH PRACTITIONERS' MONITORING PROGRAM (HPMP):
- RECONSIDER DATE FOR MARCH 2016 FULL BOARD MEETING:
- SET DATES FOR JANUARY AND MARCH REGULATION COMMITTEE MEETINGS:

Janet Knisely, Ph.D and Sherman Master, MD with the Virginia Commonwealth University presented to the Board information on the Health Practitioners' Monitoring Program including the mission of the program and the goals to achieve their mission. Some of the topics discussed during the presentation were the inception of the program, the intake process, toxicology testing process, case management, ongoing monitoring and reviewing the statistics of the program. A handout of their Power Point slides was provided.

The Board unanimously agreed to change the date of the March 2016 Board meeting from March 29, 2016 to March 25, 2016 due to a scheduling conflict with Ms. Juran.

Ms. Juran indicated that the date for the Regulation Committee meeting had recently been scheduled for January 5, 2016 and that no further action was needed for that meeting. The Board unanimously agreed to schedule the March Regulation Committee meeting on March 24, 2016.

REPORTS:

- Chairman's Report

Ms. Warriner informed the board that she had received a note from Dean DiPiro, Dean of the Virginia Commonwealth University School of Pharmacy congratulating the Board on receiving the NABP Fred T. Mahaffey award earlier this year. Additionally, she congratulated Ms. Logan for recently being appointed to the Board of Health Professions and thanked Ms. Shinaberry for her past participation on this board. Lastly, she thanked Ms. Thornbury for representing the board during the recent ACPE accreditation site visit at the Appalachian College of Pharmacy.

- Report on Board of Health Professions

Mr. Logan was appointed to the Board of Health Professions and since his appointment the board of health professions has not had a meeting.



- Report on ACPE visit to Appalachian College of Pharmacy
- Report on licensure program

Ms. Thornbury provided a report on the ACPE site visit to the Appalachian College of Pharmacy. Ms. Thornberry stated it was a very positive experience and very informative. She was thankful for the opportunity to attend this site visit and encouraged other board members to do so as the opportunity arises.

In Mr. Johnson's absence, Ms. Juran provided the licensure report. She indicated the board currently licenses 36,838 individuals and facilities. The Board issued 763 licenses and registrations for the period of September 1, 2015 through November 29, 2015. Inspectors conducted 356 facility inspections including 154 routine inspections of pharmacies: 36 (23%) resulted in no deficiency, 53 (35%) with deficiencies and 65 (42%) with deficiencies and a consent order. Ms. Shinaberry commented that she noticed approximately 30% of all major deficiencies involved sterile compounding.

ACTION ITEM:

Additionally, Ms. Shinaberry requested if staff could break out the hospital pharmacy from the community pharmacy statistics in the licensure report. Ms. Juran indicated this would have to be done manually, but that she would look into the feasibility of it.

- Report on disciplinary program

Ms. Reiniers-Day provided the Board with a handout and discussed the Board's Open Disciplinary Case Report comparing the case stages between the four report dates of March 24, 2015; June 12, 2015; September 28, 2015; and November 30, 2015. For the final date, she reported that there were no cases at the entry stage; 69 at the investigation stage; 158 at the probable cause stage; one at the administrative proceedings division stage; three at the informal stage; three at the formal stage; and 105 at the pending closure stage.

Further, Ms. Reiniers-Day discussed the importance of having the Special Conference Committees attend informal conferences on a monthly basis to avoid a backlog of informal conferences, but also cases for presentation. She thanked Ms. Allen and Mr. Boone for attending on November 23rd when two informal conferences were held and 54 cases were presented.

- Executive Director's report

Ms. Juran provided a handout which highlighted the meetings she or staff has attended since the last full board meeting. She reported Mr. Johnson and Ms. O'Halloran convened a job analysis meeting recently for the pharmacy technician exam. Additionally, Ms. O'Halloran attended training on sterile compounding offered by NABP for board staff and inspectors. She provided a brief update on staffing issues and mentioned two upcoming presentations that she will offer in the next month.

**CONSIDERATION OF
CONSENT ORDERS**

- Closed Meeting: Upon a motion by Ms. Thornbury, and duly seconded by Ms. Elliott , the Board voted 10-0 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 two Consent Orders. Additionally, she moved that Cathy M. Reiniers-Day, Caroline D. Juran, James Rutkowski and Loni Dickerson attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Board in its deliberations.
- Reconvene The Board voted unanimously that only public business matters lawfully exempt 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: Upon a motion by Ms. Allen and duly seconded by Mr. Elliott, the Board voted 10-0 in favor of accepting the Consent Orders as presented by Ms. Reiniers-Day in the matters of Denise A. Coffman and Sandy Rivers, pharmacy technicians.
- ADJOURN: With all business concluded, the meeting concluded at approximately 1:40 pm.

Cynthia Warriner, Chairman

Caroline D. Juran, Executive Director

(DRAFT/UNAPPROVED)

**VIRGINIA BOARD OF PHARMACY
PUBLIC HEARING FOR ADDRESSING HOURS OF CONTINUOUS WORK BY
PHARMACISTS**

December 1, 2015
Second Floor
Board Room 2

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: The public hearing was called to order at 9:10a.m.

PRESIDING: Cynthia Warriner, Chairman

MEMBERS PRESENT: Michael I. Elliott
Freeda Cathcart
Ryan K. Logan
Rafael Saenz
Rebecca Thornbury
Ellen B. Shinaberry
Jody H. Allen

MEMBERS ABSENT: Melvin L. Boone, Sr.
Sheila K. W. Elliot

STAFF PRESENT: Caroline D. Juran, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
Lisa Hahn, Chief Deputy Director, DHP
James Rutkowski, Assistant Attorney General
Elaine J. Yeatts, Senior Policy Analyst, DHP
Beth O'Halloran, Individual Licensing Manager
Sharon Davenport, Administrative Assistant

STAFF ABSENT: J. Samuel Johnson, Jr., Deputy Executive Director

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

CALL FOR COMMENT: Ms. Warriner called for comment to the proposed amendments to Regulation 18VAC110-20-110 for addressing hours of continuous work by pharmacists. No public comment was provided.

A public comment period will remain open through January 29, 2016 on the Virginia Regulatory Townhall website.

ADJOURN: The public hearing adjourned at 9:15am.

Cynthia Warriner, Chairman

Caroline D. Juran, Executive Director

Date

Date

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

Tuesday, December 15, 2015
Commonwealth Conference Center
Second Floor
Board Room 3

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 ("Board") was called to order at 9:30 a.m.

PRESIDING: Jody Allen, Committee Chair

MEMBERS PRESENT: Ryan Logan, Committee Member

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

Alina D. Hunter
Registration No. 0230-023983

Alina D. Hunter appeared to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the November 13, 2015 Notice.

Closed Meeting: Upon a motion by Mr. Logan, and duly seconded by Ms. Allen, 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 Alina D. Hunter. 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. Logan, and duly seconded by Ms. Allen, the Committee made certain Findings of Fact and Conclusions of Law and unanimously voted to issue an order that takes no action on Ms. Hunter's pharmacy technician registration.

Julie N. Watson
Registration No: 0230-008511

Julie N. Watson appeared to discuss the reinstatement of her pharmacy technician registration and allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the December 11, 2015, and July 15, 2015 Notices.

Closed Meeting:

Upon a motion by Mr. Logan, and duly seconded by Ms. Allen, 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 Julie N. Watson. 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. Logan, and duly seconded by Ms. Allen, the Committee unanimously voted to issue an Order granting Ms. Watson's, reinstatement application for her pharmacy technician registration and that said registration be placed under terms and conditions.

Adjourn:

With all business concluded, the meeting adjourned at 1:00 p.m.

Jody H. Allen, Chair

Cathy M. Reiniers-Day
Deputy Executive Director

Date

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(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF PILOT INFORMAL CONFERENCE COMMITTEE

Tuesday, December 29, 2015
Commonwealth Conference Center
Second Floor
Board Room 3

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

CALL TO ORDER: The meeting was called to order at 9:05 a.m.

PRESIDING: Jodi Allen, Committee Chairperson

MEMBERS PRESENT: Cynthia Warriner

STAFF PRESENT: Caroline D. Juran, Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director
Beth O'Halloran, Individual Licensing Manager
Anne Joseph, Deputy Executive Director, APD

University of Virginia Health System
Pharmacy – Technology Check Technician
Pharmacy System

The purpose of the informal conference was to act upon the Application of University of Virginia Health System (UVAHS) Pharmacy for approval of an innovative (pilot) program (“Application”) and waiver of compliance with certain provisions of Board of Pharmacy Regulations. Present for the meeting from UVAHS Pharmacy were Raphael Saenz, Administrator of Pharmacy Services and Pharmacist-In-Charge, Mathew Jenkins, Pharmacy Operations Manager, Matthew Allsbrook, PGY2 Pharmacy Administration Resident.

UVAHS Pharmacy, requested a waiver of Board of Pharmacy Regulations so that pharmacy technicians, rather than pharmacists, may perform the second medication check for first doses and drugs placed into automated drug dispensing cabinets. Additionally, UVAHS requested a waiver to allow a 1% random daily verification by a pharmacist of medications verified by pharmacy technicians rather than 5% verification.

Mr. Saenz and Mr. Jenkins provided an overview of the future process by which the pharmacy technician will be checking the technology in place indicating that medications go through four to five independent barcode scanning events prior to being dispensed to a patient. The pharmacy also dispenses medications to approximately 20 ambulatory care units using automated dispensing cabinets. UVAHS currently does not have the technology to perform barcode scanning of

medications in its ambulatory clinics at the point of administration to the patients and plans to implement this in 2017. The request is for the pharmacist to perform a 1% check for medications dispensed for cart fill from the Talyst AutoCarousel system which is used also for first doses. Additionally, request was made for a 1% pharmacist check for medications dispensed for the intent to fill and stock the automated dispensing cabinets.

Closed Meeting:

Upon a motion by Ms. Allen, and duly seconded by Ms. Warriner, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A (7) of the Code of Virginia, for the purpose of briefing by staff members pertaining to probable litigation and to act upon the application for approval of an Innovative (pilot) program for UVAHS Pharmacy. Additionally, she moved that Caroline D. Juran, J. Samuel Johnson, Jr., Beth O'Halloran, and Anne Joseph 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 § 2.2-3711 of the Code, the Committee re-convened in open meeting and announced the decision.

Decision:

After consideration of the application and statements concerning the innovative (pilot) program, Ms. Allen stated the Committee shall offer a consent order that approves the innovative (pilot) program for a period of three (3) years from the date the Order is entered by the Board with the following terms and conditions that were read by Ms. Joseph:

1. The requirement of 18VAC110-20-270(C), 18VAC110-20-420(A)(8)(d), 18VAC110-20-460(A), and 18VAC110-20-490(C)(1) of the Regulations shall be waived to allow pharmacy technicians to perform final verification for accuracy of all Schedule VI and over-the-counter products prior to leaving the pharmacy and to allow pharmacists to perform a daily random check of 5.0% of medications verified by pharmacy technicians. Documentation of this check shall include the pharmacist's initials for each medication checked and a description of all

- discrepancies found.
2. Any technician performing such final verification shall hold current registration with the Board.
 3. Pharmacists shall retain responsibility for maintaining the UVAHS Pharmacy medication barcode library.
 4. This variance is allowed for inpatient settings and for ambulatory care settings in which patient barcode scanning is utilized at the final point of administration of medications. UVAHS Pharmacy shall notify the Board when barcode scanning is implemented in its ambulatory care units.
 5. UVAHS Pharmacy shall comply with all other requirements of the Regulations Governing the Practice of Pharmacy.
 6. At least one year after implementation of the program, UVAHS Pharmacy shall be subject to one unannounced inspection of the program and shall be responsible for the cost of said inspection.
 7. Any operational changes or modifications to the innovative (pilot) program shall be approved by the Board prior to initiation of the modification.
 8. UVAHS Pharmacy shall report any significant errors or problems to the Board immediately. The Executive Director of the Board, in consultation with the Committee Chair, is authorized to review the error report and require UVAHS Pharmacy to re-institute 100% pharmacist verification of all Schedule VI and over-the-counter medications leaving the pharmacy pending further review.
 9. Any violation of this Order shall constitute grounds for the rescission of the approval, and an administrative proceeding shall be convened to determine whether the approval shall be rescinded.

Virginia Oncology Associates Lake Wright
In-Office Dispensary – Remote Prescription
Approval

The purpose of the informal conference was to act upon the Application of Virginia Oncology Associates (VOA) Lake Wright In-Office Dispensary – Remote Prescription Approval for approval of an innovative (pilot) program (“Application”) and waiver of compliance with certain provisions of Board of Pharmacy Regulations 18VAC110-30-40. Present for the meeting from VOA Lake Wright were Mickey Dozier, Clinical Manager, Torrea Harris, Pharmacy

Manager, Jennifer Lee, Senior Manager Information Services, and Joel Andres, Government Relations Director from Kemper Consulting.

VOA Lake Wright, a practice of oncologists licensed to sell controlled substances, requested a waiver of 18VAC110-30-40 of the Regulations which require the practitioner who is licensed to sell controlled substances, prior to dispensing the controlled substance, to inspect the prescription product to verify its accuracy in all respects, and to place his initials on the record of sale as certification of the accuracy of and responsibility for the entire transaction. Ms. Dozier and Ms. Harris presented the future process for which the physicians licensed to dispense controlled substances would inspect and verify an electronic image of the prescription and drug via email.

Closed Meeting:

Upon a motion by Ms. Warriner, and duly seconded by Ms. Allen, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A (7) of the Code of Virginia, for the purpose of briefing by staff members pertaining to probable litigation and to act upon the application for approval of an Innovative (pilot) program for VOA Lake Wright. Additionally, she moved that Caroline D. Juran, J. Samuel Johnson, Jr., Beth O'Halloran, and Anne Joseph 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 § 2.2-3711 of the Code, the Committee re-convened in open meeting and announced the decision.

Decision:

After consideration of the application and statements concerning the innovative (pilot) program, Ms. Allen stated the Committee denied the application. The Order is entered by the Board with the following conclusions of law that were read by Ms. Joseph:

1. The selling and storage area is locked and alarmed but has no additional security measures in place to prevent and detect the diversion of controlled substances. The proposed process would allow the pharmacy technician to practice

- for extended periods of time within the storage and selling area without personal supervision by the practitioner during the hours of operation.
2. VOA Lake Wright presented a sample of the images that would be electronically transmitted to the prescriber for inspection and verification. The sample image does not appear to provide legible and sufficient information for safely verifying the accuracy of the drug product.
 3. Based on the foregoing, the Committee concludes that the proposed waiver of the requirements of 18VAC110-30-40 (B)(2) of the Regulations for the VOA Lake Wright Remote Prescription Approval system does not adequately address the criteria enumerated in §54.1-3307.2 of the Code of Virginia.

ADJOURN:

With all business concluded, the meeting adjourned at 4:00 p.m.

Jody Allen, Committee Chairman

J. Samuel Johnson, Jr.
Deputy Executive Director

Date

Date

DRAFT/UNAPPROVED

**VIRGINIA BOARD OF PHARMACY
MINUTES OF REGULATION COMMITTEE MEETING – PERIODIC REGULATORY
REVIEW**

January 5, 2016
Second Floor
Board Room 2

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

- CALL TO ORDER:** The meeting was called to order at 1:15pm
- PRESIDING:** Ellen B. Shinaberry, Chairman
- MEMBERS PRESENT:** Ryan K. Logan
Cynthia Warriner
Melvin L. Boone, Sr.
Rebecca Thornbury
- STAFF PRESENT:** Caroline D. Juran, Executive Director
J. Samuel Johnson, Deputy Executive Director
Cathy Reiniers-Day, Deputy Executive Director
Elaine J. Yeatts, DHP Senior Policy Analyst
Beth O'Halloran, Individual Licensing Manager
- APPROVAL OF AGENDA:** The agenda was approved as presented.
- MOTION:** **The Committee voted unanimously to approve the agenda as requested for the Regulation Committee meeting (motion by Warriner, second by Boone)**
- PUBLIC COMMENT:** Tim Musselman, Executive Director, Virginia Pharmacists Association (VPhA) provided further explanation of the written comments submitted to the Board requesting a strengthening of 18VAC110-20-270 to address concerns with pharmacists not being provided adequate pharmacy technician support.
- AGENDA ITEMS:** Ms. Yeatts reviewed the procedure with the Committee of this periodic review process. The Committee is to consider the public comment recently received and recommend regulations to the full board for its consideration which should be drafted or amended. If the full board agrees, a Notice of Intended Regulatory Action (NOIRA) will be adopted which simply identifies the areas of regulation the board may address. Once the executive branch review is completed and approval to publish

the NOIRA is received, another public comment period will be opened for 30 days. Based on the comment received, the Board will then develop the proposed regulatory language. After review and approval by the Governor, the proposed regulations will be published and another public comment period will be opened for 60 days. Comment will be reviewed by the Board, final regulation will be adopted, and once the Governor approves the final regulation, a 30-day final adoption period will begin.

The Committee reviewed written comments, provided as a handout by staff, regarding areas of regulation to consider amending during the periodic review. The handout included comments from pharmacist Jon Horton and pharmacist Jamin Engel submitted to Regulatory Town Hall, an email from VPhA, and a letter from NACDS. The committee determined it would not recommend the drafting of a regulation to allow for pharmacy technicians checking pharmacy technicians when using unit dose dispensing systems since this process could be considered on a case-by-case basis through the submission of an innovative pilot program application. Additionally, the Committee determined it would not recommend an allowance for regionalization of hospital packaging and compounding as this does not appear to be permissible under federal or state law. The Committee recommended including 18VAC110-20-190 and 18VAC110-20-270 in the NOIRA and will ensure the rulemaking aligns with any federal changes resulting from the Drug Quality and Security Act.

- Review of Parts V - XII of Regulations Governing the Practice of Pharmacy, Chapter 20

The Committee discussed this agenda item and considered staff's recommendations. The Committee's decisions regarding which regulations to include in the NOIRA are captured in Attachment 1.

- Review of Regulations Governing Wholesale Distributors, Manufacturers, and Warehousemen, Chapter 50

The Committee discussed this agenda item and considered staff's recommendations. The Committee's decisions regarding which regulations to include in the NOIRA are captured in Attachment 1.

The Committee rejected staff's proposed amendment of 18VAC110-20-330 to require an expiration date on a prescription label.

- Draft regulatory language for NOIRA regarding unprofessional conduct to induce or incentivize a patient to transfer prescriptions.

Ms. Juran reviewed the excerpt of the Regulation Committee minutes from May 12, 2014 included in the agenda packet and the research summary presented at the time. The committee reviewed the proposed amendment prepared by staff for the Regulation Committee's review on May 12, 2014 as well as an excerpt from the full board meeting minutes from June 4, 2014.

MOTION:

The Committee voted unanimously to approve the proposed amendment to 18VAC110-20-25 as presented which would add “#11. Advertising or soliciting that may jeopardize the health, safety, or welfare of the patient including, but not limited to, incenting or inducing the transfer of a prescription absent professional rationale” to the regulation on unprofessional conduct. (motion by Warriner, second by Thornbury)

ADJOURN:

Next Regulation Committee meeting is tentatively scheduled for March 24, 2016.

With all business concluded, the meeting adjourned at approximately 5:00 pm.

Ellen B. Shinaberry, Chairman

Caroline D. Juran, Executive Director

DATE:

DATE:

Below are regulations in *Regulations Governing the Practice of Pharmacy*, Chapter 20, Parts V-XII and *Regulations Governing Wholesale Distributors, Manufacturers, and Warehousemen*, Chapter 50 identified by the Regulation Committee to be considered by the full board for inclusion in the Notice of Intended Regulatory Action (NOIRA) as part of the periodic regulatory review.

18VAC110-20-10

- Review definition for “robotic pharmacy system”.

18VAC110-20-190

- Consider amending physical requirements for a prescription department’s enclosure.
- Consider amending A, 2 to not allow locking of enclosure if front door to pharmacy is locked and the entire pharmacy is covered by the security system.

Part VI Drug Inventory and Records

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

- Consider adding language in subsection A from Guidance Document 110-16 regarding clarifications for performing inventories.
- Consider deleting language in subsection B regarding the red “C” unless this is based on federal rules.
- Consider clarifying in subsection C that chart orders used in long term care facilities must include a quantity or duration of treatment.

Part VII Prescription Order and Dispensing Standards

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

- Consider separating subsections A and B from the rest of the regulation.
- Consider addressing VPhA’s concern with pharmacists not being provided adequate pharmacy technician support in subsection B.
- Regarding subsection E, consider appropriateness of requiring pharmacists to not return a forged prescription.
- Regarding subsection F and on-hold prescriptions, Warriner questioned if a pharmacist is required to pull the originally filed prescription and refile it. Staff to review issue.
- Consider adding language from Guidance Document 110-32 regarding use of drop boxes into a new subsection G, but the last sentence regarding a prohibition for patients to leave containers which contain drug or drugs should be reworded to regulate pharmacists, not the consumer.

18VAC110-20-275 Delivery of dispensed prescriptions

- Consider amending to address delivery of Schedule II-VI drugs to a central desk at other facilities, e.g., assisted living facilities, hotels, places of employment, etc. Staff to consult DEA.
- Consider addressing concerns with white bagging and brown bagging.

18VAC110-20-277 Prescription Requirements

- Consider adding new regulation 18VAC110-20-277 to clarify that prescriptions, unless electronically transmitted, must include manual signature and that all prescriptions must include a quantity or duration of treatment.

18VAC110-20-280 Transmission of a prescription order by facsimile machine

- Determined that staff's suggested amendments to clarify that signature must be manual for written prescriptions unless electronically transmitted is unnecessary if proposed 18VAC110-20-277 is adopted.
- Consider whether there is value in the allowance in 18VAC110-20-280 A, 4, C for residents of long term care facilities and provider pharmacies or if it should be removed.

18VAC110-20-290 Dispensing of Schedule II drugs

- Consider adding language from Guidance Document 110-41 regarding allowable changes to a Schedule II.

Part VIII Labeling and Packaging Standards for Prescriptions

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

- Consider amending requirement for how to identify pharmacist verifying accuracy of the process.
- Consider reviewing all regulations that require a pharmacist's initials to determine if there is a better method for identifying the responsible pharmacist.

Part X Unit Dose Dispensing Systems

18VAC110-20-425 Robotic Pharmacy Systems

- Consider streamlining robotic pharmacy system regulations by striking #5 and simplifying #4. May also need to amend the definition of robot.
- Consider strengthening requirements for pharmacist accountability in assigning bar codes.

Part XI Pharmacy Services to Hospitals

18VAC110-20-470 Emergency room

- In #2, consider changing "practitioner" to "prescriber".

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

- Consider streamlining requirements for automated dispensing devices in hospitals.
- Consider clarifying that drug for emergency use may include drugs for first doses.
- Consider clarifying drugs stored in automated dispensing device for emergency purposes not restricted to quantities for emergency boxes.

Part XII Pharmacy Services to Long-Term Care Facilities

18VAC110-20-550 Stat-drug box

- Consider clarifying in 5, b whether one unit of liquid is allowable in each drug schedule.
- Clarify that a facility may possess multiple stat drug boxes and that contents do not have to be uniform between boxes.

18VAC110-20-555 Use of automated dispensing devices

- Consider whether requirements in 18VAC110-20-490 and 18VAC110-20-555 should be similar.

REGULATIONS GOVERNING WHOLESALE DISTRIBUTORS, MANUFACTURERS, AND WAREHOUSERS

Part I General Provisions

18VAC110-50-40 Safeguards against diversion of drugs

- Consider amending B, 2 that communication line must be hardwired, but sensors may be wireless.
- Consider amending B, 3 to require the security system to be capable of sending an alarm signal to the monitoring entity when breached if the communication line is not operable.

Part II Wholesale Distributors

18VAC110-50-60 Special or limited-use licenses

- Consider expanding ability to issue limited use for other entities such as third party logistic providers if law passed during 2016 General Assembly session to create this licensing category.

18VAC110-50-70 Minimum required information

- Consider placing information from Guidance Document 110-34 regarding submission of social security number or control number into regulation.

18VAC110-50-80 Minimum qualifications, eligibility, and responsible party

- Consider requiring federal criminal history record check, not simply the Virginia Central Criminal Records Exchange since Virginia database would likely not have information on responsible parties for nonresident wholesale distributors.
- For consistency, consider similar requirements in 18VAC110-20-80 for responsible party of manufacturers.



COMMONWEALTH of VIRGINIA

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Director

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March 4, 2016

MEMORANDUM

TO: The Honorable William A. Hazel Jr. MD
Secretary of Health and Human Resources

FROM: David E. Brown, DC. Director
Department of Health Professions

RE: **Report on Pharmacy Benefit Managers**

A Workgroup was convened by the Department of Health Professions to look at issues involving Pharmacy Benefit Managers (PBMs) and to make recommendations regarding the need for additional oversight of PBMs. The Workgroup included representatives from the Virginia Boards of Pharmacy and Medicine, various state agencies (VDH, DHRM, DMAS), Virginia Bureau of Insurance, Medical Society of Virginia, Virginia Pharmacists Association, National Community Pharmacists Association, Virginia Association of Chain Drug Stores, Pharmaceutical Care Management Association, Virginia Association of Health Plans, Anthem Blue Cross and Blue Shield, and Express-Scripts.

The Workgroup concluded that there were five options but was able to reach a consensus on only two of them. There was consensus on the need to convene a meeting of key stakeholders to address concerns with the prior authorization process and for the Board of Pharmacy to review the practices of white bagging and brown bagging to address issues of concern.

A copy of the Workgroup's report is provided for your information. Please let us know if any additional information or assistance is needed.

cc: Dr. Jennifer Lee
Del. Keith Hodges
Del. Chris Jones
PBM Workgroup Members

DEB/lzr

Report of the Pharmacy Benefit Managers Workgroup

Virginia Department of Health Professions

March 4, 2016

Workgroup Participants

Virginia Department of Health Professions (David E. Brown, D.C., Director, Chairman)
Virginia Board of Pharmacy (Ellen B. Shinaberry, member; Caroline D. Juran, Executive Director)
Virginia Board of Medicine (Kenneth J. Walker, MD, member; William L. Harp, MD, Executive Director)
National Community Pharmacists Association (John Beckner)
Anthem Blue Cross and Blue Shield (Geoffrey S. Ferguson)
Virginia Association of Health Plans (Douglas Gray)
Virginia Department of Health, Division of Disease Prevention (Diana Jordan)
Virginia Department of Health, Office of Licensure and Certification (T.C. Jones, IV)
Medical Society of Virginia (Michael Jurgensen)
Virginia Association of Chain Drug Stores (Rusty Maney)
Pharmaceutical Care Management Association (Jessica S. Mazer, Esq)
Virginia Pharmacists Association (Timothy S. Musselman)
Virginia Department of Medical Assistance Services (Donna Proffitt)
Express-Scripts (John Sisto)
Virginia Bureau of Insurance (Van Tompkins)
Virginia Department of Human Resource Management (Sara Wilson)

Alternates

Virginia Association of Chain Drug Stores (Bill Cropper)
Virginia Board of Pharmacy (Cynthia Warriner)
Virginia Department of Human Resource Management (Walter E. Norman)
Medical Society of Virginia (Kirsten Roberts)

Staff

Laura Z. Rothrock, Executive Assistant & Operations Manager, Director's Office, Department of Health Professions

Introduction:

In a letter from United States Senator Mark R. Warner dated February 19, 2015, the Virginia Board of Pharmacy was requested to look into a constituent's concern involving pharmacy benefit managers (PBM) and provide an appropriate response. The constituent requested that Senator Warner assist him with concerns regarding pharmacy benefit manager oversight as the Virginia State Corporation Commission, Bureau of Insurance, and Board of Pharmacy had informed him that they did not have legal authority to oversee or act on his complaint. The constituent alleged CVS Caremark and other PBMs discriminate against independent pharmacies by requiring documentation during the credentialing and re-credentialing process that are not required of chain pharmacies. He stated refusing to provide the documentation will result in a termination of the contract with the PBM for reimbursement of prescriptions. The constituent indicated that the un-level playing field threatens the survival of independent pharmacies and their ability to conduct normal business.

In a letter dated February 24, 2015 on behalf of the Board Chairman, the Executive Director for the Board of Pharmacy, after speaking with a representative of the Bureau of Insurance, confirmed to Senator Warner that neither agency has the authority to license PBMs or address the concerns expressed by the constituent. The letter indicated that there appears to be a possible lack of oversight in state law in regulating pharmacy benefit managers and that the board would discuss the issue further at its next meeting in March 2015.

At the March 24, 2015 Board of Pharmacy full board meeting, the Board heard comment from the National Community Pharmacists Association, the Medical Society of Virginia, the Virginia Pharmacists Association, EPIC Pharmacies, and owners of two independent pharmacies. Concerns included: lack of oversight of PBMs; impact PBM decision-making may have on patient access to medications, particularly in a rural setting; burdensome credentialing and re-credentialing processes that lack standards and demand too much of the pharmacist's time; PBMs' ability to designate drugs as specialty drugs and requiring them to be dispensed by mail order pharmacies often owned by PBMs; concerns with mail order pharmacies complying with statutory requirement for a bona fide pharmacist-patient relationship; and, an exclusion of the Bureau of Insurance in HB 1942 and SB 1262 during the 2015 General Assembly session to adjudicate patient disputes or disagreements regarding denial of access to medications by insurance carriers or the PBMs with which the carriers contract. Commenters requested that the Regulation Committee of the Board of Pharmacy further review concerns with patient safety, medication access, and determine if registration or licensure of PBMs is warranted. A 2013 report of the National Association of Boards of Pharmacy which considered the issue of regulation of PBMs was provided by the Medical Society of Virginia for the Board's consideration. Following deliberation, the Board concluded that some of the concerns do not fall within the Board's jurisdiction, but that the issue should be referred to the Regulation Committee for a more thorough review.

The Regulation Committee of the Board of Pharmacy considered this matter on May 11, 2015. Public comments provided to the Committee addressed concerns with patient safety based on an inability to obtain prescribed drugs in a timely manner and an increasing number of drugs requiring prior authorizations or being classified as specialty drugs which require dispensing

from mail order pharmacies often owned by PBMs. The Committee expressed concern for those persons employed by PBMs who determine or communicate information regarding drug coverage as this may be considered the practice of pharmacy and these individuals generally are unlicensed persons. Based on the significant amount of public comment received, complexity of issues, and impact on multiple healthcare professions, David Brown, D.C., Director of the Department of Health Professions (DHP), and Caroline Juran, Executive Director of the Board of Pharmacy, recommended that Dr. Brown discuss with William A. Hazel Jr., MD, Secretary of Health and Human Resources, the possibility of forming a workgroup of various stakeholders to review the possible lack of oversight of PBMs. At the June 15, 2015 Board of Pharmacy full board meeting, Dr. Brown reported that Secretary Hazel agreed that a broad-based workgroup should be convened and led by DHP. Any recommendations would be relayed to Secretary Hazel.

Current Oversight:

Current oversight distinguishes between self-insured and fully-insured health plans. An example of a self-insured plan is the plan offered to state employees through the Department of Human Resources Management. There is no state oversight for self-insured (Employee Retirement Income Security Act, aka ERISA) health plans. They are regulated federally. Self-insured plans may require patients to use mail order pharmacies.

Fully-insured health plans are regulated by state and federal law. The Bureau of Insurance (BOI) has the authority to oversee the administration of benefits by fully-insured health plans but does not have authority to directly oversee the PBMs with which the health plans may contract to fulfill certain functions. Oversight of PBMs is indirect, through the contracting fully-insured health plan. Fully-insured health plans may offer financial incentives to patients to use mail order pharmacies but may not require it unless the health plan deems the drug a specialty drug which the health plan may require to be obtained from a specialty pharmacy. The Virginia Department of Health Office of Licensure and Certification (VDH OLC) issues a certificate of quality assurance to fully-insured health plans and focuses more on the quality of services provided by the plan, such as reviewing whether the plan has a clear and strong utilization management/review program, its tracking of clinical performance data (for health maintenance organizations), network adequacy, and a complaint system in place. VDH OLC does not oversee PBMs. Additionally, while the Board of Pharmacy regulates the practice of pharmacy and mail order pharmacies, including specialty pharmacies, which may be associated with a PBM, it does not have direct oversight of PBMs. Oversight of PBMs is limited to the health plan being responsible for its contract PBMs as is the case with other subcontractors the health plan has contracted with to deliver health care benefits to beneficiaries, e.g., behavioral health, vision, and dental.

Role of a PBM and Specialty Pharmacy:

There is no legal definition for a pharmacy benefit manager in Virginia law. PBMs act as a third-party administrator for employers and health plans, managing the pharmacy benefits and negotiating favorable prices with pharmaceutical manufacturers and providers, e.g., pharmacies. The largest PBMs currently include Express Scripts, CVS Caremark, and OptumRx. In the last

decade, large businesses have merged, and many PBMs now have financial relationships with specialty pharmacies, mail order pharmacies, and community pharmacies. Health plans make decisions as to formulary management, plan design, and cost-sharing. The PBM administers the plan per the contract with the client. PBMs' clients include the federal government, state governments, large employers, and health plans. Common approaches in the industry for PBMs to mitigate the high costs of drugs include requiring prior authorizations of certain drugs, requiring certain drugs to be dispensed from a specialty pharmacy or mail order pharmacy, the development of pharmacy networks, disease management, and claims processing. In the 2013 National Association of Boards of Pharmacy *Report of the Task Force on the Regulation of Pharmacy Benefit Managers*, which updated and broadened information from the 1999 Task Force on Licensing of Pharmacy Benefit Managers, the following activities performed by a PBM were identified as activities which may encompass the practice of pharmacy: disease state management; disease compliance management; drug adherence management; drug interaction management; drug utilization management; formulary management; generic alternative program management; generic incentive program management; medical and/or drug data analysis; patient drug utilization review services; prior authorization services; provider profiling and outcomes assessment; refill reminder program management; therapy guidelines management; stop therapy protocol management; wellness management; maintenance of confidential patient information; and, direction or design of the clinical programs for a pharmacy or a group of pharmacies.

While there is no legal definition for a specialty pharmacy, these are mail order pharmacies that have historically been used to dispense drugs that are extremely expensive, have a restricted or limited distribution, or are complex and require special storage, handling, or ongoing monitoring for safety and efficacy. However, there appears to be an increasing trend in the industry to expand the role of specialty pharmacies and require more commonly used drugs that are not complex or expensive to be dispensed from specialty pharmacies. The plan design determines which drugs qualify as a specialty drug and therefore, must be dispensed from a specialty pharmacy. There are no standard criteria for a specialty drug; and the specialty pharmacies may have a financial relationship with the PBMs or may be operated by an independent pharmacy, chain pharmacy or a Health System.

Drugs which require prior authorization cannot be dispensed to the patient until approval is received from the health plan or the PBM, unless the patient is willing to pay the cash price. The purposes of prior authorization are decreasing overall healthcare costs as well as managing health and safety by ensuring the patient is receiving the least expensive, yet most effective drug therapy. Health plans determine which drugs require prior authorization, and this status can vary based on contractual agreements the PBM may have in place with the drug manufacturer or health plan. Patients are often informed by the dispensing pharmacist if a drug requires prior authorization. The pharmacist then notifies the prescriber who must provide the required information to the PBM for processing of the approval request.

Workgroup Activities:

The Workgroup met on October 19, 2015, November 13, 2015, and December 16, 2015. Public comment was received at each meeting; discussion focused primarily on the subjects listed below.

“White bagging and brown bagging”

These are relatively new patient delivery models used by specialty pharmacies that may or may not be owned or associated with a PBM. Brown bagging involves specialty pharmacies mailing specialty drugs to the patient’s residence, and white bagging involves specialty drugs being mailed to the prescriber or another pharmacy, e.g., hospital pharmacy, for subsequent administration to a specific individual in the clinical setting. A hospital pharmacist whose health system participates in white bagging indicated to the Workgroup: the specialty pharmacy dispenses the drug(s) pursuant to a patient-specific prescription; the receiving pharmacy may not be aware that drugs are being shipped to it prior to the package arriving; the receiving pharmacy may be required to further compound or reconstitute the already dispensed drug prior to administration and without reviewing the prescription, a process which may not comply with the law; the patient may be delayed in receiving the drug from the specialty pharmacy as it must be mailed from the specialty pharmacy even though the receiving pharmacy may have the prescribed drugs in stock; and the drugs appear to be delivered by the specialty pharmacy in a manner that does not comply with Board of Pharmacy Regulation 18VAC110-20-275. Mr. Gray stated there is a general lack of consistency for how these processes occur. There was consensus among the Workgroup that the Board of Pharmacy should review the practices of white bagging and brown bagging to address any issues of concern.

Parity regarding access to and requirements of plans

Comment was received from several independent pharmacy owners that there is a disparity between chain pharmacies and independent pharmacies regarding access to plans. These individuals stated patients have a right to choose their supplier of drugs, and forcing patients to use mail order pharmacies is violating that right. It was noted that Virginia law does have a freedom of choice requirement in §38.2-3407.7 regarding fully-insured health plans; and therefore, these plans cannot require a patient to use a mail order pharmacy. However, self-insured health plans may require patients to use mail order pharmacies, and both self-insured and fully-insured health plans may require drugs to be obtained from a specialty pharmacy.

Prior authorizations

Several issues related to prior authorizations were discussed. There was general consensus among the pharmacists offering comment and the pharmacy associations that the prior authorization process is overly burdensome; can delay patient access to drugs up to 7-10 days; can increase cost to the patient when the branded drug is covered and the generic drug is not, thereby pushing the patient into the Medicare “donut hole” faster; and can result in the pharmacist not being reimbursed if he or she chooses to provide the patient with the drug prior to receiving approval of the prior authorization or over a weekend when the mail order supply did not arrive in time. Those representing the health plans and PBMs indicated §38.2-3407.15:2 requires fully-insured health plans to process prior authorizations, once the required information is received, within 24 hours for emergencies and 2 business days for non-emergencies. It was also noted that the state does not have oversight of Medicare Part D. There was acknowledgement that the process is time-consuming for prescribers as well, often requiring dedicated administrative staff in the office for processing prior authorization requests. There appeared to be consensus that prior authorizations should not be eliminated, as many acknowledged there are benefits to both patients and payers for drug utilization management.

e.g., identifying prescribing errors and mitigating the significant increase in drug costs imposed by pharmaceutical manufacturers, but that process improvements for prior authorization are needed.

The Workgroup also identified the current model as a reactive prior authorization process and acknowledged that patients, prescribers, pharmacists, health plans, and PBMs would benefit from a more proactive process. Online resources for prescribers to determine drug coverage at the point of prescribing was briefly discussed, but challenges with time and accuracy of information create barriers to this solution. The National Adoption Scorecard for Electronic Prior Authorization from *covermymeds*® was reviewed and discussed. There was general consensus that the proactive process with electronic prior authorizations would significantly reduce the amount of time for all involved in handling prior authorizations and reduce the time delay in patients having access to the prescribed drugs. The Workgroup acknowledged that electronic prior authorizations cannot be utilized until electronic prescribing is commonplace. New York will be the first state to require all prescriptions to be electronically transmitted as of March 2016, and there is interest in monitoring the success of this requirement. In the interim, there was consensus that the Medical Society of Virginia, along with the Virginia Pharmacists Association, should meet with Virginia Health Plans and other key stakeholders with appropriate technical expertise to address current concerns with the prior authorization process and develop a strategy for implementing electronic prior authorizations in the near future and expanding the use of e-prescribing by prescribers.

Credentialing process

Comment was received from several independent pharmacy owners, including the pharmacist who wrote Senator Warner, that the credentialing process of the health plans is overly burdensome, lacks standards regarding the process and frequency at which they occur, and impacts patient care by reducing the pharmacist's time available for patient care. The process often involves verification of state licensure, DEA registration, National Provider Identification number, valid Medicare participation, valid pharmacist-in-charge, liability coverage, review of any disciplinary action, and review of state and federal tax files. In response to allegations in the letter to Senator Warner that CVS Caremark discriminated against an independent pharmacy by requesting information from it that CVS Caremark did not request from chain pharmacies, a representative from CVS Caremark indicated it requests the same information from all pharmacies. There was discussion regarding why CVS Caremark needed a pharmacy floorplan, as this information is maintained confidentially by the Board of Pharmacy to reduce security risks. Presently, no uniform standards exist in State law regarding information which can be requested by a PBM during the credentialing and re-credentialing process. It was suggested that such standards could possibly be enacted through the current oversight structure of health plans. Monitoring of the PBMs for compliance of such standards and any enforcement action against the PBM would then be the responsibility of the health plan, since the current oversight model provides health plans with the responsibility for their PBM contracts.

PBM communication with patients

Comment was received from independent pharmacy owners, the Virginia Pharmacists Association, and the National Community Pharmacy Association regarding concerns with PBMs calling patients of specific pharmacies to encourage them to use a different pharmacy. Those

representing health plans and PBMs acknowledged that patients may be notified via different methods to maximize health benefits and reduce costs. Whether it is appropriate for PBMs, or health plans to require PBMs to use their access to patient identification information for this purpose was called into question. Additionally, there was some concern that such notifications may be confusing to patients.

Filing complaints/Appeals Process

There was concern expressed by some Workgroup members that both patients and providers are generally unaware of who to contact or how to file a complaint regarding concerns with their drug coverage or access. Those members associated with health plans reported that patients receive this information in the insurance documents provided by the employer or health plan; however, it was suggested that perhaps this information should be more prominent or user-friendly. It was noted that the health plan contact information for patients who have any issues is already on their health plan benefit identification card. However, it was suggested that the card should also include the number of the appropriate regulatory entity for escalating a complaint when the patient does not feel the issue has been satisfactorily resolved by the health plan. Regarding what entity is appropriate for receiving complaints, there was some discussion that complaints should be filed with the employer, but there was concern that many employers may not know how to address such complaints. It was noted that current law within Title 38.2 of Virginia Code, along with BOI regulations, require fully-insured health plans to make available an internal appeals process, but that the timeframe for resolution within such appeal processes may vary among the health plans. The law also currently addresses an external review of adverse determinations rendered by health carriers and the qualifying conditions for such review. Furthermore, as a self-insured health plan, the insurer for state employers has an ombudsman to receive complaints; however, Virginia does not have a designated ombudsman for addressing concerns with fully-insured health plans. VDH OLC and the BOI investigate matters after identifying a pattern of complaints but do not generally investigate individual complaints.

Impact on rural communities

Independent pharmacy owners, the Virginia Pharmacists Association, and the National Community Pharmacists Association expressed concern that current PBM practices impact their ability to dispense prescriptions and are resulting in the closing of many independent pharmacies. One pharmacist indicated that four (4) pharmacies have closed recently in his rural area and should he be forced to close, patients would then have to drive 40 miles roundtrip to the nearest pharmacy. Because pharmacists are often the most accessible, if not the only, healthcare professional in rural settings, it was stated that healthcare questions may go unanswered, and compliance with optimal drug therapy may suffer. Independent pharmacies do not believe the current practices allow for a level playing field, as they feel PBMs are incentivized to drive business to the mail order and specialty pharmacies that have a financial relationship with the PBMs. During Workgroup discussions, those representing health plans and PBMs noted that other factors may also be impacting pharmacy care in rural settings such as current requirements of the Centers for Medicare and Medicaid Services (CMS), increased competition with chain pharmacies, and the willingness of other pharmacies to accept certain reimbursement rates. Additionally, they recommended that the viability of the business prior to closure should be taken into consideration, as some closures may result from the selling of a successful business.

Recent actions regarding additional oversight

An antitrust attorney commented that the Federal Trade Commission (FTC) is not adequately reviewing anticompetitive standards with current PBMs. He felt additional oversight of PBMs is warranted, because no one is currently looking after the patients' rights and that what the Workgroup is considering is very basic. Those representing health plans and PBMs indicated the FTC has repeatedly opined that PBMs operate in a competitive environment. There was also discussion of the passing of an Iowa law impacting PBMs and a federal court judge's decision that ERISA does not preempt states from regulating PBMs. The decision is currently under appeal. Those representing health plans and PBMs noted that there have been other cases that uphold the ERISA preemption, and that this case is not in the Virginia circuit. During public comment, it was stated that many states are taking reasonable reform action of PBMs and that recently 26 transparency bills and 34 audit reform bills were introduced across the states. Those representing health plans and PBMs noted that the Virginia General Assembly has already addressed and enacted bills on these subjects. The public commenter also stated that simply licensing PBMs does not equal oversight and that enforcement powers are necessary.

The National Association of Boards of Pharmacy convened a task force in 2014 to review oversight of PBMs. It identified several tasks that may constitute the practice of pharmacy for which licensure and Board of Pharmacy oversight is appropriate. Presently, the Mississippi Board of Pharmacy is the only board of pharmacy to directly oversee PBMs. Based on Virginia's current model, there was discussion that it may be more appropriate to place potential oversight with the VDH OLC. While VDH OLC does not have a formal position on this matter, it is willing to assume this oversight if resources are provided.

Establishment of drug formularies

Title 38.2 of the Code of Virginia authorizes a health plan to apply a formulary to the prescription drug benefits if the formulary is developed, reviewed at least annually, and updated as necessary in consultation with and with the approval of a pharmacy and therapeutics (P&T) committee consisting of practicing licensed pharmacists, physicians, and other licensed health care providers. While it was stated a PBM may elect to use an independent P&T committee for the clinical review of drugs, there is no express requirement in law for an independent review. The law does not address the role of PBMs in the establishment of drug formularies; however, during discussions it was stated that PBMs may negotiate costs with drug manufacturers and may offer drug formulary recommendations to health plans who determine the drug formularies. The PBMs and health plans stated that ultimately the employer determines what drugs will be covered. It was noted that one pharmacy employer commented that he has never been asked to provide input into the process.

Drug waste

Because mail order pharmacies typically dispense 90-day supplies, a concern was expressed by the National Community Pharmacists Association that requiring or incentivizing patients to use mail order pharmacies may result in wasted drugs if the patient does not complete the entire course of medication. During discussion it was noted that sources for drug waste other than mail order pharmacies may exist and that this issue should be discussed more broadly to include discussions on the appropriateness of current benefit design and if the Boards of Pharmacy or Medicine should consider restrictions on prescribing or dispensing.

Specialty drugs

There were some comments by Workgroup members and the public regarding the increasing number of drugs being classified by health plans as specialty drugs which often must be dispensed by specialty pharmacies. There is no uniform definition for a specialty drug or specialty pharmacy. At one time, the practice was reserved for expensive or complex drug therapy, but presently it appears specialty drugs are no longer limited to these types of drugs. Commenters in support believe the use of specialty pharmacies increases patient safety and helps decrease overall healthcare costs. Commenters in opposition stated it appears to impact patient safety by unnecessarily delaying patients' receipt of the drug and drive business toward specialty pharmacies that are often owned by PBMs.

Potential Policy Options:

Below are potential policy options that may be taken. There was general consensus for options #1 and 2.

1. The Medical Society of Virginia along with the Virginia Pharmacists Association will meet with the Virginia Health Plans and other key stakeholders with technical expertise to address current concerns with the prior authorization process and develop a strategy for implementing electronic prior authorizations in the near future and encourage the use of e-prescribing by prescribers.
2. The Board of Pharmacy will review the practices of white bagging and brown bagging to address any identified issues of concern, including the promulgation of regulations to reduce the potential for patient harm and promote consistency within the processes.

Other Possible Policy Options/Considerations:

Those representing pharmacists, pharmacies, and the Medical Society of Virginia generally supported options #3-5. VDH OLC found option #5 feasible with sufficient resources. Those representing health plans and PBMs did not support options #3-5.

3. The Board of Pharmacy will consider the issue involving specialty drugs and whether it should and has the legal authority to define the criteria for a specialty drug.
4. Future policy discussions should include the impact that the closing of pharmacies in a rural setting would have on patient care in that environment.
5. Increase oversight of the administration of pharmacy benefits by reviewing relevant statutes. Such oversight could provide VDH OLC with ability to:
 - a. license PBMs;
 - b. describe in regulation information which may be collected and/or prohibited from being collected by a PBM during the credentialing process of providers/pharmacies;
 - c. define "specialty drug" to describe the criteria to be used in determining drug eligibility; and
 - d. receive complaints against PBMs and take enforcement action when warranted.

Board of Pharmacy

Report of the 2016 General Assembly

HB 314 Drugs; administration by certain school employees.

Chief patron: Orrock

Summary as passed House:

Administration of drugs by certain school employees. Provides that a prescriber may authorize an employee of a school for students with disabilities licensed by the Board of Education, or a private school accredited pursuant to § 22.1-19 of the Code of Virginia as administered by the Virginia Council for Private Education, who is trained in the administration of insulin and glucagon to assist with the administration of insulin or administer glucagon to a student diagnosed as having diabetes and who requires insulin injections during the school day or for whom glucagon has been prescribed for the emergency treatment of hypoglycemia pursuant to a written order or standing protocol and provides immunity from civil damages to such employees for ordinary negligence in acts or omissions resulting from the rendering of such treatment, provided that the insulin is administered in accordance with the child's medication schedule or such employee has reason to believe the individual receiving the glucagon is suffering or about to suffer life-threatening hypoglycemia. The bill also allows nurse practitioners and physician assistants to provide training programs on the administration of drugs to students of private schools accredited pursuant to § 22.1-19 of the Code of Virginia as administered by the Virginia Council for Private Education.

HB 319 Health regulatory boards; continuing education for certain individuals.

Chief patron: Rasoul

Summary as passed House:

Volunteer health care providers. Requires health regulatory boards to promulgate regulations providing for the satisfaction of board-required continuing education for individuals registered, certified, licensed, or issued a multistate licensure privilege by a health regulatory board through delivery of health care services, without compensation, to low-income individuals receiving health services through a local health department or a free clinic organized in whole or primarily for the delivery of those health services. The bill has a delayed effective date of January 1, 2017.

HB 527 Nonresident medical equipment suppliers; registration with Board of Pharmacy

Chief patron: Hodges

Summary as passed House:

Registration of nonresident medical equipment suppliers. Requires any person located outside the Commonwealth other than a registered nonresident pharmacy that ships, mails, or delivers to a consumer in the Commonwealth any hypodermic syringes or needles, medicinal oxygen, Schedule VI controlled

device, those Schedule VI controlled substances with no medicinal properties that are used for the operation and cleaning of medical equipment, sterile water and saline for irrigation, or solutions for peritoneal dialysis pursuant to a lawful order of a prescriber to be registered with the Board of Pharmacy. The bill requires registrants to renew registration by March 1 of each year and to notify the Board of Pharmacy of any substantive change in information previously submitted to the Board within 30 days. The bill also requires nonresident medical equipment suppliers to maintain a valid, unexpired license, permit, or registration in the state in which it is located, if required by the resident state, or to furnish proof that it meets the minimum statutory and regulatory requirements for medical equipment suppliers in the Commonwealth if the state in which the nonresident medical equipment supplier is located does not require a license, permit, or registration. The bill also requires nonresident medical equipment suppliers to maintain records of distribution of medical equipment into the Commonwealth in such a manner that they are readily retrievable from records of distribution into other jurisdictions and to provide the records to the Board, its authorized agent, or any agent designated by the Superintendent of State Police upon request within seven days of receipt of such request.

HB 528 Prescription drugs; manufacture and distribution in the Commonwealth.

Chief patron: Hodges

Summary as passed:

Manufacture and distribution of prescription drugs in the Commonwealth. Eliminates the requirement that the Board of Pharmacy establish and implement a pedigree system for recording each distribution of a controlled substance from sale by a pharmaceutical manufacturer to a dispenser or person who will administer the controlled substance; defines "co-licensed partner" as a person who, with at least one other person, has the right to engage in the manufacturing or marketing of a prescription drug, consistent with state and federal law, and specifies that a co-licensed partner may be a manufacturer of a controlled substance; and defines "third-party logistics provider" as a person who provides or coordinates warehousing of or other logistics services for a drug or device in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of the drug or device but does not take ownership of the product or have responsibility for directing the sale or disposition of the product. The bill specifies that bulk drug substances used for compounding drugs distributed by a supplier other than a licensed wholesale distributor or registered nonresident wholesale distributor must be provided by a supplier who is approved by the Board of Pharmacy as well as the federal Food and Drug Administration and requires every pharmacy, nonresident pharmacy, wholesale distributor, and nonresident wholesale distributor to comply with federal requirements for an electronic, interoperable system to identify, trace, and verify prescription drugs as they are distributed. The bill authorizes the Board of Pharmacy to deny, revoke, suspend, or take other disciplinary actions against holders of a third-party logistics provider permit, manufacturer permit, or nonresident manufacturer permit; applies the inspection and audit requirements that apply to wholesale distributors to nonresident wholesale drug distributors, third-party logistics providers, manufacturers, and nonresident manufacturers; creates a permitting process for third-party logistics providers; allows holders of a manufacturer permit to distribute the drug manufactured, made, produced, packed, packaged, repackaged, relabeled, or prepared to anyone other than the end user without the need to obtain a wholesale distributor permit; and creates a process for registration of nonresident manufacturers of prescription drugs.

HB 586 Health regulatory boards; confidentiality of certain information obtained by boards.

Chief patron: Yost

Summary as passed House:

Confidentiality of certain information obtained by health regulatory boards in disciplinary proceedings. Provides that in disciplinary actions involving allegations that a practitioner is or may be unable to practice with reasonable skill and safety to patients and the public because of a mental or physical disability, a health regulatory board shall consider whether to disclose and may decide not to disclose in its notice or order the practitioner's health records or his health services, although such information may be considered by the board in a closed hearing and included in a confidential exhibit to a notice or order. The bill provides that the public notice or order shall identify, if known, the practitioner's mental or physical disability that is the basis of its determination.

HB 629 Prescription drugs; pharmacies may participate in voluntary drug disposal programs.

Chief patron: Hodges

Summary as passed House:

Prescription drug disposal. Provides that pharmacies may participate in voluntary drug disposal programs, provided that such programs are operated in accordance with state and federal law by a pharmacy, and requires the Board of Pharmacy to maintain a list of such pharmacies on a website maintained by the Board. The bill also provides that no person that participates in a drug disposal program shall be liable for any theft, robbery, or other criminal act related to participation in the pharmacy drug disposal program or for any acts of simple negligence in the collection, storage, or destruction of prescription drugs collected through such pharmacy drug disposal program, provided that the pharmacy practice site is acting in good faith and in accordance with applicable state and federal law and regulations.

HB 657 Prescription Monitoring Program; indicators of misuse, disclosure of information.

Chief patron: O'Bannon

Summary as passed House:

Prescription Monitoring Program; indicators of misuse; disclosure of information. Directs the Director of the Department of Health Professions to develop, in consultation with an advisory panel that shall include representatives of the Boards of Medicine and Pharmacy, criteria for indicators of unusual patterns of prescribing or dispensing of covered substances by prescribers or dispensers and authorizes the Director to disclose information about the unusual prescribing or dispensing of a covered substance by an individual prescriber or dispenser to the Enforcement Division of the Department of Health Professions.

HB 829 Prescribers of covered substances; continuing education.

Chief patron: Stolle

Summary as passed House:

Prescribers of covered substances; continuing education. Authorizes the Director of the Department of Health Professions to disclose information to the Board of Medicine about prescribers who meet a certain threshold for prescribing covered substance for the purpose of requiring relevant continuing education.

The threshold shall be determined by the Board of Medicine in consultation with the Prescription Monitoring Program. The bill also directs the Board of Medicine to require prescribers identified by the Director of the Department of Health Professions to complete two hours of continuing education in each biennium on topics related to pain management, the responsible prescribing of covered substances, and the diagnosis and management of addiction. Prescribers required to complete continuing education shall be notified of such requirement no later than January 1 of each odd-numbered year. The provisions of the bill will expire on July 1, 2022.

HB 1044 Prescription Monitoring Program; disclosure of certain information.

Chief patron: Landes

Summary as passed House:

Prescription Monitoring Program; disclosures. Provides that the Director of the Department of Health Professions may disclose information in the possession of the Prescription Monitoring Program about a specific recipient who is a member of a Virginia Medicaid managed care program to a physician or pharmacist licensed in the Commonwealth and employed by the Virginia Medicaid managed care program to determine eligibility for and to manage the care of the specific recipient in a Patient Utilization Management Safety or similar program. The bill also requires the Prescription Monitoring Program advisory committee to provide guidance to the Director regarding such disclosures.

HB 1077 Drug Control Act; adds certain chemical substances to Schedule I.

Chief patron: Garrett

Summary as introduced:

Drug Control Act; Schedule I. Adds certain chemical substances to Schedule I of the Drug Control Act. The Board of Pharmacy has added these substances to Schedule I in an expedited regulatory process. A substance added via this process is removed from the schedule after 18 months unless a general law is enacted adding the substance to the schedule. This bill is identical to SB 480.

HB 1292 Schedule IV drugs; adds eluxadoline to list.

Chief patron: Pillion

Summary as passed House:

Schedule IV drugs; eluxadoline. Adds eluxadoline to the list of Schedule IV drugs.

SB 287 Prescription Monitoring Program; reports by dispensers shall be made within 24 hours or next day.

Chief patron: Wexton

Summary as passed Senate:

Prescription Monitoring Program. Provides that, beginning January 1, 2017, reports by dispensers to the Prescription Monitoring Program (the Program) shall be made within 24 hours or the dispenser's next business day, whichever comes later. The bill also allows the Director of the Department of Health Professions to disclose information about a specific recipient to a prescriber for the purpose of establishing the treatment history of the specific recipient when the prescriber is consulting on the treatment of such recipient; allows the Director to disclose information on a specific recipient to a dispenser for the purpose of establishing a prescription history to assist the dispenser in providing clinical consultation on the care and treatment of the recipient; removes the requirement that information disclosed to a dispenser for the purpose of determining the validity of a prescription be disclosed only when the recipient is seeking a covered substance from the dispenser or the facility in which the dispenser practices; and provides that a prescriber may include information obtained from the Program for the purpose of establishing the treatment history of a specific recipient in the recipient's medical record.

SB 513 Prescription Monitoring Program; requirements of prescribers of opiates.

Chief patron: Dunnavant

Summary as passed Senate:

Prescription Monitoring Program; requirements of prescribers opioids. Requires a prescriber to obtain information from the Prescription Monitoring Program at the time of initiating a new course of treatment that includes the prescribing of opioids anticipated to last more than 14 consecutive days. Currently, a prescriber must request such information when a course of treatment is expected to last 90 days. The bill also eliminates the requirement that a prescriber request information about a patient from the Prescription Monitoring Program when prescribing benzodiazepine; allows a prescriber to delegate the duty to request information from the Prescription Monitoring Program to another licensed, registered, or certified health care provider who is employed at the same facility under the direct supervision of the prescriber or dispenser who has routine access to confidential patient data and has signed a patient data confidentiality agreement; and creates an exemption from the requirement that a prescriber check the Prescription Monitoring Program for cases in which (i) the opioid is prescribed to a patient currently receiving hospice or palliative care; (ii) the opioid is prescribed to a patient as part of treatment for a surgical procedure, provided that such prescription is not refillable; (iii) the opioid is prescribed to a patient during an inpatient hospital admission or at discharge; (iv) the opioid is prescribed to a patient in a nursing home or a patient in an assisted living facility that uses a sole source pharmacy; (v) the Prescription Monitoring Program is not operational or available due to temporary technological or electrical failure or natural disaster; or (vi) the prescriber is unable to access the Prescription Monitoring Program due to emergency or disaster and documents such circumstances in the patient's medical record. The bill requires the Director of the Department of Health Professions to report to the House Committee on Health, Welfare and Institutions and the Senate Committee on Education and Health on utilization of the Prescription Monitoring Program and any impact on the prescribing of opioids. The provisions of the bill expire on July 1, 2019.

SB 701 Cannabidiol oil and THC-A oil; permitting of pharmaceutical processors to manufacture and provide.

Chief patron: Marsden

Summary as passed Senate:

Cannabidiol oil and THC-A oil; permitting of pharmaceutical processors to manufacture and provide. Authorizes a pharmaceutical processor, after obtaining a permit from the Board of Pharmacy and under the supervision of a licensed pharmacist, to manufacture and provide cannabidiol oil and THC-A oil. The bill requires the Board of Pharmacy to adopt regulations establishing health, safety, and security requirements for permitted processors. The bill also requires that a practitioner who issues a written certification for cannabidiol and THC-A oil and the patient or his primary caregiver to register with the Board and requires a permitted pharmaceutical processor, prior to providing the patient or his primary caregiver and the practitioner who issues a written certification have registered with the Board. Finally, the bill provides criminal liability protection for pharmaceutical processors. An enactment clause provides that except for provisions requiring the Board of Pharmacy to promulgate regulations, the provisions of the bill do not become effective unless reenacted by the 2017 Session of the General Assembly.