COMMONWEALTH OF VIRGINIA

Meeting of the Board of Pharmacy

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

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

Tentative Agenda of Full Board Meeting

March 24, 2015

9:00AM

TOPIC	PAGES
Call to Order of Full Board Meeting: Ellen B. Shinaberry, Chairman	
• Welcome & Introductions	
• Reading of Emergency Evacuation Script	
• Approval of Agenda	
• Approval of Previous Board Meeting Minutes:	
· December 4, 2014, Telephone Conference Call	1-2
· December 9, 2014, Public Hearing for Scheduling Certain Controlled Substances	3-4
· December 9, Full Board Meeting	5-14
· December 16, 2014, Special Conference Committee	15-16
· January 22, 2015, Special Conference Committee	17-18
· February 5, 2015, Formal Hearing	19-22
· March 11, 2015, Special Conference Committee	handout
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	
Regulatory Actions: Elaine Yeatts	
• Legislative Update	23-39
• Regulatory Update	40-41
o Amend 18VAC110-20-727 Pharmacists Repackaging for Clients of a CSB or BHA	42
New Business: Caroline D. Juran	
• Consider Adoption of NOIRA for Drug Disposal	43-45
• Consider Use of Camera-Facilitated Prescription Verification Process by Practitioners of the Healing Arts to Sell Controlled Substances	46-52
• Staff Request to Consider Participating in Multistate Pharmacy Jurisprudence Examination (MPJE)	
o VA BOP Federal and State Drug Law Examination Handbook	53-71
o Relevant Sections of 2015 NAPLEX/MPJE Candidate Registration Bulletin	72-103

- Discuss Constituent Concern Raised with Senator Warner's Office regarding Pharmacy Benefit Manager Oversight 104-106
- Amend Guidance Document 110-36 107-116
- Identify Subjects for Possible 2016 Legislative Proposals
  - Impact of Drug Supply Chain Security Act
  - Pharmacist Access to PMP 117-118

Reports:

- Report on VCU, School of Pharmacy – Joseph T. DiPiro, Dean
- Chairman's Report – Ellen B. Shinaberry
- Report on Board of Health Professions – Ellen B. Shinaberry
- Report on Prescription Monitoring Program – Ralph Orr
- Report on Licensure Program – J. Samuel Johnson, Jr.
- Report on Disciplinary Program – Cathy M. Reiniers-Day
- Executive Director's Report –Caroline D. Juran

Consideration of consent orders and possible summary suspensions, if any

Adjourn

******The Board will have a working lunch at approximately 12pm ******

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF TELEPHONE CONFERENCE CALL

Wednesday, December 4, 2014

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

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

TIME & PURPOSE: Pursuant to § 54.1-2408.1(A) of the Code of Virginia, a telephone conference call of the Virginia Board of Pharmacy ("TCC") was held on December 4, 2014, at 10:00 a.m., to consider the summary suspension of the registration of Denise A. Coffman to practice as a pharmacy technician in the Commonwealth of Virginia.

PRESIDING: Empsy Munden

MEMBERS PRESENT:
Melvin Boone, Sr.
Michael Elliott
Sheila Elliott
Ryan Logan
Rebecca Thornbury
Cynthia Warriner

MEMBERS ABSENT:
Jody H. Allen
Dinny Li
Ellen B. Shinaberry

STAFF PRESENT:
Cathy M. Reiniers-Day, Deputy Executive Director
Mykl Egan, DHP Adjudication Specialist
James Schliessmann, Senior Assistant Attorney General
James E. Rutkowski, Assistant Attorney General

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

With seven (7) members participating and three (3) members unable to participate, it was established that a quorum could not have been convened in a regular meeting to consider this matter.

DENISE A. COFFMAN
Registration No. 0230-001342

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

MOTION:

Upon a motion by Ms. Warriner, and duly seconded by Ms. Thornbury, the Board voted 7-0 in favor of the motion that, according to the evidence presented, the continued practice by Denise A. Coffman as a pharmacy technician poses a substantial danger to the public; and therefore, the registration of Denise A. Coffman to practice as a pharmacy technician be summarily suspended. Further, a Consent Order shall be offered to Ms. Coffman for the indefinite suspension of her pharmacy technician registration for not less than two years in lieu of a formal hearing.

ADJOURN:

With all business concluded, the telephone conference call adjourned at 10:18 a.m.

Cathy M. Reiniers-Day
Deputy Executive Director

Empsy Munden, Chair

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
PUBLIC HEARING FOR SCHEDULING CERTAIN CONTROLLED SUBSTANCES

December 9, 2014
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 9:03a.m.

PRESIDING: Ellen Shinaberry, Chairman

MEMBERS PRESENT:
Jody Allen
Melvin Boone
Michael Elliott
Ryan K. Logan
Empsy Munden
Rebecca Thornbury
Cynthia Warriner

MEMBERS ABSENT:
Sheila Elliott
Dinny Li

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

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

CALL FOR COMMENT: Ms. Shinaberry called for comment to consider placement of the chemical substances N-(1-amino-3methyl-1-oxobutan-2-yl)-(cyclohexylmethyl) indazole-3-carboxamide; (other name; AB-CHMINACA), N-(1-amino-3methyl-1oxobutan-2-yl)-1-(5-fluoropentyl)indazole-3-carboxamide: (other name: 5-fluoro-AMB), and 3,4-methylenedioxy-N, N-dimethylcathinone: (other names: Dimethylone, bk-MDDMA) in Schedule I of the Drug Control Act. Linda Jackson, Director, Virginia Department of Forensic Science (DFS) provided brief comments regarding the occurrence of these chemicals in recent DFS laboratory test results. Additionally, she stated that the Drug Enforcement Administration is currently considering placement of these chemicals into Schedule I federally. No additional public comment was provided.

If approved by the Board of Pharmacy, the placement of these

substances in Schedule I in the Virginia Drug Control Act shall go into effect 30 days following publication of the proposed regulation and remain in effect for a period of 18 months. The chemicals will be de-scheduled unless a general law is passed by the General Assembly placing the chemicals into Schedule I.

ADJOURN: The public hearing adjourned at 9:10am.

Ellen Shinaberry, Chairman

Caroline D. Juran, Executive Director

Date

Date

DRAFT/UNAPPROVED

VIRGINIA BOARD OF PHARMACY
MINUTES OF BOARD MEETING

December 9, 2014
Second Floor
Board Room 2

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: The meeting was called to order at 9:10am

PRESIDING: Ellen B. Shinaberry, Chairman

MEMBERS PRESENT:
Jody H. Allen
Melvin L. Boone, Sr.
Michael Elliott
Ryan Logan
Empsy Munden
Rebecca Thornbury
Cynthia Warriner
Sheila Elliott (arrived at 11:25AM)

MEMBERS ABSENT: Dinny Li

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

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

APPROVAL OF AGENDA: An amended agenda was provided to the Board. Additionally, Ms. Shinaberry requested an additional item be added under new business – consideration for requiring mandatory continuing education for pharmacists on the topic of opioid use or abuse. The amended agenda was approved as presented, along with the request for the additional new business item.

APPROVAL OF MINUTES: The Board reviewed draft minutes for the September 9, 2014 (Full Board Meeting), September 9, 2014 (Panel Formal Hearing), September 16, 2014 (Special Conference Committee), October 21, 2014, Special Conference Committee, and the October 28, 2014 (Panel Formal Hearing). Corrections were made to the September 9, 2014 full board

meeting minutes.

MOTION: **The Board voted unanimously to approve the minutes as amended. (motion by Allen, second by Boone)**

PUBLIC COMMENTS:

Andrew D. Howard, M.D., F.A.C.P. and Javit Thekkumkattil, Vice President, Pharmacy Operations and Clinical Services of Fresenius Medical Care, addressed the Board regarding their request to be able to service dialysis clinics in Virginia as alternate delivery sites. Dr. Howard commented on how it would be beneficial based on a 2008 federal Act that became effective in 2011 that pays for dialysis services under a bundled payment. He stated that 30% of the patients at their dialysis centers in Virginia are requesting that the drugs be delivered directly to their clinics instead of the patient's residence. Dialysis patients take an average of 10-12 medications per patient. Delivery to dialysis centers would also assist medicine reconciliation and help ensure patients receive their medications. Patients on average spend up to 18 hours a week in the clinic, at least 3 days a week, 4 hours a day. Pharmacist consultation would be provided to patients 24 hours, every day. Dr. Howard stated that a majority of the states are allowing the delivery of Schedule VI drugs to the dialysis clinics and they request that Virginia do the same.

Gill Abernathy, INOVA Health System, addressed the Board concerning the recommendation for amending guidance document 110-36 for compounding. Ms. Abernathy expressed concern for the recommendation prohibiting the use of "closed system transfer devices" (CSTD) to extend beyond use dates. She stated a prohibition would have significant financial implications for hospital pharmacies. She recommended the Board provide its reasoning to the public should it decide to prohibit use of CSTDs to extend beyond use dates.

Jamin Engle, Sentara Rockingham Hospital, stated that he disagreed with the use of CSTDs to extend the beyond use date. He stated that it is a safety concern and it can lead to a higher risk of contamination.

DHP DIRECTOR'S REPORT:

Dr. Brown updated the Board on the Governor's Taskforce on Prescription Drug and Heroin Abuse. It was found that the amount of deaths from drug abuse now exceeds the amount of deaths caused by automobile accidents. Dr. Brown stated that he is co-chairing the Education workgroup, Ms. Juran is co-chair for the Storage and Disposal workgroup, Ralph Orr, Director of the Prescription Monitoring Program serves as staff on the Data and Monitoring workgroup, Jamie Hoyle, Chief Deputy Director of DHP and Laura Rothrock, Executive Administrative Assistant to the Director serves as staff for the Taskforce. The first meeting was held in November and there is a second meeting scheduled later in December.

Regarding legislation, the bill for requiring criminal background checks for registered nurses and licensed practical nurses is moving forward. Earlier this year, research was conducted to see how many registered sex offenders are licensees of DHP. At this time, six or seven matches have been found and it is being reviewed whether or not these individuals self-disclosed this information during the application process. Dr. Brown announced the elimination of DHP's Human Resources Department in October and that the agency is now using the shared human resource services through the Department of Human Resources Management. Dr. Brown stated that this decision will save the agency over $100,000 a year.

REGULATORY ACTIONS:

- Regulatory Update:

Ms. Yeatts reviewed the chart of regulatory actions found in the agenda packet. She indicated final regulations regarding continuous quality improvement programs will become effective December 31, 2014.

LEGISLATIVE UPDATE:

Ms. Yeatts reported that the agency has submitted multiple bills for the upcoming General Assembly session. The five legislative proposals adopted by the Board will move forward.

Jody Allen excused herself briefly from the meeting at 10:00am.

CONIDERATION OF SCHEDULING ACTION RESULTING FROM PUBLIC HEARING:

The Board reviewed the issue heard earlier that morning during the public hearing for placing certain chemicals into Schedule I. Ms. Yeatts explained that if the Board approved placing the three chemicals into Schedule I via regulation that the scheduling action would remain in place for 18 months, unless a general law was passed during the General Assembly session to permanently place the chemicals into Schedule I.

MOTION:

The Board voted unanimously to approve placing the following chemicals into Schedule I:

- **N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)indazole-3-carboxamide (other name: AB-CHMINACA); cannabimimetic agent;**
- **N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)indazole-3-carboxamide (other name: 5-fluoro-AMB); cannabimimetic agent;**
- **3,4-methylenedioxy-N,N-dimethylcathinone (other names: Dimethylone, bk-MDDMA); substituted cathinone;**

(motion by Warriner, second by Thornbury) (Allen not present for vote)

REQUEST FROM FRESENIUS MEDICAL CARE TO PERFORM ALTERNATE DELIVERY OF CERTAIN

Ms. Juran presented a request from Fresenius Medical Care requesting approval for the use of dialysis clinics as alternate delivery sites. Ms. Juran referenced past board decisions regarding similar requests. There was some concern regarding the security of the drugs at the dialysis

DRUGS TO DIALYSIS CENTERS:

clinics since a prescriber would not always been on-site during hours of operation. Mr. Johnson stated that the clinics would have to obtain a controlled substances registration certificate and would be subject to routine inspections. Drug to be delivered to the clinics would be limited to Schedule VI dialysis drugs. It was discussed that the population receiving dialysis treatment may have specials needs such as difficulty in finding transportation and risk of drugs being stolen from residences.

MOTION:

The Board voted 4 to 3 to allow Fresenius Medical Care to provide alternate delivery of Schedule VI dialysis medications to its dialysis centers. (motion by Munden, second by Elliott; Allen not present for vote)

REQUEST FROM JOINT COMMISSION TO ACCEPT THEIR SCREENING CHECKLIST FOR SATISFYING INSPECTION REPORT REQUIREMENT IN §54.1-3434.1:

Ms. Juran reviewed with the Board a request from the Joint Commission to allow its screening checklist to be submitted by nonresident pharmacies in lieu of an inspection report from the resident regulatory body as required in §54.1-3434.1. It was stated that the checklist did not appear to inspect for compliance with USP Chapter 795 or general pharmacy standards regarding security, recordkeeping, etc. It was requested that staff inform the Joint Commission that it should consider including additional elements on its screening checklist.

Ms. Allen returned to meeting at 10:40am.

MOTION:

The Board voted unanimously to decline the request from the Joint Commission to allow its screening checklist to be submitted by nonresident pharmacies in lieu of an inspection report from the resident regulatory body as required in §54.1-3434.1. (motion by Thornbury, second by Allen)

REQUEST TO CONSIDER REQUIRING PTCB FOR PHARMACY TECHNICIAN REGISTRATION:

Ms. Shinaberry addressed the Board with information she had obtained while attending the NABP District Meeting regarding the certification and licensure of pharmacy technicians. She stated that other states vary in their educational requirements of pharmacy technicians. NABP does endorse the Pharmacy Technician Certification Board (PTCB) as a national standard for pharmacy technicians. It was stated that requiring PTCB certification may increase patient safety. It was suggested that this matter be referred to the Regulation Committee for further consideration. The Regulation Committee will tentatively meet in May. Should it recommend a statutory amendment to require PTCB certification, the full board could consider a legislative proposal in June.

MOTION:

The Board voted unanimously to refer the request to require PTCB certification for pharmacy technician registration to the Regulation Committee for further consideration. (motion by Allen, second by Logan)

CONSIDER AMENDING

A request was made by staff for the Board to consider amending

GUIDANCE DOCUMENT 110-34 REGARDING LICENSURE OF WHOLESALE DISTRIBUTORS AND MANUFACTURERS:

Guidance Document 110-34 to require wholesale distributors and manufacturers which hold new drug applications or abbreviated new drug applications to obtain licensure as a manufacturer or non-resident wholesale distributor, whichever is applicable, regardless of whether they physically posses or ship the drug. The Board previously provided guidance that licensure was not necessary if the facility did not physically possess or ship the drug. However, it is generally believed that while these facilities may not physically possess or ship prescription drugs, they still control the flow of distribution as the NDA or ANDA holder. Ms. Juran has received requests from the executive directors of the New York and Delaware Boards of Pharmacy to license these entities so they can comply with the requirements imposed by New York and Delaware. Ms. Yeatts offered minor edits to the proposed amendments to further clarify the intent of the guidance.

MOTION:

The Board voted unanimously to amend Guidance Document 110-34 as presented and amended. (motion by Warriner, second by Allen)

CONSIDER AMENDING GUIDANCE DOCUMENT 110-9 BASED ON RECOMMENDATIONS FROM AD HOC INSPECTION COMMITTEE:

On June 4, 2014, an Ad Hoc Inspection Committee met and recommended that the Board amend Major Deficiency 25A and Major Deficiency 26 within Guidance Document 110-9 to include gloved fingertip testing. During the full Board's review of Guidance Document 110-9 it was noted that Minor Deficiency 42 also needs amending based on the final continuous quality improvement regulations taking effect on December 31, 2014. It was suggested that pharmacists and pharmacy technicians should be provided a 6-month grace period to where the inspectors will use this time for educating and not sanctioning for noncompliance with CQI requirements. The Board also requested that staff alert licensees to the grace period and effective date for CQI regulations in the next newsletter.

MOTION:

The Board voted unanimously to amend Major Deficiency 25A and Major Deficiency 26 within Guidance Document 110-9 by including "gloved fingertip testing" and to amend Minor Deficiency 42, based on final CQI regulations becoming effective December 31, 2014, and to begin citing deficiencies for noncompliance with CQI requirements beginning July 1, 2015. (motion by Thornbury, second by Warriner)

Sheila Elliott arrived at 11:25am

REQUEST FROM STAFF FOR GUIDANCE REGARDING ACCEPTABLE SECURITY SYSTEMS IN WHOLESALE DISTRIBUTORS:

Ms. Juran presented a request to the Board from a wholesale distributor to allow them to use a combination of various security systems, in lieu of motion detectors covering all drug storage areas. She explained that the long standing interpretation of Regulation 18VAC110-50-40 has been that the facility's security system must utilize motion sensors and the sensors must cover all prescription drug storage areas as motion sensors have been revered as the "generally acceptable and suitable device". However, a wholesale distributor is requesting approval to use a layering of various security devices. Two representatives from the wholesale

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distributor in question addressed the Board and presented background information on the use of "audio sensors" in their facility. The representative in charge of security for the company stated that audio sensors have been accepted in other states. He stated that the audio sensors fully cover the prescription drug storage areas in addition to other types of security devices used throughout the facility. He explained that the audio sensors assist a security company in evaluating false alarms that can often result from motion sensors detecting birds flying around in a large warehouse.

MOTION:

The Board voted unanimously to grant the request of the wholesale distributor to allow a layering of security system devices, e.g., door contacts, cameras, motion sensors, and audio sensors, throughout the facility and to not require motion detectors to cover all prescription drug storage areas. (motion by Warriner, second by Munden)

LUNCH:

The board had a working lunch at approximately 12:15pm and presented former board members R. Crady Adams, Robert M. Rhodes and Pratt Stelly with plaques of appreciation for their time and service to the Board of Pharmacy.

Meeting reconvened at approximately 1:10pm.

CONSIDER AMENDING GUIDANCE DOCUMENT 110-36 BASED ON RECOMMENDATIONS FROM COMPOUNDING WORKGROUP:

The Board reviewed a request to consider amending Guidance Document 110-36 based on recommendations from the Compounding Workgroup which met during the summer of 2014. The Board discussed the public comment received earlier regarding the recommendation to prohibit the use of closed system transfer devices (CSTD) to extend the beyond use date of a single dose vial. Ms. Shinaberry shared information received from Eric Kastango, Principal, Clinical IQ and from a microbiologist with the FDA. Both supported prohibiting the use of CSTDs to extend beyond use dates of single dose vials. Ms. Juran shared written comments provided by Becton, Dickinson and Company which supported the use of CSTDs to extend beyond use dates of single dose vials. Based on the conflicting information, it was suggested that the recommendation to prohibit use of CSTDs to extend beyond use dates of single dose vials be sent to the Regulation Committee in May for further review.

MOTION:

With the exception of the recommended amendment to prohibit use of closed system transfer devices (CSTD) to extend beyond use dates of single dose vials, the Board voted unanimously to adopt the amendments to Guidance Document 110-36 as presented and recommended by the Compounding Workgroup and to have the Regulation Committee in May further consider the recommendation to prohibit the use of CSTDs to extend beyond use dates of single dose vials. (motion by M. Elliott, second by Allen)

AMEND GUIDANCE DOCUMENT 110-12, BYLAWS:

To conform the Board's bylaws to recent changes in law regarding special conference committees, staff presented proposed amendments to Guidance Document 110-12.

MOTION:

The Board voted unanimously to amend Guidance Document 110-12 as presented. (motion by Munden, second by S. Elliott)

REQUEST TO MANDATE CE IN A SPECFIC TOPIC FOR PHARMACISTS:

In light of the Governor's Taskforce on Prescription Drug and Heroin Abuse, Ms. Shinaberry recommended the Board be proactive in educating pharmacists and consider requiring pharmacists to obtain in 2015 up to 2 hours of continuing education (CE) in the subject of opioid use or abuse. Ms. Juran explained that 54.1-3314.1 provides the Board authority to require pharmacists to obtain up to 2 hours of CE in a specific topic if the Board informs pharmacists prior to January 1 of the year in which the requirement is imposed. The requirement applies only for a single year, does not apply to pharmacy technicians, and does not require pharmacists to obtain additional hours of CE. It simply requires, of the 15 hours to be obtained by a pharmacist, that a specific number of hours be obtained in a specific topic. It was suggested that Board staff could publish the requirement in the next newsletter and inform all pharmacists in writing prior to January 1, 2015.

MOTION:

Pursuant to 54.1-3314.1, the Board voted unanimously to require pharmacists to obtain at least one hour of continuing education (CE) in the subject of opioids use or abuse during the 2015 calendar year and prior to renewing his license to practice in 2016. (motion by Warriner, second by Logan)

REPORTS:

- Chairman's Report:

Ms. Shinaberry reported that the District I & II meeting held in Williamsburg in October was a success. She thanked Ms. Juran and Ms. Warriner for their hard work in organizing the meeting. Ms. Shinaberry spoke about her recent trip to the NABP Interactive Forum held December 2nd -3rd in Mt. Prospect, Illinois. She stated it was a great networking opportunity where pharmacists from all over the United States and Canada met and discussed topics affecting boards such as collaborative practice agreements and conflict of interest.

- Report on Board of Health Professions:

Ms. Shinaberry provided an update regarding recent activities of the Board of Health Professions. Ms. Shinaberry stated that 12 new members were appointed to the Board of Health Professions. They are currently discussing job placements for veterans, heroin and prescription drug abuse, and consideration of a mid-level provider license. Scope of practice for dental hygienists and telemedicine are the upcoming topics of review.

- Report on NABP/AACP Districts 1 & 2 Meeting:

Ms. Warriner praised the Board for the outstanding turnout for the NABP/AACP Districts 1 & 2 Meeting held in Williamsburg, VA. The meeting was October 5th -7th and was held at the Williamsburg Lodge. Ms. Warriner thanked all members involved in the planning and organizing of the meeting. She stated it was her understanding that the meeting had the highest attendance in the past eight years. The 2015 Districts 1 and 2 Meeting will be held in New Hampshire. A final report will be sent to them with any suggestions that this Board may have for them.

- Report on NABP Taskforce:

Ms. Allen reported on her trip she took for the NABP Taskforce held in Chicago, October 22nd -23rd. The meeting consisted of examining robberies and thefts of pharmacies. They reviewed actions taken by other state boards and collaborated on how to form a model state act that may modify security to help ensure the safety of pharmacists.

- Report on Licensure Program:

Mr. Johnson reported the Board currently licenses over 36,000 individuals and facilities. The Board issued 1,115 licenses and registrations for the period of September 1, 2014 through November 30, 2014, including 199 pharmacists, 317 pharmacy interns, and 412 pharmacy technicians. Inspectors conducted 439 facility inspections including 200 routine inspections of pharmacies: 69 (34%) resulted in no deficiency, 53 (27%) with deficiencies and 78 (39%) with deficiencies and a consent order. While there was an increase in inspections resulting in a consent order over the previous quarter, this is the fourth consecutive quarter where deficiencies and a consent order have been below 40%. Mr. Johnson reviewed the report of Major & Minor Inspection Deficiencies including "repeat" deficiencies. Of the 78 inspections that resulted in a consent order, four pharmacies had 5 or more minor deficiencies. Mr. Johnson also discussed a chart providing a graphic display of inspection deficiencies by quarter since September 2012.

- Report on Disciplinary Program:

Ms. Reiniers-Day provided the Board with the Open Disciplinary Case Report comparing the case stages between the four report dates of March 25, 2014; June 3, 2014; September 9, 2014; and December 8, 2014. For the final date, the number of open cases are two at the entry stage; 78 at the investigation stage; 105 at the probable cause stage; 11 at the administrative proceedings division stage; 4 at the informal stage; three at the formal stage; and 158 at the pending closure stage.

- Executive Director's Report:

Ms. Juran reported to the Board that a request had recently been received from the National Transportation Safety Board (NTSB) regarding its safety study concerning the risk of drug-induced impairment in transportation accidents. The NTSB requested all Boards of Medicine and Pharmacy to remind its licensees of the importance of routinely discussing with patients the effect their diagnosed medical conditions or

prescribed drugs may have on their ability to safely operate a motor vehicle. In response to the request, the Department of Health Professions has placed on alert on the Board of Pharmacy's website, along with other websites of those boards that license prescribers. She also reported that the November e-newsletter was published, emailed to those licensees that have provided an email address to the Board, and is now available on the board's website. The piloting of the physician selling inspection process is moving forward. Ms. Juran stated that she is currently co-chairing the Storage and Disposal Workgroup as a part of the Governor's Prescription Drug and Heroin Abuse Taskforce. She and the Workgroup are currently researching whether the Board needs to promulgate regulations to support the new federal drug disposal regulations. Ms. Juran and Mr. Johnson are working with the NABP, along with the executive directors of the Arkansas, Oklahoma and Louisiana Boards of Pharmacy to develop recommendations for a more uniform inspection report. Additionally, Ms. Juran and Mr. Johnson will be traveling to Mt. Prospect, IL in January for a Verified Pharmacy Practice (VPP) Inspection Committee Meeting to finalize recommendations for a more uniform inspection report. Ms. Juran also stated she will be participating on the NABP Legislative Taskforce being held in Mt. Prospect, IL on January 20th-21st. Travel costs for NABP meetings recently attended by members and staff and those scheduled in January have been paid for by NABP.

Ms. Juran left the meeting at this time due to illness.

CONSIDERATION OF CONSENT ORDERS:

MOTION FOR CLOSED MEETING:

The Board voted unanimously to enter into a closed meeting pursuant to § 2.2-3711(A) (27) of the Code of Virginia for the purpose of deliberation to reach a decision regarding a Consent Order. Additionally, it was moved that Cathy Reiniers-Day, Jim Rutkowski, Sammy Johnson and Heather Hurley attend the closed meeting because their presence was deemed necessary and would aid the Board in its deliberation. (motion by Munden, second by Warriner)

MOTION TO CERTIFY THE PURPOSE OF THE CLOSED MEETING:

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

MOTION:

The Board voted unanimously to accept the Consent Order as presented by Ms. Reiniers-Day in the matter of Rianna Lynn Hodgen, pharmacy technician (motion by Allen, second by Warriner)

MOTION:

The Board voted unanimously to accept the Consent Order as

presented by Ms. Reiniers-Day in the matter of Jerri Denice Mallory, pharmacy technician (motion by Thornbury, second by Logan)

ADJOURN: With all business concluded, the meeting concluded at approximately 3:05pm.

Ellen B. Shinaberry, Chairman

DATE:

Caroline D. Juran, Executive Director

DATE:

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
SPECIAL CONFERENCE COMMITTEE MINUTES

Tuesday, December 16, 2014
Commonwealth Conference Center
Second Floor
Board Room 1

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

CALL TO ORDER: A meeting of a Special Conference Committee of the Board of Pharmacy was called to order at 9:30 a.m.

PRESIDING: Ellen Shinaberry, Committee Chair

MEMBERS PRESENT: Cindy Warriner, Committee Member

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

DICKSON C. NWOSU
License Number 0202-010223

Dickson C. Nwosu appeared with his attorney, Barbara Queen, to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the September 30, 2014, Notice.

Closed Meeting: Upon a motion by Ms. Warriner, and duly seconded by Ms. Shinaberry, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Dickson C. Nwosu. Additionally, she 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 Ms. Warriner, and duly seconded by Ms. Shinaberry, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to enter an Order that

imposes a monetary penalty.

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

Upon such timely request for a formal hearing, the decision of this Special Conference Committee shall be vacated.

ADJOURN: With all business concluded, the meeting adjourned at 2:05 p.m.

_____
Ellen Shinaberry, Chair

_____
Cathy M. Reiniers-Day
Deputy Executive Director

_____
Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
SPECIAL CONFERENCE COMMITTEE MINUTES

Thursday, January 22, 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 was called to order at 1:00 p.m.

PRESIDING: Empsy Munden, Committee Chair

MEMBERS PRESENT: Jody H. Allen, Committee Member

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

EUGENE G. GLASS
License Number 0202-006040

Eugene G. Glass appeared to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the January 5, 2015, Notice.

Closed Meeting: Upon a motion by Ms. Allen, and duly seconded by Ms. Munden, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Eugene G. Glass. Additionally, she 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 Ms. Allen, and duly seconded by Ms. Munden, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to enter an Order with certain terms and conditions.

As provided by law, this decision shall become a

final Order thirty (30) days after service of such Order on Mr. Glass, unless a written request is made to the Board requesting a formal hearing on the allegations made against him is received from Mr. Glass within such time. If service of the Order is made by mail, three (3) additional days shall be added to that period.

Upon such timely request for a formal hearing, the decision of this Special Conference Committee shall be vacated.

ADJOURN: With all business concluded, the meeting adjourned at 4:40 p.m.

Empsy Munden, Chair

Cathy M. Reiniers-Day
Deputy Executive Director

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF A PANEL OF THE BOARD

Thursday, February 5, 2015
Commonwealth Conference Center
Second Floor
Board Room 2

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

CALL TO ORDER:	A meeting of a panel of the Board of Pharmacy ("Board") was called to order at 11:00 a.m.
PRESIDING:	Ellen Shinaberry, Chair
MEMBERS PRESENT:	Jody Allen Melvin Boone Empsy Munden Rebecca Thornbury Cindy Warriner
STAFF PRESENT:	Caroline D. Juran, Executive Director Cathy M. Reiniers-Day, Deputy Executive Director Sharon Davenport, Administrative Assistant James Rutkowski, Assistant Attorney General James Schliessmann, Senior Assistant Attorney General Mykl D. Egan, DHP Adjudication Specialist
QUORUM:	With six (6) members of the Board present, a panel was established.
JEANN LEE GILLESPIE License No. 0202-211184	A formal hearing was held in the matter of Jeann Lee Gillespie to discuss allegations that she may have violated the laws and regulations governing the practice of pharmacy in Virginia. Ms. Gillespie was not present at the hearing. The Board proceeded with the hearing in Ms. Gillespie's absence as the Notice of Hearing, dated January 8, 2015, was mailed to her legal address of record, both by regular and certified mail. Ms. Shinaberry ruled that adequate notice was provided to Ms. Gillespie. James Schliessmann, Senior Assistant Attorney General, prosecuted the case with the assistance of Mykl D. Egan, DHP Adjudication Specialist. Michele Crone, DHP Senior Investigator, testified on behalf of the Commonwealth.

Closed Meeting:	Upon a motion by Ms. Munden, and duly seconded by Ms. Warriner, the panel voted 6-0, to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia ("Code"), for the purpose of deliberation to reach a decision in the matter of Jeann Lee Gillespie. Additionally, she moved that Cathy Reiniers-Day, Caroline Juran, Sharon Davenport and James Rutkowski attend the closed meeting.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the panel re-convened in open meeting and announced the decision.
Decision:	Upon a motion by Ms. Warriner, and duly seconded by Ms. Munden, the panel voted 6-0 to accept the Findings of Fact and Conclusions of Law as proposed by Mr. Schliessmann and read by Mr. Rutkowski. Upon a motion by Ms. Warriner and duly seconded by Ms. Munden, the panel voted 6-0 to indefinitely suspend Jeann Lee Gillespie's right to renew her license to practice pharmacy.
STEPHANIE REYNOLDS Registration No: 0230-023121	James Schliessmann, Senior Assistant Attorney General, presented a summary of the evidence in the case for the Board to consider a summary suspension. Mykl D. Egan, DHP Adjudication Specialist, was also present. Upon a motion by Ms. Warriner, and duly seconded by Mr. Boone, the Board voted 6-0 in favor of the motion that, according to the evidence presented, the continued practice by Stephanie Reynolds as a pharmacy technician poses a substantial danger to the public; and therefore, the registration of Stephanie Reynolds to practice as a pharmacy technician be summarily suspended. Further, in lieu of a formal hearing, a Consent Order shall be offered to Ms. Reynolds for the indefinite suspension of her pharmacy technician registration for one year.

CONSIDERATION OF CONSENT ORDERS

Closed Meeting:	Upon a motion by Ms. Munden, and duly seconded by Ms. Thornbury, the Board voted 6-0 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 Consent Orders. Additionally, she moved that Cathy M. Reiniers-Day, Caroline D. Juran, Sharon Davenport and James Rutkowski 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:
Registration No. 0230-019341

Upon a motion by Ms. Thornbury and duly seconded by Ms. Warriner, the Board voted 6-0 in favor of accepting the Consent Order as presented by Ms. Reiniers-Day in the matter of Rianna L. Hodgen, a pharmacy technician.

MOTION:
Registration No. 0230-008907

Upon a motion by Mr. Boone and duly seconded by Ms. Warriner, the Board voted 6-0 in favor of accepting the Consent Order as presented by Ms. Reiniers-Day in the matter of Jerri D. Mallory, a pharmacy technician.

MOTION:
License No. 0202-210861

Upon a motion by Ms. Allen and duly seconded by Ms. Warriner, the Board voted 6-0 in favor of accepting the Consent Order as presented by Ms. Reiniers-Day in the matter of Dale A. Moore, a pharmacist.

JENNIFER D. WHITE
Registration No. 0230-018248

A formal hearing was held in the matter of Jennifer D. White to discuss her petition for reinstatement of her pharmacy technician registration following a mandatory suspension on March 13, 2014.

James Schliessmann, Senior Assistant Attorney General, prosecuted the case with the assistance of Mykl D. Egan, DHP Adjudication Specialist.

An Affidavit signed by Gayle Miller, Senior Investigator, was presented by Mr. Schliessmann and accepted by Ms. Shinaberry. Further, Pat Sheehan, DHP Senior Investigator, and George Fetko, a pharmacist and Ms. White's former employer, testified on behalf of the Commonwealth.

Ms. White testified on her own behalf.

Closed Meeting:

Upon a motion by Ms. Munden, and duly seconded by Mr. Boone, the panel voted 6-0, to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia ("Code"), for the purpose of deliberation to reach a decision in the matter of Jennifer D. White. Additionally, she moved that Cathy Reiniers-Day, Caroline Juran, Sharon Davenport, and James Rutkowski attend the closed meeting.

Reconvene:

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

Decision:

Upon a motion by Ms. Warriner, and duly seconded by Ms. Munden, the panel voted 6-0 to accept the Findings of Fact and Conclusions of Law as proposed by Mr. Schliessmann, amended by the Board and read by Mr. Rutkowski.

Upon a motion by Ms. Warriner and duly seconded by Ms. Munden, the panel voted 6-0 to deny Ms. White's petition for reinstatement of her pharmacy technician registration.

Adjourn:

With all business concluded, the meeting adjourned at 2:40 p.m.

Ellen Shinaberry, Chair

Cathy M. Reiniers-Day
Deputy Executive Director

Date

Report of the 2015 General Assembly

Board of Pharmacy

HB 1445 Cannabidiol oil and THC-A oil; possession of marijuana.

Chief patron: Albo

Summary as passed:

Possession or distribution of marijuana for medical purposes; epilepsy. Provides an affirmative defense in a prosecution for the possession of marijuana if the marijuana is in the form of cannabidiol oil or THC-A oil possessed pursuant to a valid written certification issued by a practitioner of medicine or osteopathy licensed by the Board of Medicine for purposes of treating or alleviating a patient's symptoms of intractable epilepsy. The bill provides that a practitioner shall not be prosecuted for distribution of marijuana under the circumstances outlined in the bill. The bill contains an emergency clause.

EMERGENCY

02/26/15 Governor: Approved by Governor-Chapter 7 (effective 2/26/15)

HB 1458 Naloxone or other opioid antagonist; pharmacist may dispense in cases of opiate overdose.

Chief patron: O'Bannon

Summary as passed House:

Naloxone; administration in cases of opiate overdose. Provides that a pharmacist may dispense naloxone or other opioid antagonist used for overdose reversal pursuant to an oral, written, or standing order in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health, that a person may possess and administer naloxone or other opioid antagonist used for overdose reversal to a person who is believed to be experiencing or about to experience a life-threatening opiate overdose, and that firefighters and law-enforcement officers who have completed a training program may possess and administer naloxone. The bill also provides that a person who in good faith prescribes, dispenses or administers naloxone or other opioid antagonist used for overdose reversal in an emergency to an individual who is believed to be experiencing or about to experience a life-threatening opioid overdose shall not be liable for any civil damages for ordinary negligence in acts or omissions resulting from the rendering of such treatment if acting in accordance with the provisions of § 54.1-3408 or in his role as a member of an emergency medical services agency.

HB 1564 Schedule I drugs; adding several substances to list.

Chief patron: Garrett

Summary as introduced:

Schedule I drugs. Adds N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)indazole-3-carboxamide (other name: AB-CHMINACA), N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)indazole-3-carboxamide (other name: 5-fluoro-AMB), and 3,4-methylenedioxy-N,N-dimethylcathinone (other names: Dimethylone, bk-MDDMA) to Schedule I of the Drug Control Act, in accordance with the action of the Board of Pharmacy adding these substances to Schedule I pursuant to § 54.1-3443. This bill is identical to SB 1380.

HB 1733 Prescription drug orders; delivery to PACE program facility.

Chief patron: Hodges

Summary as introduced:
Delivery of prescription drug orders; PACE programs. Provides that prescription drug orders dispensed to a patient and delivered to a program of all-inclusive care for the elderly (PACE) facility licensed by the Department of Medical Assistance Services may be stored, retained, and repackaged at the facility on behalf of a patient for subsequent delivery or administration The bill requires that repackaging of dispensed prescription drugs retained by the PACE facility be performed by a pharmacist, pharmacy technician, nurse, or other person who has successfully completed a Board-approved training program for such purpose. The bill directs the Board of Pharmacy to promulgate regulations related to training, packaging, labeling, and recordkeeping for such repackaging.

HB 1736 Wholesale distributors; notice to Board of Pharmacy when ceasing distribution of certain drugs.

Chief patron: Hodges

Summary as passed House:

Wholesale distributors; notice to Board of Pharmacy when ceasing distribution to a dispenser due to suspicious ordering. Requires a wholesale distributor or nonresident wholesale distributor that ceases distribution of Schedule II through V drugs to a pharmacy, licensed physician dispenser, or licensed physician dispensing facility located in the Commonwealth due to suspicious orders of controlled substances to notify the Board of Pharmacy within five days of the cessation. The bill defines "suspicious orders of controlled substances," provides that a wholesale distributor or nonresident wholesale distributor shall be immune from civil liability for notifying the Board of Pharmacy unless such notice was given in bad faith or with malicious intent, and provides that the Board of Pharmacy shall not impose any disciplinary or enforcement action against a licensee or permit holder solely on the basis of notice received from a wholesale distributor or nonresident wholesale distributor.

HB 1737 Outsourcing facilities; new regulatory framework created for permitting.

Chief patron: Hodges

Summary as introduced:
Outsourcing facilities and nonresident outsourcing facilities and compounding for office-based administration. Creates a new regulatory framework for permitting of outsourcing facilities thatcompound drugs and are located within the Commonwealth and registering nonresident outsourcing facilities in the Commonwealth.

HB 1738 Hospices; notice to dispenser of patient's death within 48 hours.

Chief patron: Hodges

Summary as passed House:

Hospices; notice to dispenser of patient's death. Requires every hospice licensed by the Department of Health or exempt from licensure pursuant to § 32.1-162.2 with a hospice patient residing at home at the time of death to notify every pharmacy that has dispensed partial quantities of a Schedule II controlled substance for a patient with a medical diagnosis documenting a terminal illness, as authorized by federal law, within 48 hours of the patient's death.

HB 1750 Investigational drugs; expanded access.

Chief patron: Ransone

Summary as passed House:

Expanded access to investigational drugs, biological products, and devices. Provides that a person who has a terminal condition shall be eligible for expanded access to an investigational drug, biological product, or device when (i) no comparable or satisfactory alternative treatment options approved by the U.S. Food and Drug Administration are available to treat his terminal condition; (ii) the potential benefits of the use of the investigational drug, biological product, or device outweigh the risks of use of the investigational drug, biological product, or device; (iii) his treating physician has recommended use of the investigational drug, biological product, or device; and (iv) the person or his legally authorized representative or his parent or legal guardian has provided informed written consent to use of the investigational drug, biological product, or device. The bill also provides that a manufacturer may provide an investigational drug, biological product, or device for treatment of such eligible person's terminal condition and may do so free of charge or may require the person to pay costs associated with manufacture of the investigational drug, biological product, or device and that health insurance providers may, but are not required to, provide coverage for costs associated with use of the investigational drug, biological product, or device. The bill provides immunity from civil liability for health care providers who recommend an investigational drug, biological product, or device and for manufacturers of investigational drugs, biological products, or devices that make such drugs, products, or devices available to a person who meets the criteria set forth in the bill.

HB 1810 Prescription Monitoring Program; civil subpoenas.

Chief patron: Herring

Summary as introduced:
Prescription monitoring program; subpoenas. Provides that information in possession of the Prescription Monitoring Program shall not be available for civil subpoena, nor shall such information be disclosed, discoverable, or compelled to be produced in any civil proceeding, nor shall such records be deemed admissible as evidence in any civil proceeding for any reason.

HB 1839 Controlled substances; scheduling.

Chief patron: Robinson

Summary as introduced:
Scheduling of certain controlled substances. Removes hydrocodone combination products from Schedule III and classifies alfaxalone, suvorexant, and tramadol as Schedule IV controlled substances.

HB 1841 Prescription Monitoring Program; requirements for dispensers.

Chief patron: Herring

Summary as passed House:

Prescription Monitoring Program; requirements for dispensers. Requires the Department of Health Professions to register every dispenser licensed by the Board of Pharmacy with the Prescription Monitoring Program and eliminates the requirement that such registration occur upon filing of an application for licensure or renewal of a license. The bill also limits the requirement that a prescriber who prescribes benzodiazepine or an opiate request information from the Director of the Department of Health Professions to determine what other covered substances are currently prescribed to a patient to cases in which the course of treatment is anticipated at the onset of treatment to last more than 90 days. The bill provides that the provisions of this act relating to registration of dispensers shall become effective on January 1, 2016.

HB 1914 Pharmacists; possession of epinephrine and oxygen for emergencies.

Chief patron: Hodges

Summary as introduced:
Pharmacists; oxygen and epinephrine. Provides that a prescriber may authorize pharmacists to possess epinephrine and oxygen for administration in treatment of emergency medical conditions.

HB 1963 Health Professions, Department of; disclosure of confidential information.

Chief patron: O'Bannon

Summary as introduced:

Department of Health Professions; disclosure of confidential information. Allows the Director of the Department of Health Professions to disclose information about a suspected violation of state or federal law or regulation to other agencies within the Health and Human Resources Secretariat or to federal law-enforcement agencies having jurisdiction over the suspected violation or to request an inspection or investigation of a licensee by such state or federal agency when the Director has reason to believe that a possible violation of federal or state law has occurred.

HB 2063 Telemedicine services; provision of health care services.

Chief patron: Kilgore

Summary as passed House:

Telemedicine services; prescriptions. Amends the definition of telemedicine services to encompass the use of electronic technology or media, including interactive audio or video, for the purpose of diagnosing or treating a patient or consulting with other health care providers regarding a patient's diagnosis or treatment. The measure also provides that for the purpose of prescribing a Schedule VI controlled substance to a patient via telemedicine services, a prescriber may establish a bona fide practitioner-patient relationship by an examination through face-to-face interactive, two-way, real-time communications services or store-and-forward technologies when certain conditions are met. This bill is identical to SB 1227.

HB 2192 Practitioners of the healing arts; prohibits dispensing controlled substances unless licensed.

Chief patron: Garrett

Summary as passed House:

Board of Pharmacy; practitioners dispensing controlled substances. Prohibits a practitioner of the healing arts from dispensing controlled substances unless licensed by the Board of Pharmacy to sell controlled substances. The bill requires facilities from which practitioners of the healing arts dispense controlled substances to obtain a permit from the Board but exempts facilities in which only one practitioner of the healing arts is licensed by the Board to sell controlled substances from fees associated with obtaining and renewing such permit. The bill also requires the Board of Pharmacy to promulgate regulations to implement the provisions of this act within 280 days of its enactment.

HB 2216 Epinephrine; possession and administration in private schools.

Chief patron: Greason

Summary as passed House:

Epinephrine; possession and administration in private schools. Requires the Board of Education to adopt regulations for the possession and administration of epinephrine in private schools for students with disabilities. The bill authorizes employees of licensed private schools for students with disabilities and accredited private schools to possess and administer epinephrine to a student believed in good faith to be having an anaphylactic reaction and provides liability protection for such employees.

SB 817 Prescription Monitoring Program; disclosure of information.

Chief patron: Howell

Summary as passed Senate:

Prescription Monitoring Program; disclosure of information. Requires the Director of the Department of Health Professions to disclose information from the Prescription Monitoring Program relevant to a specific investigation, supervision, or monitoring of a specific recipient for purposes of the administration of criminal justice to a probation or parole officer or local community-based probation officer who has completed the Virginia State Police Drug Diversion School designated by the Director of the Department of Corrections or his designee.

SB 1018 Practical nurse or registered nurse; establishes criminal history record check for applicants.

Chief patron: Dance

Summary as passed Senate:

Board of Nursing; criminal history record check for applicants for licensure. Establishes state and federal criminal history background check requirements for applicants for licensure as a practical nurse or registered nurse. The bill has a delayed effective date of January 1, 2016. This bill incorporates SB 1294.

SB 1393 Pharmacists; compounding of drugs for use in executions.

Chief patron: Saslaw

Summary as passed Senate:

Compounding of drugs for use in executions. Empowers the Director of the Department of Corrections to make and enter into contracts with a pharmacy or outsourcing facility to compound the drugs necessary to carry out execution by lethal injection. The bill provides that information relating to the identity of the persons or entities compounding such drugs, the identities of persons or entities engaged to manufacture or supply the materials used to compound the drug products, and the name of the materials or components used to compound drug products for use in an execution are confidential, exempt from the Freedom of Information Act, and not subject to discovery or introduction as evidence in a civil proceeding except for good cause shown. Pharmacists are authorized to compound drugs for lethal injections and the Board of Pharmacy can inspect or investigate a pharmacy or outsourcing facility or person compounding such drugs but any documents related to the inspection or investigation are confidential, exempt from the Freedom of Information Act and are not subject to discovery or introduction as evidence in any civil proceeding unless good cause is shown.

02/24/15 House: Defeated by House (42-Y 56-N)

VIRGINIA ACTS OF ASSEMBLY — CHAPTER

An Act to amend and reenact §§ 54.1-3435 and 54.1-3435.01 of the Code of Virginia, relating to wholesale distributors; notice to Board of Pharmacy when ceasing distribution to a dispenser due to suspicious orders.

[H 1736]

Approved

Be it enacted by the General Assembly of Virginia:

1. That §§ 54.1-3435 and 54.1-3435.01 of the Code of Virginia are amended and reenacted as follows:

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

A. It shall be unlawful for any person to engage in the wholesale distribution of prescription drugs in ~~this~~ *the* Commonwealth without a valid unrevoked license issued by the Board. The applicant for licensure as a wholesale distributor, as defined in § 54.1-3401, in ~~this~~ *the* Commonwealth shall apply to the Board for a license, using such forms as the Board may furnish; renew such license using such forms as the Board may furnish, if granted, annually on a date determined by the Board in regulation; notify the Board within ~~thirty~~ *30* days of any substantive change in the information reported on the application form previously submitted to the Board; and remit a fee as determined by the Board.

B. A wholesale distributor that ceases distribution of Schedule II through V drugs to a pharmacy, licensed physician dispenser, or licensed physician dispensing facility located in the Commonwealth due to suspicious orders of controlled substances shall notify the Board within five days of the cessation. For the purposes of this section, "suspicious orders of controlled substances" means, relative to the pharmacy's, licensed physician dispenser's, or licensed physician dispensing facility's order history and the order history of similarly situated pharmacies, licensed physician dispensers, or licensed physician dispensing facilities, (i) orders of unusual size, (ii) orders deviating substantially from a normal pattern, and (iii) orders of unusual frequency.

C. A wholesale distributor shall be immune from civil liability for giving notice in accordance with subsection B unless the notice was given in bad faith or with malicious intent.

D. The Board shall not impose any disciplinary or enforcement action against any licensee or permit holder solely on the basis of a notice received from a wholesale distributor pursuant to subsection B.

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

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

A. Any person located outside ~~this~~ *the* Commonwealth who engages in the wholesale distribution of prescription drugs into ~~this~~ *the* Commonwealth shall be registered with the Board. The applicant for registration as a nonresident wholesale distributor shall apply to the Board using such forms as the Board may furnish; renew such registration, if granted, using such forms as the Board may furnish, annually on a date determined by the Board in regulation; notify the Board within ~~thirty~~ *30* days of any substantive change in the information previously submitted to the Board; and remit a fee, which shall be the fee specified for wholesale distributors located within the Commonwealth.

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

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

D. *A nonresident wholesale distributor that ceases distribution of Schedule II through V drugs to a pharmacy, licensed physician dispenser, or licensed physician dispensing facility located in the Commonwealth due to suspicious orders of controlled substances shall notify the Board within five days of the cessation. For the purposes of this section, "suspicious orders of controlled substances" means, relative to the pharmacy's, licensed physician dispenser's, or licensed physician dispensing facility's order history and the order history of similarly situated pharmacies, licensed physician dispensers, or licensed physician dispensing facilities, (i) orders of unusual size, (ii) orders deviating substantially from a normal pattern, and (iii) orders of unusual frequency.*

E. A nonresident wholesale distributor shall be immune from civil liability for giving notice in

accordance with subsection D unless the notice was given in bad faith or with malicious intent.

F. The Board shall not impose any disciplinary or enforcement action against any licensee or permit holder solely on the basis of a notice received from a nonresident wholesale distributor pursuant to subsection D.

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

VIRGINIA ACTS OF ASSEMBLY — CHAPTER

An Act to amend and reenact §§ 54.1-3401, 54.1-3406, 54.1-3410.2, and 54.1-3434.4 of the Code of Virginia and to amend the Code of Virginia by adding in Article 2 of Chapter 34 of Title 54.1 a section numbered 54.1-3434.05 and by adding in Article 2.1 of Chapter 34 of Title 54.1 a section numbered 54.1-3434.5, relating to outsourcing facilities and nonresident outsourcing facilities and compounding for office-based administration.

[H 1737]

Approved

Be it enacted by the General Assembly of Virginia:

1. That §§ 54.1-3401, 54.1-3406, 54.1-3410.2, and 54.1-3434.4 of the Code of Virginia are amended and reenacted and that the Code of Virginia is amended by adding in Article 2 of Chapter 34 of Title 54.1 a section numbered 54.1-3434.05 and by adding in Article 2.1 of Chapter 34 of Title 54.1 a section numbered 54.1-3434.5 as follows:

§ 54.1-3401. Definitions.

As used in this chapter, unless the context requires a different meaning:

"Administer" means the direct application of a controlled substance, whether by injection, inhalation, ingestion, or any other means, to the body of a patient or research subject by (i) a practitioner or by his authorized agent and under his direction or (ii) the patient or research subject at the direction and in the presence of the practitioner.

"Advertisement" means all representations disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or which are likely to induce, directly or indirectly, the purchase of drugs or devices.

"Agent" means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser. It does not include a common or contract carrier, public warehouseman, or employee of the carrier or warehouseman.

"Anabolic steroid" means any drug or hormonal substance, chemically and pharmacologically related to testosterone, other than estrogens, progestins, corticosteroids, and dehydroepiandrosterone.

"Animal" means any nonhuman animate being endowed with the power of voluntary action.

"Automated drug dispensing system" means a mechanical or electronic system that performs operations or activities, other than compounding or administration, relating to pharmacy services, including the storage, dispensing, or distribution of drugs and the collection, control, and maintenance of all transaction information, to provide security and accountability for such drugs.

"Biological product" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein other than a chemically synthesized polypeptide, or analogous product, or arsphenamine or any derivative of arsphenamine or any other trivalent organic arsenic compound, applicable to the prevention, treatment, or cure of a disease or condition of human beings.

"Biosimilar" means a biological product that is highly similar to a specific reference biological product, notwithstanding minor differences in clinically inactive compounds, such that there are no clinically meaningful differences between the reference biological product and the biological product that has been licensed as a biosimilar pursuant to 42 U.S.C. § 262(k) in terms of safety, purity, and potency of the product.

"Board" means the Board of Pharmacy.

"Bulk drug substance" means any substance that is represented for use, and that, when used in the compounding, manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug; however, "bulk drug substance" shall not include intermediates that are used in the synthesis of such substances.

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

corporation's charter.

"Compounding" means the combining of two or more ingredients to fabricate such ingredients into a single preparation and includes the mixing, assembling, packaging, or labeling of a drug or device (i) by a pharmacist, or within a permitted pharmacy, pursuant to a valid prescription issued for a medicinal or therapeutic purpose in the context of a bona fide practitioner-patient-pharmacist relationship, or in expectation of receiving a valid prescription based on observed historical patterns of prescribing and dispensing; (ii) by a practitioner of medicine, osteopathy, podiatry, dentistry, or veterinary medicine as an incident to his administering or dispensing, if authorized to dispense, a controlled substance in the course of his professional practice; or (iii) for the purpose of, or as incident to, research, teaching, or chemical analysis and not for sale or for dispensing. The mixing, diluting, or reconstituting of a manufacturer's product drugs for the purpose of administration to a patient, when performed by a practitioner of medicine or osteopathy licensed under Chapter 29 (§ 54.1-2900 et seq.), a person supervised by such practitioner pursuant to subdivision A 6 or A 19 of § 54.1-2901, or a person supervised by such practitioner or a licensed nurse practitioner or physician assistant pursuant to subdivision A 4 of § 54.1-2901 shall not be considered compounding.

"Controlled substance" means a drug, substance, or immediate precursor in Schedules I through VI of this chapter. The term shall not include distilled spirits, wine, malt beverages, or tobacco as those terms are defined or used in Title 3.2 or Title 4.1. The term "controlled substance" includes a controlled substance analog that has been placed into Schedule I or II by the Board pursuant to the regulatory authority in subsection D of § 54.1-3443.

"Controlled substance analog" means a substance the chemical structure of which is substantially similar to the chemical structure of a controlled substance in Schedule I or II and either (i) which has a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in Schedule I or II or (ii) with respect to a particular person, which such person represents or intends to have a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in Schedule I or II. "Controlled substance analog" does not include (a) any substance for which there is an approved new drug application as defined under § 505 of the federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355) or that is generally recognized as safe and effective pursuant to §§ 501, 502, and 503 of the federal Food, Drug, and Cosmetic Act (21 U.S.C. §§ 351, 352, and 353) and 21 C.F.R. Part 330; (b) with respect to a particular person, any substance for which an exemption is in effect for investigational use for that person under § 505 of the federal Food, Drug, and Cosmetic Act to the extent that the conduct with respect to that substance is pursuant to such exemption; or (c) any substance to the extent not intended for human consumption before such an exemption takes effect with respect to that substance.

"DEA" means the Drug Enforcement Administration, U.S. Department of Justice, or its successor agency.

"Deliver" or "delivery" means the actual, constructive, or attempted transfer of any item regulated by this chapter, whether or not there exists an agency relationship.

"Device" means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals or to affect the structure or any function of the body of man or animals.

"Dialysis care technician" or " dialysis patient care technician" means an individual who is certified by an organization approved by the Board of Health Professions pursuant to Chapter 27.01 (§ 54.1-2729.1 et seq.) and who, under the supervision of a licensed physician, nurse practitioner, physician assistant, or a registered nurse, assists in the care of patients undergoing renal dialysis treatments in a Medicare-certified renal dialysis facility.

"Dialysis solution" means either the commercially available, unopened, sterile solutions whose purpose is to be instilled into the peritoneal cavity during the medical procedure known as peritoneal dialysis, or commercially available solutions whose purpose is to be used in the performance of hemodialysis not to include any solutions administered to the patient intravenously.

"Dispense" means to deliver a drug to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing and administering, packaging, labeling, or compounding necessary to prepare the substance for that delivery. However, dispensing shall not include the transportation of drugs mixed, diluted, or reconstituted in accordance with this chapter to other sites operated by such practitioner or that practitioner's medical practice for the purpose of administration of such drugs to patients of the practitioner or that practitioner's medical practice at such other sites. For practitioners of medicine or osteopathy, "dispense" shall only include the provision of drugs by a practitioner to patients to take with them away from the practitioner's place of practice.

"Dispenser" means a practitioner who dispenses.

"Distribute" means to deliver other than by administering or dispensing a controlled substance.

"Distributor" means a person who distributes.

"Drug" means (i) articles or substances recognized in the official United States Pharmacopoeia National Formulary or official Homeopathic Pharmacopoeia of the United States, or any supplement to any of them; (ii) articles or substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals; (iii) articles or substances, other than food, intended to affect the structure or any function of the body of man or animals; (iv) articles or substances intended for use as a component of any article specified in clause (i), (ii), or (iii); or (v) a biological product. "Drug" does not include devices or their components, parts, or accessories.

"Drug product" means a specific drug in dosage form from a known source of manufacture, whether by brand or therapeutically equivalent drug product name.

"Electronic transmission prescription" means any prescription, other than an oral or written prescription or a prescription transmitted by facsimile machine, that is electronically transmitted directly to a pharmacy without interception or intervention from a third party from a practitioner authorized to prescribe or from one pharmacy to another pharmacy.

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

"FDA" means the U.S. Food and Drug Administration.

"Hashish oil" means any oily extract containing one or more cannabinoids, but shall not include any such extract with a tetrahydrocannabinol content of less than 12 percent by weight.

"Immediate precursor" means a substance which the Board of Pharmacy has found to be and by regulation designates as being the principal compound commonly used or produced primarily for use, and which is an immediate chemical intermediary used or likely to be used in the manufacture of a controlled substance, the control of which is necessary to prevent, curtail, or limit manufacture.

"Interchangeable" means a biosimilar that meets safety standards for determining interchangeability pursuant to 42 U.S.C. § 262(k)(4).

"Label" means a display of written, printed, or graphic matter upon the immediate container of any article. A requirement made by or under authority of this chapter that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any, of the retail package of such article or is easily legible through the outside container or wrapper.

"Labeling" means all labels and other written, printed, or graphic matter on an article or any of its containers or wrappers, or accompanying such article.

"Manufacture" means the production, preparation, propagation, conversion, or processing of any item regulated by this chapter, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of the substance or labeling or relabeling of its container. This term does not include compounding.

"Manufacturer" means every person who manufactures.

"Marijuana" means any part of a plant of the genus Cannabis whether growing or not, its seeds, or its resin; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds, or its resin. Marijuana shall not include any oily extract containing one or more cannabinoids unless such extract contains less than 12 percent of tetrahydrocannabinol by weight, nor shall marijuana include the mature stalks of such plant, fiber produced from such stalk, or oil or cake made from the seeds of such plant, unless such stalks, fiber, oil, or cake is combined with other parts of plants of the genus Cannabis.

"Medical equipment supplier" means any person, as defined in § 1-230, engaged in the delivery to the ultimate consumer, pursuant to the lawful order of a practitioner, of hypodermic syringes and needles, medicinal oxygen, Schedule VI controlled devices, those Schedule VI controlled substances with no medicinal properties that are used for the operation and cleaning of medical equipment, solutions for peritoneal dialysis, and sterile water or saline for irrigation.

"Narcotic drug" means any of the following, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis: (i) opium, opiates, and any salt, compound, derivative, or preparation of opium or opiates; (ii) any salt, compound, isomer, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in clause (i), but not including the isoquinoline alkaloids of opium; (iii) opium poppy and poppy straw; (iv) coca leaves and any salt, compound, derivative, or preparation of coca leaves, and any salt, compound, isomer, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, but not including decocainized coca leaves or extraction of coca leaves which do not contain

cocaine or ecgonine.

"New drug" means (i) any drug, except a new animal drug or an animal feed bearing or containing a new animal drug, the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling, except that such a drug not so recognized shall not be deemed to be a "new drug" if at any time prior to the enactment of this chapter it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use, or (ii) any drug, except a new animal drug or an animal feed bearing or containing a new animal drug, the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

"Nuclear medicine technologist" means an individual who holds a current certification with the American Registry of Radiological Technologists or the Nuclear Medicine Technology Certification Board.

"Official compendium" means the official United States Pharmacopoeia National Formulary, official Homeopathic Pharmacopoeia of the United States, or any supplement to any of them.

"Official written order" means an order written on a form provided for that purpose by the U.S. Drug Enforcement Administration, under any laws of the United States making provision therefor, if such order forms are authorized and required by federal law, and if no such order form is provided then on an official form provided for that purpose by the Board of Pharmacy.

"Opiate" means any substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining liability. It does not include, unless specifically designated as controlled under Article 4 (§ 54.1-3437 et seq.), the dextrorotatory isomer of 3-methoxy-n-methylmorphinan and its salts (dextromethorphan). It does include its racemic and levorotatory forms.

"Opium poppy" means the plant of the species Papaver somniferum L., except the seeds thereof.

"Original package" means the unbroken container or wrapping in which any drug or medicine is enclosed together with label and labeling, put up by or for the manufacturer, wholesaler, or distributor for use in the delivery or display of such article.

"Outsourcing facility" means a facility that is engaged in the compounding of sterile drugs and is currently registered as an outsourcing facility with the U.S. Secretary of Health and Human Services and that complies with all applicable requirements of federal and state law, including the Federal Food, Drug, and Cosmetic Act.

"Person" means both the plural and singular, as the case demands, and includes an individual, partnership, corporation, association, governmental agency, trust, or other institution or entity.

"Pharmacist-in-charge" means the person who, being licensed as a pharmacist, signs the application for a pharmacy permit and assumes full legal responsibility for the operation of the relevant pharmacy in a manner complying with the laws and regulations for the practice of pharmacy and the sale and dispensing of controlled substances; the "pharmacist-in-charge" shall personally supervise the pharmacy and the pharmacy's personnel as required by § 54.1-3432.

"Poppy straw" means all parts, except the seeds, of the opium poppy, after mowing.

"Practitioner" means a physician, dentist, licensed nurse practitioner pursuant to § 54.1-2957.01, licensed physician assistant pursuant to § 54.1-2952.1, pharmacist pursuant to § 54.1-3300, TPA-certified optometrist pursuant to Article 5 (§ 54.1-3222 et seq.) of Chapter 32, veterinarian, scientific investigator, or other person licensed, registered, or otherwise permitted to distribute, dispense, prescribe and administer, or conduct research with respect to a controlled substance in the course of professional practice or research in the Commonwealth.

"Prescriber" means a practitioner who is authorized pursuant to §§ 54.1-3303 and 54.1-3408 to issue a prescription.

"Prescription" means an order for drugs or medical supplies, written or signed or transmitted by word of mouth, telephone, telegraph, or other means of communication to a pharmacist by a duly licensed physician, dentist, veterinarian, or other practitioner authorized by law to prescribe and administer such drugs or medical supplies.

"Prescription drug" means any drug required by federal law or regulation to be dispensed only pursuant to a prescription, including finished dosage forms and active ingredients subject to § 503(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 353(b)).

"Production" or " produce" includes the manufacture, planting, cultivation, growing, or harvesting of a controlled substance or marijuana.

"Proprietary medicine" means a completely compounded nonprescription drug in its unbroken,

original package which does not contain any controlled substance or marijuana as defined in this chapter and is not in itself poisonous, and which is sold, offered, promoted, or advertised directly to the general public by or under the authority of the manufacturer or primary distributor, under a trademark, trade name, or other trade symbol privately owned, and the labeling of which conforms to the requirements of this chapter and applicable federal law. However, this definition shall not include a drug that is only advertised or promoted professionally to licensed practitioners, a narcotic or drug containing a narcotic, a drug that may be dispensed only upon prescription or the label of which bears substantially the statement "Warning - may be habit-forming," or a drug intended for injection.

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

"Reference biological product" means the single biological product licensed pursuant to 42 U.S.C. § 262(a) against which a biological product is evaluated in an application submitted to the U.S. Food and Drug Administration for licensure of biological products as biosimilar or interchangeable pursuant to 42 U.S.C. § 262(k).

"Sale" includes barter, exchange, or gift, or offer therefor, and each such transaction made by any person, whether as an individual, proprietor, agent, servant, or employee.

"Therapeutically equivalent drug products" means drug products that contain the same active ingredients and are identical in strength or concentration, dosage form, and route of administration and that are classified as being therapeutically equivalent by the U.S. Food and Drug Administration pursuant to the definition of "therapeutically equivalent drug products" set forth in the most recent edition of the Approved Drug Products with Therapeutic Equivalence Evaluations, otherwise known as the "Orange Book."

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

"Warehouser" means any person, other than a wholesale distributor, engaged in the business of selling or otherwise distributing prescription drugs or devices to any person who is not the ultimate user or consumer. No person shall be subject to any state or local tax by reason of this definition.

"Wholesale distribution" means distribution of prescription drugs to persons other than consumers or patients, subject to the exceptions set forth in § 54.1-3401.1.

"Wholesale distributor" means any person engaged in wholesale distribution of prescription drugs including, but not limited to, manufacturers; repackers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses conducting wholesale distributions, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies conducting wholesale distributions. No person shall be subject to any state or local tax as a wholesale merchant by reason of this definition.

The words "drugs" and "devices" as used in Chapter 33 (§ 54.1-3300 et seq.) and in this chapter shall not include surgical or dental instruments, physical therapy equipment, X-ray apparatus, or glasses or lenses for the eyes.

The terms "pharmacist," "pharmacy," and "practice of pharmacy" as used in this chapter shall be defined as provided in Chapter 33 (§ 54.1-3300 et seq.) unless the context requires a different meaning.

§ 54.1-3406. Records confidential; disclosure of information about violations of federal law.

A. No agent of the Board or agent designated by the Superintendent of the Department of State Police having knowledge by virtue of his office of any prescriptions, papers, records, or stocks of drugs shall divulge such knowledge, except in connection with a criminal investigation authorized by the Attorney General or attorney for the Commonwealth or with a prosecution or proceeding in court or before a regulatory board or officer, to which investigation, prosecution or proceeding the person to whom such prescriptions, papers or records relate is a subject or party. This section shall not be construed to prohibit the Board president or his designee and the Director of the Department of Health Professions from discharging their duties as provided in this title.

B. Notwithstanding the provisions of § 54.1-2400.2, the Board shall have the authority to submit to the U.S. Secretary of Health and Human Services information resulting from an inspection or an investigation indicating that a compounding pharmacy or outsourcing facility may be in violation of federal law or regulations with the exception of compounding for office-based administration in accordance with §54.1-3410.2.

§ 54.1-3410.2. Compounding; pharmacists' authority to compound under certain conditions; labeling and record maintenance requirements.

A. A pharmacist may engage in compounding of drug products when the dispensing of such compounded products is (i) pursuant to valid prescriptions for specific patients and (ii) consistent with

the provisions of § 54.1-3303 relating to the issuance of prescriptions and the dispensing of drugs.

Pharmacists shall label all compounded drug products that are dispensed pursuant to a prescription in accordance with this chapter and the Board's regulations, and shall include on the labeling an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding.

B. A pharmacist may also engage in compounding of drug products in anticipation of receipt of prescriptions based on a routine, regularly observed prescribing pattern.

Pharmacists shall label all products compounded prior to dispensing with (i) the name and strength of the compounded medication or a list of the active ingredients and strengths; (ii) the pharmacy's assigned control number that corresponds with the compounding record; (iii) an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding; and (iv) the quantity.

C. In accordance with the conditions set forth in subsections A and B, pharmacists shall not distribute compounded drug products for subsequent distribution or sale to other persons or to commercial entities, including distribution to pharmacies or other entities under common ownership or control with the facility in which such compounding takes place; however, a pharmacist may distribute to a veterinarian in accordance with federal law.

Compounded products for companion animals, as defined in regulations promulgated by the Board of Veterinary Medicine, and distributed by a pharmacy to a veterinarian for further distribution or sale to his own patients shall be limited to drugs necessary to treat an emergent condition when timely access to a compounding pharmacy is not available as determined by the prescribing veterinarian.

A pharmacist may, however, deliver compounded products dispensed pursuant to valid prescriptions to alternate delivery locations pursuant to § 54.1-3420.2.

A pharmacist may ~~also~~ provide *a reasonable amount of* compounded products to practitioners of medicine, osteopathy, podiatry, *or* dentistry~~, or veterinary medicine~~ to administer to their patients ~~in the course of their professional practice~~, either personally or under their direct and immediate supervision, *if there is a critical need to treat an emergency condition, or as allowed by federal law or regulations. A pharmacist may also provide compounded products to practitioners of veterinary medicine for office-based administration to their patients.*

Pharmacists *who provide compounded products for office-based administration for treatment of an emergency condition or as allowed by federal law or regulations* shall label all compounded products distributed to practitioners other than veterinarians for administration to their patients with (i) the statement "For Administering in Prescriber Practice Location Only"; (ii) the name and strength of the compounded medication or list of the active ingredients and strengths; (iii) the facility's control number; (iv) an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding; (v) the name and address of the pharmacy; and (vi) the quantity.

Pharmacists shall label all compounded products for companion animals, as defined in regulations promulgated by the Board of Veterinary Medicine, and distributed to a veterinarian for either further distribution or sale to his own patient or administration to his own patient with (a) the name and strength of the compounded medication or list of the active ingredients and strengths; (b) the facility's control number; (c) an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding; (d) the name and address of the pharmacy; and (e) the quantity.

D. Pharmacists shall personally perform or personally supervise the compounding process, which shall include a final check for accuracy and conformity to the formula of the product being prepared, correct ingredients and calculations, accurate and precise measurements, appropriate conditions and procedures, and appearance of the final product.

E. Pharmacists shall ensure compliance with USP-NF standards for both sterile and non-sterile compounding.

F. Pharmacists may use bulk drug substances in compounding when such bulk drug substances:

1. Comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if such monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding; or are drug substances that are components of drugs approved by the FDA for use in the United States; or are otherwise approved by the FDA;

2. Are manufactured by an establishment that is registered by the FDA; or

3. Are distributed by a licensed wholesale distributor or registered nonresident wholesale distributor, or are distributed by a supplier otherwise approved by the FDA to distribute bulk drug substances if the pharmacist can establish purity and safety by reasonable means, such as lot analysis, manufacturer reputation, or reliability of the source.

G. Pharmacists may compound using ingredients that are not considered drug products in accordance with the USP-NF standards and guidance on pharmacy compounding.

H. Pharmacists shall not engage in the following:

1. The compounding for human use of a drug product that has been withdrawn or removed from the market by the FDA because such drug product or a component of such drug product has been found to be unsafe. However, this prohibition shall be limited to the scope of the FDA withdrawal;

2. The regular compounding or the compounding of inordinate amounts of any drug products that are essentially copies of commercially available drug products. However, this prohibition shall not include (i) the compounding of any commercially available product when there is a change in the product ordered by the prescriber for an individual patient, (ii) the compounding of a commercially manufactured drug only during times when the product is not available from the manufacturer or supplier, (iii) the compounding of a commercially manufactured drug whose manufacturer has notified the FDA that the drug is unavailable due to a current drug shortage, (iv) the compounding of a commercially manufactured drug when the prescriber has indicated in the oral or written prescription for an individual patient that there is an emergent need for a drug that is not readily available within the time medically necessary, or (v) the mixing of two or more commercially available products regardless of whether the end product is a commercially available product; or

3. The compounding of inordinate amounts of any preparation in cases in which there is no observed historical pattern of prescriptions and dispensing to support an expectation of receiving a valid prescription for the preparation. The compounding of an inordinate amount of a preparation in such cases shall constitute manufacturing of drugs.

I. Pharmacists shall maintain records of all compounded drug products as part of the prescription, formula record, formula book, or other log or record. Records may be maintained electronically, manually, in a combination of both, or by any other readily retrievable method.

1. In addition to other requirements for prescription records, records for products compounded pursuant to a prescription order for a single patient where only manufacturers' finished products are used as components shall include the name and quantity of all components, the date of compounding and dispensing, the prescription number or other identifier of the prescription order, the total quantity of finished product, the signature or initials of the pharmacist or pharmacy technician performing the compounding, and the signature or initials of the pharmacist responsible for supervising the pharmacy technician and verifying the accuracy and integrity of compounded products.

2. In addition to the requirements of subdivision I 1, records for products compounded in bulk or batch in advance of dispensing or when bulk drug substances are used shall include: the generic name and the name of the manufacturer of each component or the brand name of each component; the manufacturer's lot number and expiration date for each component or when the original manufacturer's lot number and expiration date are unknown, the source of acquisition of the component; the assigned lot number if subdivided, the unit or package size and the number of units or packages prepared; and the beyond-use date. The criteria for establishing the beyond-use date shall be available for inspection by the Board.

3. A complete compounding formula listing all procedures, necessary equipment, necessary environmental considerations, and other factors in detail shall be maintained where such instructions are necessary to replicate a compounded product or where the compounding is difficult or complex and must be done by a certain process in order to ensure the integrity of the finished product.

4. A formal written quality assurance plan shall be maintained that describes specific monitoring and evaluation of compounding activities in accordance with USP-NF standards. Records shall be maintained showing compliance with monitoring and evaluation requirements of the plan to include training and initial and periodic competence assessment of personnel involved in compounding, monitoring of environmental controls and equipment calibration, and any end-product testing, if applicable.

J. Practitioners who may lawfully compound drugs for administering or dispensing to their own patients pursuant to §§ 54.1-3301, 54.1-3304, and 54.1-3304.1 shall comply with all provisions of this section and the relevant Board regulations.

K. Every pharmacist-in-charge or owner of a permitted pharmacy or a registered nonresident pharmacy engaging in sterile compounding shall notify the Board of its intention to dispense or otherwise deliver a sterile compounded drug product into the Commonwealth. Upon renewal of its permit or registration, a pharmacy or nonresident pharmacy shall notify the Board of its intention to continue dispensing or otherwise delivering sterile compounded drug products into the Commonwealth. Failure to provide notification to the Board shall constitute a violation of Chapter 33 (§ 54.1-3300 et seq.) or Chapter 34 (§ 54.1-3400 et seq.). The Board shall maintain this information in a manner that will allow the production of a list identifying all such sterile compounding pharmacies.

§ 54.1-3434.05. Permit to act as an outsourcing facility.

A. No person shall act as an outsourcing facility without first obtaining a permit from the Board.

B. Applications for a permit to act as an outsourcing facility shall be made on a form provided by the Board and signed by a pharmacist who will be in full and actual charge of the outsourcing facility

and who will be fully engaged in the compounding performed at the location designated on the application. Such application shall be accompanied by a fee determined by the Board in regulation. All permits shall expire annually on a date determined by the Board in regulation. No permit shall be issued or renewed for an outsourcing facility unless the facility can demonstrate compliance with all applicable federal and state laws and regulations governing outsourcing facilities.

C. As a prerequisite to obtaining or renewing a permit from the Board, the outsourcing facility shall (i) register as an outsourcing facility with the U.S. Secretary of Health and Human Services in accordance with 21 U.S.C. § 353b and (ii) submit a copy of a current inspection report resulting from an inspection conducted by the U.S. Food and Drug Administration that indicates compliance with the requirements of state and federal law and regulations, including all applicable guidance documents and Current Good Manufacturing Practices published by the U.S. Food and Drug Administration.

The inspection report required pursuant to clause (ii) shall be deemed current for the purposes of this section if the inspection was conducted (a) no more than one year prior to the date of submission of an application for a permit to the Board or (b) no more than two years prior to the date of submission of an application for renewal of a permit to the Board. However, if the outsourcing facility has not been inspected by the U.S. Food and Drug Administration within the required period, the Board may accept an inspection report or other documentation from another entity that is satisfactory to the Board, or the Board may cause an inspection to be conducted by its duly authorized agent and may charge an inspection fee in an amount sufficient to cover the costs of the inspection.

D. Every outsourcing facility shall compound in compliance with the requirements of state and federal law and regulations except §54.1-3410.2, to include all applicable guidance documents and Current Good Manufacturing Practices published by the U.S. Food and Drug Administration.

E. An outsourcing facility shall not engage in compounding of drug products to be dispensed pursuant to a valid prescription for a specific patient without first obtaining a permit to operate a pharmacy.

§ 54.1-3434.4. Prohibited acts.

A. It is unlawful for any person or entity which is not registered under this article to (i) conduct the business of shipping, mailing, or otherwise delivering Schedule II through VI controlled substances into Virginia or (ii) advertise the availability for purchase of any Schedule II through VI controlled substances by any citizen of the Commonwealth. Further, it shall be unlawful for any person who is a resident of Virginia to advertise the pharmacy services of a nonresident pharmacy ~~which~~ *or compounding services of an outsourcing facility that* has not registered with the Board, with the knowledge that the advertisement will or is likely to induce members of the public in the Commonwealth to use the pharmacy *or outsourcing facility* to obtain controlled substances.

B. Any controlled substance that is ordered or shipped in violation of any provision of this chapter, shall be considered as contraband and may be seized by any law-enforcement officer or any agent of the Board of Pharmacy.

§ 54.1-3434.5. Nonresident outsourcing facilities to register with the Board.

A. Any outsourcing facility located outside the Commonwealth that ships, mails, or delivers in any manner Schedule II through VI drugs or devices into the Commonwealth shall be considered a nonresident outsourcing facility and shall be registered with the Board.

B. Applications for registration to act as a non-resident outsourcing facility shall be made on a form provided by the Board and signed by a pharmacist who is licensed as a pharmacist in Virginia and who is in full and actual charge of the outsourcing facility, is fully engaged in the compounding performed at the location stated on the application, and is fully responsible for the outsourcing facility's compliance with state and federal law and regulations. Such application shall be accompanied by a fee determined by the Board in regulation. All registrations shall expire annually on a date determined by the Board in regulation.

C. As a prerequisite to registering or renewing a registration with the Board, the outsourcing facility shall (i) register as an outsourcing facility with the U.S. Secretary of Health and Human Services in accordance with 21 U.S.C. § 353b and (ii) submit a copy of a current inspection report resulting from an inspection conducted by the U.S. Food and Drug Administration that indicates compliance with the requirements of state and federal law and regulations, including all applicable guidance documents and Current Good Manufacturing Practices published by the U.S. Food and Drug Administration.

The inspection report required pursuant to clause (ii) shall be deemed current for the purposes of this section if the inspection was conducted (a) no more than one year prior to the date of submission of an application for registration with the Board or (b) no more than two years prior to the date of submission of an application for renewal of a registration with the Board. However, if the outsourcing facility has not been inspected by the U.S. Food and Drug Administration within the required period, the Board may accept an inspection report or other documentation from another entity that is satisfactory to the Board, or the Board may cause an inspection to be conducted by its duly authorized

agent and may charge an inspection fee in an amount sufficient to cover the costs of the inspection.

D. A nonresident outsourcing facility shall not engage in compounding of drug products to be dispensed pursuant to a valid prescription for a specific patient without first obtaining a registration to operate a nonresident pharmacy. The nonresident pharmacy shall comply with all state and federal laws, regulations, and requirements except § 54.1-3410.2.

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

ENROLLED

VIRGINIA ACTS OF ASSEMBLY — CHAPTER

An Act to amend and reenact § 54.1-3304.1 of the Code of Virginia, relating to Board of Pharmacy; practitioners dispensing controlled substances.

[H 2192]

Approved

Be it enacted by the General Assembly of Virginia:

1. That § 54.1-3304.1 of the Code of Virginia is amended and reenacted as follows:

§ 54.1-3304.1. Authority to license and regulate practitioners; permits.

A. The Board of Pharmacy shall have the authority to license and regulate the dispensing of controlled substances by practitioners of the healing arts. *Except as prescribed in this chapter or by Board regulations, it shall be unlawful for any practitioner of the healing arts to dispense controlled substances within the Commonwealth unless licensed by the Board to sell controlled substances.*

B. Facilities from which practitioners of the healing arts dispense controlled substances shall obtain a permit from the Board and comply with the regulations for practitioners of the healing arts to sell controlled substances. Facilities in which only one practitioner of the healing arts is licensed by the Board to sell controlled substances shall be exempt from fees associated with obtaining and renewing such permit.

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

Agenda Item: **Regulatory Actions - Chart of Regulatory Actions**

Staff Note: Attached is a chart with the status of regulations for the Board **as of March 2, 2015**

Action: None – provided for information only

Chapter		Action / Stage Information
[18 VAC 110 - 20]	Virginia Board of Pharmacy Regulations	Prohibition against incentives to transfer prescriptions [Action 4186] NOIRA - *At Secretary's Office for 255 days*
[18 VAC 110 - 20]	Virginia Board of Pharmacy Regulations	Addressing hours of continuous work by pharmacists [Action 3755] Proposed - *At Secretary's Office for 662 days*
[18 VAC 110 - 20]	Virginia Board of Pharmacy Regulations	Maintaining floor stock of certain drugs onsite at correctional facilities [Action 4157] Fast-Track - *At Governor's Office for 202 days*
[18 VAC 110 - 20]	Virginia Board of Pharmacy Regulations	Nonresident pharmacy renewal date and access by suspended pharmacists to prescription department [Action 4215] Fast-Track - *At Governor's Office for 127 days*
[18 VAC 110 - 20]	Virginia Board of Pharmacy Regulations	Drugs and emergency medical services agencies [Action 4216] Fast-Track - *At Governor's Office for 135 days*
[18 VAC 110 - 20]	Virginia Board of Pharmacy Regulations	Administrative fees for duplicate licenses and verification [Action 3444] Final - *At Governor's Office for 51 days*
[18 VAC 110 - 20]	Virginia Board of Pharmacy Regulations	(E) Placement of specified chemical compounds into Schedule I [Action 4296] Final - *Register Date: 1/12/15* *Effective: 2/11/15*

Board of Pharmacy
Regulatory/Policy Actions – Post-2015 General Assembly

EMERGENCY REGULATIONS:

Legislative source	Mandate	Promulgating agency	Board adoption date	Effective date Within 280 days of enactment
HB1737	Permits for outsourcing facilities	Board of Pharmacy	9/29/15	Enactment date not yet determined
HB2192	Permits for physician selling drugs facilities	Board of Pharmacy	9/29/15	Enactment date not yet determined

EXEMPT REGULATORY ACTIONS

Legislative source	Mandate	Promulgating agency	Adoption date	Effective date
HB1564	Deletion of chemicals scheduled by regulation	Board of Pharmacy	9/29/15	11/18/15

REGULATORY ACTIONS by APA

Legislative source	Mandate	Promulgating agency	Adoption date	Effective date
HB1733	Training program & regs for storage, etc. for PACE facilities	Board of Pharmacy	9/29/15	?

NON-REGULATORY ACTIONS

Legislative source	Mandate	Affected agency	Action needed	Due date
HB1736	Notice of BOP by wholesale distributors of cessation of sales	Board of Pharmacy	Letter to WD's	After July 1, 2015
HB1695	Limitation on mental health records/actions in disciplinary proceedings	All boards	DHP workgroup with Director	No set date
SB1167	Availability of epinephrine to persons in all settings	Board of Pharmacy	No action by DHP; cooperate with interested parties on workgroups	No set date
Letter from Chair	Drugs available to wildlife rehabilitators	Boards of Pharmacy & Veterinary Medicine	Workgroup with board representation, DGIF, VVMA & Wildlife Center	By November 1, 2015
HB1458	Development of protocol for dispensing of naxolone	Boards of Pharmacy & Medicine with VDH	Workgroup to develop protocol	After July 1, 2015
HB1841	Registration of prescribers and dispensers with PMP	DHP – PMP	Work with IT on registration plan	After July 1, 2015

18VAC110-20-727. Pharmacists repackaging for clients of a CSB or BHA.

A. As an alternative to repackaging as defined in 18VAC110-20-725, a pharmacist at a CSB or BHA may repackage a client's prescription drugs that have been dispensed by another pharmacy into compliance packaging ~~that complies with the requirements of 18VAC110-20-340 B and subsections G, H, and J of 18VAC110-20-725. A primary provider pharmacy may also provide this service in compliance with the provisions of 18VAC110-20-535.~~ under the following conditions:

1. A prescription drug order shall not be repackaged beyond the assigned expiration date noted on the prescription label of the dispensed drug, if applicable, or beyond one year from the date the drug was originally dispensed by a pharmacy, whichever date is earlier;

2. The compliance packaging must comply with the requirements of 18VAC110-20-340 B;

3. A record of repackaging shall be made and maintained for one year from the date of repackaging and shall include the following:

a. Date of repackaging;
b. Name of client;
c. Prescription number of the originally dispensed prescription drug order;
d. Pharmacy name;
e. Drug name and strength;
f. Quantity of drug repackaged; and
g. Initials of the person performing the repackaging and verifying the accuracy of the repackaged drug container.

4. Any portion of a prescription drug order remaining at the CSB or BHA that has exceeded any labeled expiration date or one year from the original pharmacy dispensing date on the label shall be separated from unexpired drugs, stored within a designated area of the board-approved drug storage location, and destroyed within 30 days of expiration with the written agreement of the client. Remaining portions of discontinued prescription drug orders retained by the CSB or BHA shall also be separated from active stock and either returned to the client or destroyed within 30 days of discontinuance with the written agreement of the client.

B. A primary provider pharmacy may also provide this service in compliance with the provisions of 18VAC110-20-535.

DISPOSAL REGULATIONS: REGISTRANT FACT SHEET

On September 8, 2014, the Drug Enforcement Administration (DEA) made available for public view a final rule regarding the disposal of pharmaceutical controlled substances in accordance with the Controlled Substance Act, as amended by the Secure and Responsible Drug Disposal Act of 2010 ("Disposal Act"). The final rule is available for public view at http://www.federalregister.gov/public-inspection. The final rule will officially publish in the *Federal Register* on September 9, 2014, and will be available on http://www.regulations.gov, and our website, http://www.DEAdiversion.usdoj.gov. This Registrant Fact Sheet contains a general summary of some of the effects of the new rule on registrants. For detailed information, please visit our website or contact your local DEA office.

1. What is the Disposal Act?

- The Disposal Act amended the Controlled Substances Act (CSA) to give the DEA authority to promulgate new regulations, within the framework of the CSA, that will allow ultimate users to deliver unused pharmaceutical controlled substances to appropriate entities for disposal in a safe and effective manner consistent with effective controls against diversion. The goal of the Disposal Act is to encourage public and private entities to develop a variety of methods of collection and disposal in a secure, convenient, and responsible manner.

2. What do the implementing regulations do?

- Effective October 9, 2014, the implementing regulations allow authorized manufacturers, distributors, reverse distributors, narcotic treatment programs, hospitals/clinics with an on-site pharmacy, and retail pharmacies to collect pharmaceutical controlled substances from ultimate users by voluntarily administering mail-back programs and maintaining collection receptacles. In addition, the regulations allow authorized hospitals/clinics and retail pharmacies to voluntarily maintain collection receptacles at long-term care facilities.

- The new regulations reorganize and consolidate previously existing regulations on disposal, including the role of reverse distributors. Effective October 9, 2014, the existing regulation on disposal of controlled substances, 21 C.F.R. 1307.21, will be removed. New requirements on proper disposal procedure and security will be in a new part 1317.

- As of October 9, 2014, all Memoranda of Agreement (MOA) and Memoranda of Understanding (MOU) issued pursuant to current 21 C.F.R. 1307.21 will be null and void. Registrants should consult 21 C.F.R. 1317.05(a) for information on new MOAs and MOUs for the disposal of controlled substances.

- Effective October 9, 2014, the existing regulation on return and recall, 21 C.F.R. 1307.12, will be removed. New return and recall requirements for registrants and non-registrants are incorporated into new 21 C.F.R. 1317.10 and 1317.85.

- Effective October 9, 2014, registrants must use DEA Form 41 to record the destruction of controlled substances. However, a controlled substance dispensed for immediate administration pursuant to an order for medication in an institutional setting remains under the custody and control of that registered institution even if the substance is not fully exhausted (*e.g.*, some of the substance remains in a vial, tube, transdermal patch, or syringe after administration but cannot or may not be further utilized, commonly referred to as "drug wastage" and "pharmaceutical wastage"). Such remaining substance must be properly recorded, stored, and

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destroyed in accordance with DEA regulations (*e.g.*, 21 C.F.R. 1304.22(c)), and all applicable Federal, State, tribal, and local laws and regulations, although the destruction need not be recorded on a DEA Form 41.

3. **Who is an "ultimate user"?**

   - The CSA defines an "ultimate user" as "a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or a member of his household."

4. **What is "collection"?**

   - "Collection" means to receive a controlled substance for the purpose of destruction from an ultimate user, a person lawfully entitled to dispose of an ultimate user decedent's property, or a long-term care facility on behalf of an ultimate user who resides or has resided at that facility. The term "collector" means a registered manufacturer, distributor, reverse distributor, narcotic treatment program, hospital/clinic with an on-site pharmacy, or retail pharmacy that is authorized to so receive a controlled substance for the purpose of destruction.

5. **How can a registrant become an "authorized collector"?**

   - Manufacturers, distributors, reverse distributors, narcotic treatment programs, hospitals/clinics with an on-site pharmacy, and retail pharmacies that desire to be collectors may do so by modifying their registration to obtain authorization to be a collector. Registrants may modify their registration online at http://www.DEAdiversion.usdoj.gov. Once authorized, these entities are "authorized collectors."

   - Eligible registrants must have authority to handle schedule II controlled substances.

   - Collectors are not authorized to conduct take-back events. Law enforcement may continue to conduct take-back events at any time. Any person or community group, registrant or non-registrant, may partner with law enforcement to conduct take-back events.

6. **Who can operate a collection receptacle for the collection of pharmaceutical controlled substances?**

   - Authorized collectors may maintain collection receptacles inside their registered location; and Federal, State, tribal, or local law enforcement may continue to maintain collection receptacles inside their physical location.

   - Authorized hospitals/clinics with an on-site pharmacy, and retail pharmacies, may maintain collection receptacles at long-term care facilities.

7. **Who can operate a mail-back program for the collection of pharmaceutical controlled substances?**

   - Authorized collectors with an on-site method of destruction may operate a mail-back program.

8. **If I become an authorized collector and decide to stop, how do I do so?**

   - *Collection receptacle:* Authorized collectors maintaining a collection receptacle must dispose of all collected pharmaceutical controlled substances in their possession in accordance with the new rule, and notify the DEA that collection activities are ceasing, in writing or online at http://www.DEAdiversion.usdoj.gov.

- *Mail-back program:* Authorized collectors operating a mail-back program must make a reasonable effort to notify the public prior to discontinuing or ceasing collection; obtain the written agreement of another collector to receive all remaining mail-back packages; and notify the DEA that collection activities are ceasing, in writing or online at http://www.DEAdiversion.usdoj.gov.

9. **What can I collect as an authorized collector?**

- An authorized collector may collect pharmaceutical controlled substances and non-controlled substances. Controlled and non-controlled pharmaceuticals may be co-mingled in a single collection receptacle, however it is not required.

- Controlled substances that are collected from ultimate users shall not be co-mingled with a registrant's inventory/stock of controlled substances (*i.e.*, registrants shall not dispose of controlled substance inventory in a collection receptacle or mail-back package, or through a take-back event).

10. **Can ultimate users dispose of illicit drugs through a collection receptacle, mail-back package, or take-back event?**

- No. Ultimate users may not dispose of illicit drugs (*e.g.*, schedule I controlled substances such as marijuana, heroin, LSD) through any of the three disposal methods.

11. **I am a pharmacist. If my pharmacy chooses to become an authorized collector, will we need to collect and retain information about persons who utilize the collection receptacle, such as a person's name, prescription information, or physician information?**

- No. A collector shall not require any person to provide any personally identifying information.

12. **How does a registrant dispose of controlled substances when 21 C.F.R. 1307.21 is removed?**

- The authorized methods and procedures regarding disposal are outlined, in 21 C.F.R. 1317.05, according to whether the substances being disposed of are practitioner inventory, non-practitioner inventory, or collected controlled substances.

13. **How can a registrant destroy controlled substances?**

- The new regulations do not require a particular method of destruction, so long as the desired result is achieved. Pharmaceutical controlled substances must be rendered "non-retrievable" in compliance with all applicable Federal, State, tribal and local laws. This standard is intended to allow public and private entities to develop a variety of destruction methods that are secure, convenient, and responsible, consistent with preventing the diversion of such substances.

- "Non-retrievable" means the condition or state to which a controlled substance shall be rendered following a process that permanently alters that controlled substance's physical or chemical condition or state through irreversible means and thereby renders the controlled substance unavailable and unusable for all practical purposes. A controlled substance is considered "non-retrievable" when it cannot be transformed to a physical or chemical condition or state as a controlled substance or controlled substance analogue.

Johnson, Sammy (DHP)

From:	Shriner, Susan R <Susan.Shriner@USONCOLOGY.COM>
Sent:	Friday, January 16, 2015 3:14 PM
To:	Johnson, Sammy (DHP)
Cc:	Harris, Torrea S
Subject:	Camera-facilitated Prescription Verification Process
Attachments:	LAKE WRIGHT REMOTE PRESCRIPTION APPROVAL.PPTX; Logitech camera workstation.jpg; Physician Image.jpg; Vote button.docx

Mr. Samuel Johnson,

Our Lake Wright In-office Dispensary located in Norfolk, VA was inspected and approved by Nan Dunaway on Tuesday, January 6, 2015. At this location, there may be 12 physicians seeing patients on any given day, located on different floors of the building. We are seeking approval of a camera-facilitated Prescription Verification Process. This process will allow the physicians to view all aspects of the completed prescription accurately and efficiently. We can track the time and date of the physician review and approval and attach those to the hardcopy prescription. Below, you will find the detailed workflow of our proposed process:

1. The prescription is e-scribed to the dispensary by the physician.
2. The technician will fill the prescription.
3. The technician will stage all the necessary items (prescription, DUR, stock bottle, label, tablets) for the camera to take the image.
4. The image is then emailed to the physician for his/her review. The physician can zoom in and pan around to view the image entirely.
5. The physician will then use the "Vote" button to "Approve" or "Reject" the prescription.
6. The physician response will be emailed back to the technician.
7. If approved, the technician will complete the dispensing process. The approval will be printed and attached to the prescription hardcopy and filed away.
8. If rejected, the physician will contact the technician via telephone for corrections. After the corrections are complete, a new image will be re-sent to the physician for approval.

We look forward to hearing from you about this matter. You will find several attachments that represent the workflow process: example of image for physician review, image of Logitech camera workstation, and vote button. Please feel free to contact me if you have any further questions.

Susan R. Shriner, RPh
Clinical Pharmacist
Virginia Oncology Associates
Port Warwick
757-873-9870--Office
757-873-4099--Fax

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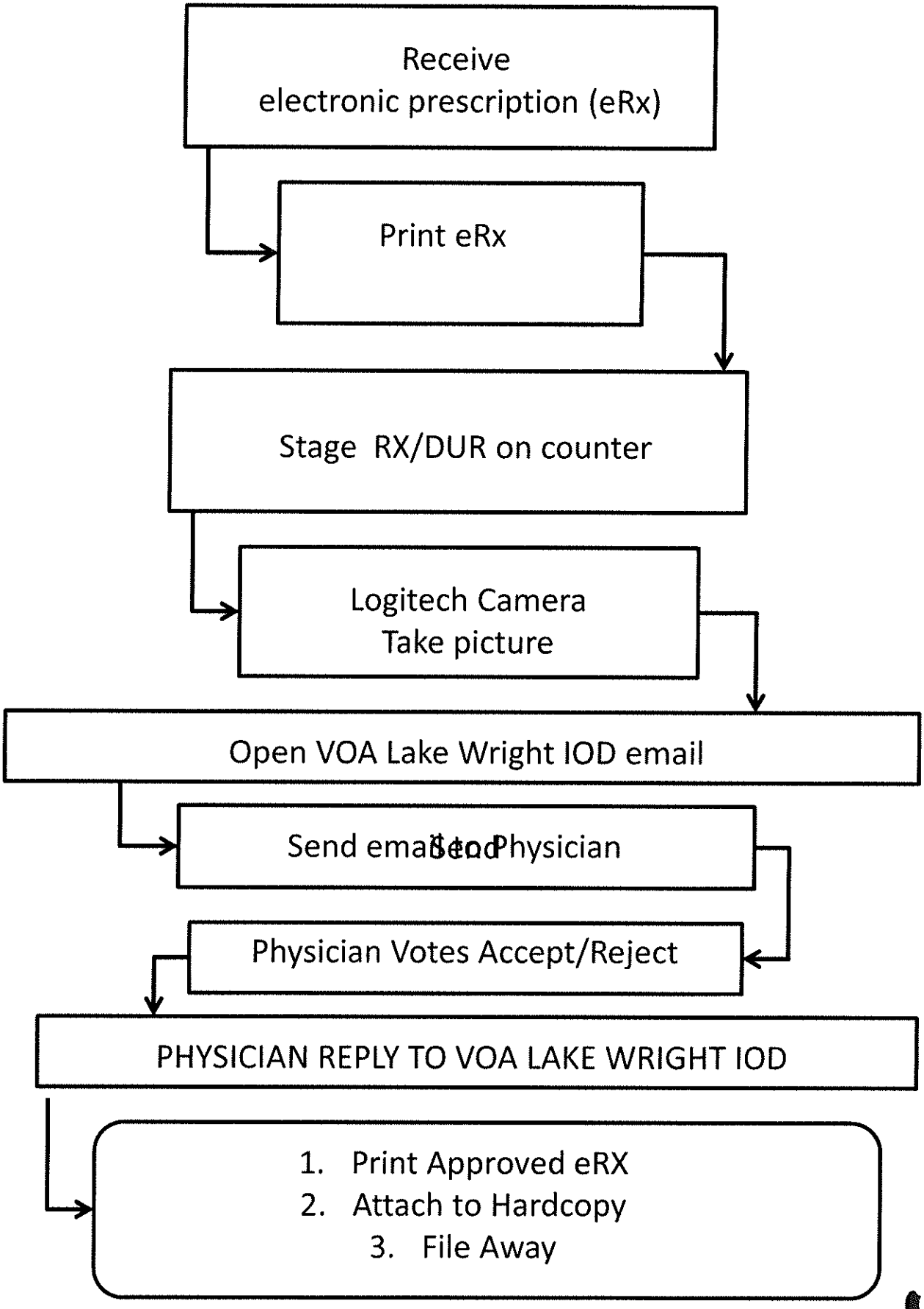
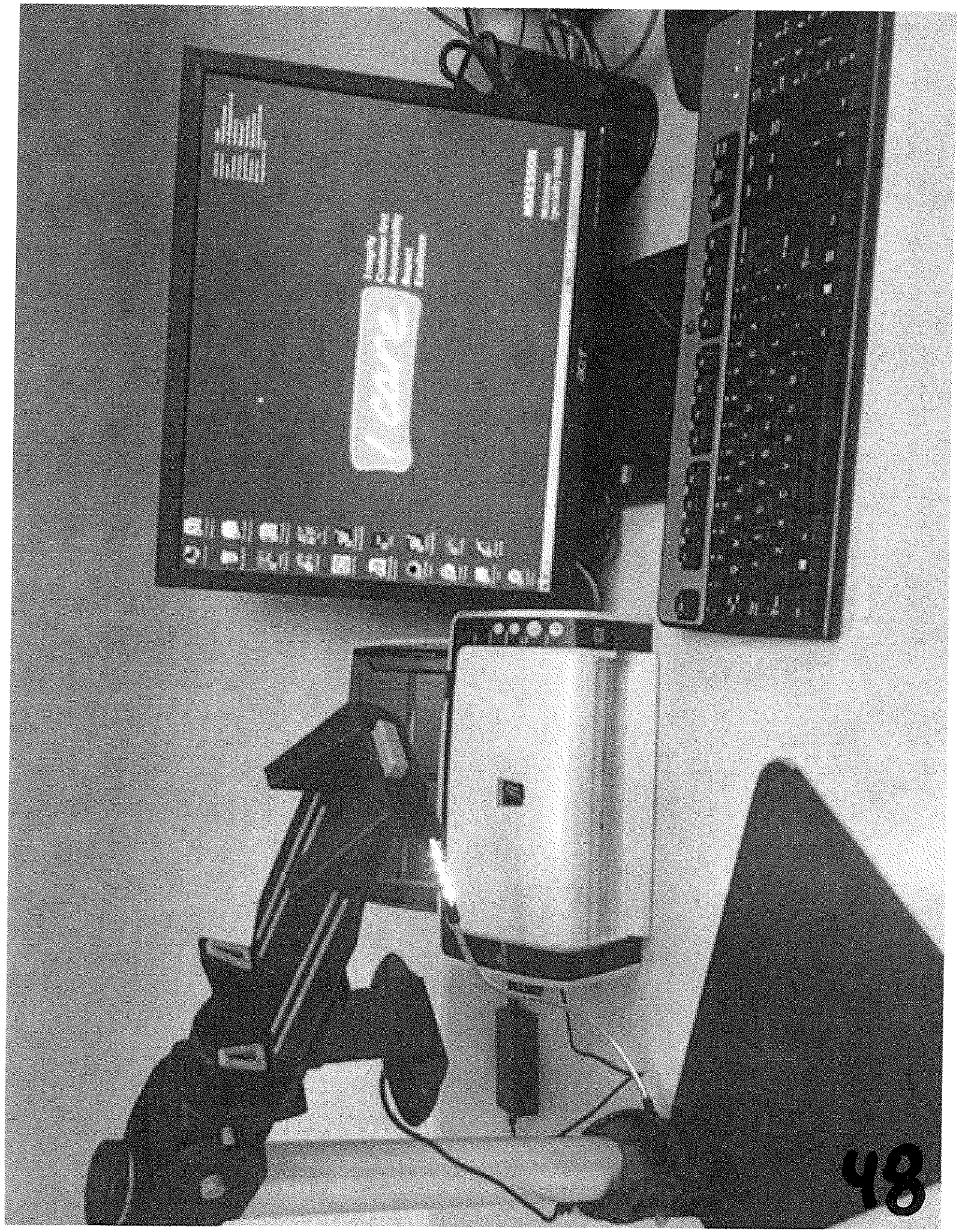
VOA LAKE WRIGHT REMOTE PRESCRIPTION APPROVAL





rom PPI
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/27/1953

: DIPHENHYDRAMINE HCL 25MG CAPSULES

1/14/2015
ablet Refills 1 Days Supply 30
o Product Selection Indicated

E CAPSULE THREE TIMES A DAY

escriber

ht Dr
503

riseRx™

N DOE
MAIN ST
RTSMOUTH State VA
7/1953 Zip 23704
s
DAVID POWELL
ENHYDRAMINE HCL 25MG CAPS

Rx# 8000001N (8)
DOE, JOHN
DIPHENHYDRAMINE HCL 25MG CAPS #30
TAKE ONE CAPSULE BY MOUTH THREE TIMES A DAY
MD POWELL, DAVID
"SAFETY CAPS"
CAPS 0 REFILLS 1
CASH

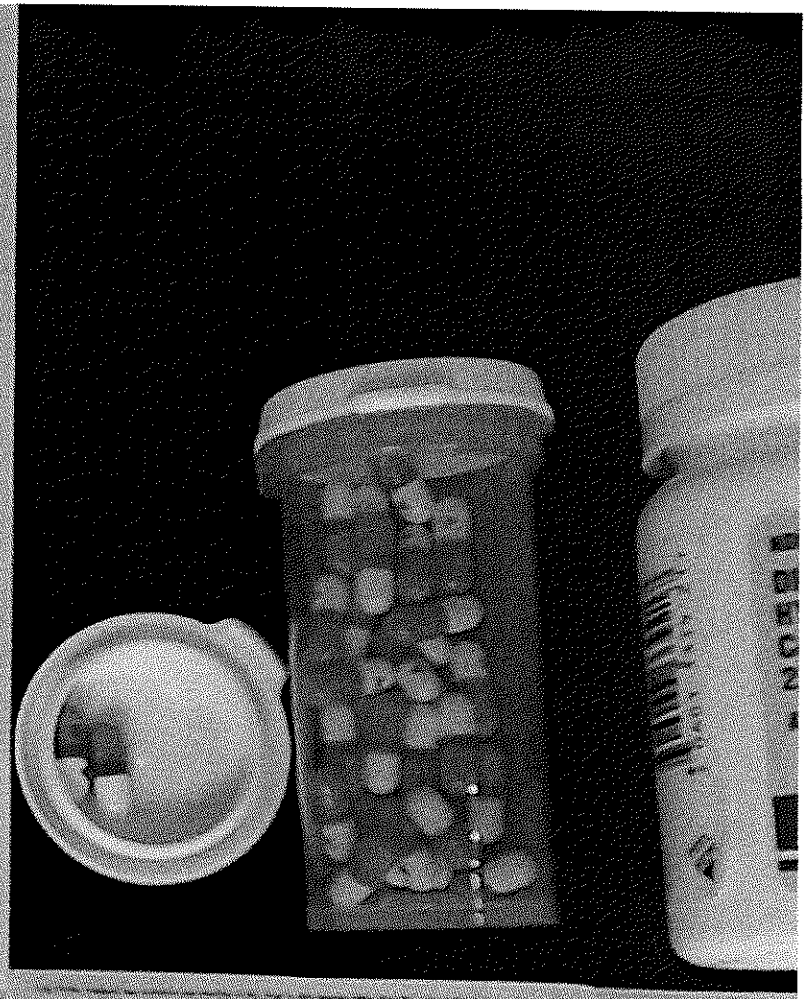
DUR Exceptions
version 1.5

Page 1 of 1

Pharmacy: VIRGINIA ONCOLOGY
Street Address: 5900 LAKE WRIGHT DR
City: NORFOLK State VA
Zip 23502

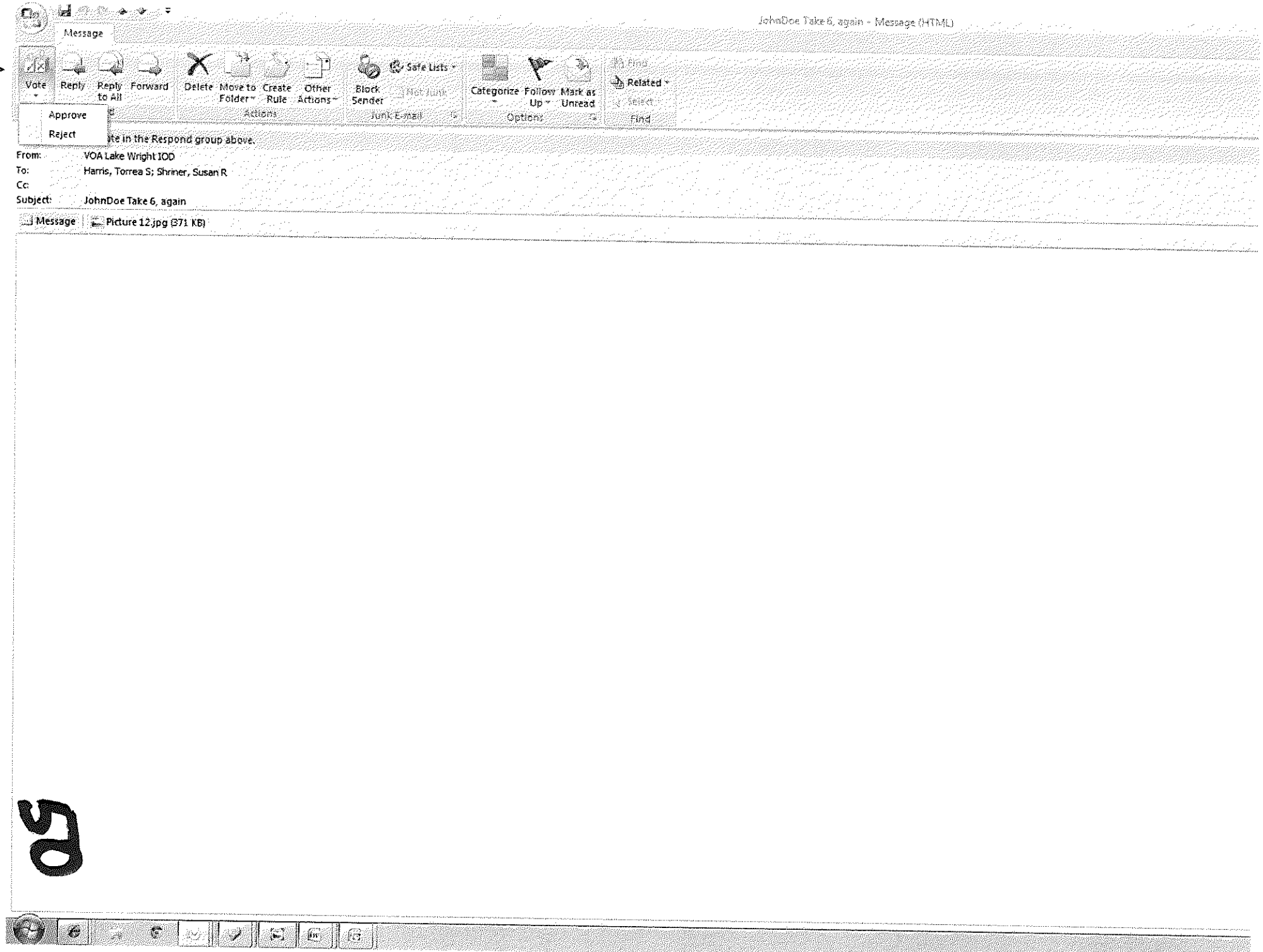
Rx Number: 8000001 Rx Number: 0000000018
Quantity: 30 CAPSULES
Total Daily Dose: 3 CAPSULES
Frequency: 3 Times Per Day

Benadryl
MINE HCl Oral Capsule 25 MG (Anti-Histamines, Diphenhydramine type) may result in
be a reported history of allergy to Benadryl (Antihistamines, Diphenhydramine type) in
reaction was experienced. PHYSICIAN SHOULD BE NOTIFIED



VIRGINIA ONCOLOGY ASSOCIATES

Rx# 8000001N
JOHN DOE
TAKE ONE CAPSULE BY MOUTH THREE TIMES A DAY
DIPHENHYDRAMINE HCL 25MG CAPS
"SAFETY CAPS"
DOE, JOHN
DIPHENHYDRAMINE
TRIAM


JohnDoe Take 6, again - Message (HTML)
Message
Vote
Reply
Reply to All
Forward
Delete
Move to Folder
Create Rule
Other Actions
Block Sender
Safe Lists
Not Junk
Categorize
Follow Up
Mark as Unread
Related
Select
Find
Actions
Junk E-mail
Options
Approve
Reject
te in the Respond group above.
From: VOA Lake Wright IOD
To: Harris, Torrea S; Shriner, Susan R
Cc:
Subject: JohnDoe Take 6, again
Message
Picture 12.jpg (371 KB)

the security technology. Additionally, Mr. Carter stated that the TransferSafe mechanism is used only to transfer prescriptions of Schedule VI drugs; the TransferRx mechanism is used to transfer prescriptions of drugs in Schedule III – VI. To comply with federal requirements, Mr. Carter stated that the TransferRx mechanism is used to transfer prescriptions for drugs in Schedules III-V only after verbal communication with a pharmacist. When using TransferRx to transfer prescriptions for drugs in Schedules VI, Mr. Carter stated the transfer information is communicated via fax in accordance with 18VAC110-20-360.

MOTION:

The Board voted unanimously that, in concept, the TransferSafe and TransferRx mechanisms as described by Walgreens appears to meet compliance with Regulation 18VAC110-20-360; TransferSafe may be used to transfer prescriptions for drugs in Schedule VI; and TransferRx may be used to transfer prescriptions for drugs in Schedules III-VI, if compliant with federal rules. (motion by Munden, second by Adams)

PRESENTATION BY WALGREENS FOR APPROVAL, IN CONCEPT, OF NEW STORE LAYOUT:

Al Carter and Rusty Maney from Walgreens presented a video to the Board showing a new store layout that Walgreens has constructed in other states. Walgreens believes the new layout will allow the pharmacist to be more accessible and have more time to counsel the customers, or assist with any questions that they might have. All phone calls are received by a central fulfillment center located in Florida, thereby decreasing staff distractions. Mr. Carter reported that pharmacists spend approximately 30% of their day fielding telephone calls. The data entry of most prescriptions is also handled remotely by the central fulfillment center in compliance with Regulation 18VAC110-20-276. The store layout physically separates the pharmacist from the area where the drugs are located; however, the pharmacist must enter that area to obtain the Schedule II drugs for the pharmacy technicians. Security cameras are located in the drug storage area and the pharmacist views monitors to supervise the pharmacy technician activity. Walgreens believes the security cameras are deterring drug diversions. Additionally, the pharmacist performs the verification of the accuracy of the dispensed drug by viewing photo images of the vial and the drug within the vial which are captured by the pharmacy technician during the dispensing process. Also, as a quality assurance, the dispensed quantity is weighed by the pharmacy technician to ensure accuracy of the dispensed quantity. The weight is viewed by the pharmacist during the verification process.
In response to Board member questions, Mr. Carter indicated the following: only one prescription can be dispensed at a time; each dispensed drug is placed in a separate bag; the pharmacist's computer screen has a privacy filter on it to eliminate customer viewing; counseling has increased from 12% to 40% in stores with the new layout; the first store with this layout opened approximately one year ago; administration of immunizations and patient counseling will occur in the separate room located near the pharmacist's computer terminal; no drugs or paraphernalia will be stored in the separate room as this room is not part of the licensed prescription department; drugs to be administered in the separate room will have already been dispensed to the specific

patient; no drug diversions have occurred as of yet in the stores with the new layout; Indiana, Illinois, New York, and the District of Columbia have approved the new store layout and currently have stores with the new layout located in the area; no state as of yet has denied the approval of the new store layout; and Mr. Carter intends to seek approval from all state Boards of Pharmacy.

MOTION:

The Board voted unanimously that, in concept, the new store layout as described by Walgreens appears to meet compliance with Regulations 18VAC110-20-150, 18VAC110-20-180, and 18VAC110-20-190 regarding physical and security standards, and the use of cameras and monitors for pharmacists on-duty to supervise pharmacy technicians and verify the accuracy of dispensed drugs appears to comply with 18VAC110-20-270. (motion by Munden, second by Stelly)

REQUEST FROM *THE PHARMACY ALLIANCE* TO DISCUSS IMPLEMENTING MANDATES TO ADDRESS "SYSTEM INDUCED ERRORS"

Priscilla Gale addressed the Board on behalf of *The Pharmacy Alliance* with concerns of working conditions in the pharmacy which may contribute to prescription errors. Ms. Gale explained that it was not right to hold the pharmacists accountable for errors and not the facility permit holders. Her concerns were related to long work hours, lack of meal times or breaks, not enough staff, loud music being played in the store and corporate policies that were distracting and increase errors. There was also discussion of corporate standards in which prescriptions were guaranteed within a certain length of time. To assist the Board in its discussion, Ms. Juran commented that several of the nine issues referenced in the email from The Pharmacy Alliance on page 85 of the agenda packet had recently been discussed or addressed by this Board. Specifically, #1, the prohibition of guaranteeing a dispensed prescription to be ready in a specific period of time had been discussed at a recent full Board meeting and Board counsel had advised that prohibiting this business practice could be construed as a possible violation of the Federal Trade Commission; #2 and #3 regarding restrictions on the number of hours a pharmacist may continuously work and mandatory meal breaks will be discussed at the June board meeting at the conclusion of the public comment period for a recently received petition for rulemaking; #7 and #8 regarding the reporting of medication errors has recently been addressed in statute and the development of the CQI regulations currently awaiting the Governor's signature; and #9 regarding a prohibition in influencing a pharmacist's decision regarding the practice of pharmacy is already addressed in Regulation 18VAC110-20-110B. Therefore, Ms. Juran recommended that the Board may want to focus its discussion on the other items listed.

ACTION ITEM:

Ms. Shinaberry recommended, and the full Board supported, that the following issues be referred to the Regulation Committee for further consideration: prohibition of any guarantee or advertisement that promotes how fast prescriptions will be dispensed; requirement that drive-thru windows be closed when there is no pharmacy technician support in the prescription department; prohibition against mandatory corporate production metrics or quotas regarding prescription dispensing or immunization

Virginia Board of Pharmacy

FEDERAL AND STATE DRUG LAW EXAMINATION HANDBOOK

September 2012

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Contacts

All questions about the FSDLE written examinations should be directed to:

ISO Quality Testing, Inc.
25400 US Hwy 19 N., Suite 285
Clearwater, FL 33763
Phone: 727-733-1110
Fax: 727-733-5758

Questions about licensing should be directed to:

Virginia Board of Pharmacy
9960 Mayland Drive, Suite 300
Henrico, VA 23233
Phone: 804-367-4456
Fax: 804-527-4472

FSDLE GUIDE AND INFORMATION

This Handbook will provide you with the necessary information regarding scheduling your Virginia Federal and State Drug Law Examination (FSDLE).

Purpose of Examination

Pharmacists, among all the health professionals, are entrusted with the most important drug control responsibilities. To ensure entry-level competence, the Virginia Board of Pharmacy administers a combined federal and state drug law examination. A single examination tests candidates' knowledge of Federal Drug Law and Virginia Pharmacy Law and Regulations.

Scheduling your FSDLE Exam through Iso-Quality Testing (IQT)

The state of Virginia has contracted with Iso-Quality Testing (IQT) to conduct its examination program. You are now able to register for your FSDLE Exam at any of IQT's locations, via the IQT website www.isoqualitytesting.com. A listing of the IQT test centers can be found by visiting their website or by calling their toll free registration number at: 866-773-1114 between 8 a.m. and 5 p.m. (Eastern Time) Monday through Friday.

Appointments are available Monday through Friday at most testing centers with some weekend availabilities. You must schedule your exam at least 5 days prior to your potential exam date.

Cancelling or rescheduling your exam: If you fail to show up for your examination at the scheduled time, do not have the proper identification, or do not have your admission document, you will not be allowed to sit for your exam and you will be considered a "No-Show", your examination fees will be forfeited, and you will be required to re-register and pay all fees prior to sitting for the exam. However, if an issue arises that prohibits you from making it to your scheduled exam, you may reschedule **up to (5) calendar days** before your scheduled exam date.

At the time of registration you will be asked a series of questions:

- **Full Legal Name –** Your official name on record given to the Virginia Board of Pharmacy.
- **Social Security number or Virginia DMV control number –** This is your personal identification number that will be used by both the Virginia Board of Pharmacy and IQT.
- **When** – The day and time you wish to take your exam.
- **Where –** The location of the Testing Center.
- **Payment –** You must pay IQT for the exam with a personal credit card. Should you require other arrangements please contact IQT.

All FSDLE data is the property of the Virginia Board of Pharmacy and may not be used for any other purpose than authorized by this order.

Format of the FSDLE and Fees

The exam consists of 100, multiple-choice questions. It includes several simulations of prescriptions, labels, and refill records. Only one correct response exists for each question. Candidates are given two hours for its completion. A passing score of 75 is required. The fee for this exam is $112 and payable to IQT at the time of registration.

Taking the Examination

Your examination will be administered via computer at an IQT Testing Center. You should arrive 10 minutes prior to your schedule appointment to allow time for you to sign in, verify your Identification, and allow you to familiarize yourself with the software. You do not need any computer experience or typing skills to take the exam. You have available to you a demo test that will familiarize you with the testing software and its features. The link for the demo test is https://www.iqttesting.com/Default.aspx?Function=SampleExam&Exam=8. This demo test is available to you any time prior to you taking your exam and you can access it as often as you like.

Identification

Prior to test administration you must provide the testing center positive identification. The identification presented must be valid government issued ID and include a current photograph, full legal name as submitted during registration, signature, and social security number or Virginia DMV control number. This information may be presented in more than one form of identification.

Acceptable forms of Identification include driver's licenses, government identification cards, passports, alien residency cards, and military identification.

Failure to provide appropriate identification at the time of examination will be considered a missed appointment. This will result in forfeiture of exam fees.

For additional information on identification and authorization please contact IQT before scheduling your exam.

Special Accommodations

Should you require special accommodations please contact the Virginia Board of Pharmacy prior to scheduling your exam.

Survey

At the end of your exam you will be asked a series of questions regarding your overall testing experience. All completed surveys are forwarded to IQT for further evaluation.

Exam Results

At the end of your exam you will be issued a pass/fail letter. You will then sign out on the daily sign in/out log. If successful in passing, you will receive your license to practice from the Virginia Board of Pharmacy within one week. It is important to note the pass letter is not considered authorization to begin practicing.

Retesting

If you fail the exam you may retake it only after a 30-day waiting period. Please visit the website www.isoqualitytesting.com to schedule your retake. You will be required to pay the examination fee of $112 each time the test is administered.

Be sure to obtain all references listed for the examination. The supplemental references listed herein are highly recommended. You should become thoroughly familiar with the study guide. To prepare for the examination the candidate is referred to the behavioral objectives for a description of the exam's content.

You should recognize that the list of competencies or behavioral objectives in this guide specifies the title, chapter, and section number of the law and regulations for which test questions exist. Only specified sections within each chapter of the law are tested. While emphasis should be placed on the sections specifically indicated, it is recommended that you master all the relevant law and regulations for full comprehension.

The examination covers all state and federal law and regulations required for competent entry-level practice. Since much of state drug law duplicates federal law, emphasis is placed on state law, and where possible, information is referenced to state law rather than to federal law. Specific mention of titles, chapters, and sections of federal drug law is limited to those areas of federal law not already covered within the body of state specific law.

It is recommended that you supplement your study of pharmacy law by reading additional text books, journals, and related academic course materials.

Recognize that laws, rules, and standards are modified from time to time, and it is your responsibility to keep your knowledge current during the course of your future professional practice.

Federal and State Drug Law Exam (FSDLE)

List of References

1. *Code of Virginia*
   Pharmacy, General Provisions
   (54.1-3300 through 54.1-3319)

2. Board of Pharmacy Regulations
   (18 VAC 110-20-10 through 18VAC 110-20-680)

3. *Code of Virginia*
   Drug Control Act
   (54.1-3400 through 54.1-3472)

4. *Code of Virginia*
   Crimes Involving Health & Safety
   (18.2-247 through 18.2-265)
   (18.2-8 through 18.2-16)

5. *Code of Virginia*
   Department of Health Professions
   General Provisions
   (54.1-2400 through 54.1-2409)

6. *Code of Virginia*
   Department of Health Professions
   (54.1-2500 through 54.1-2510)

7. *Federal Controlled Substance Act*
   (21 USC 801 et seq)
   (21 CFR 1301 et seq)

8. *Federal Food, Drug, and Cosmetic Act* (FDCA)
   (21 USC 301 et seq)

9. *Prescription Drug Marketing Act* of 1987
   (21 USC 353)

Suggested Supplemental References

1. *Pharmacy Law Digest*
   Facts and Comparisons, Inc.
   111 West Port Plaza, Suite 400
   St. Louis, MO 63146-3098
   800.223.0554

Website Links

VIRGINIA BOARD OF PHARMACY: www.dhp.virginia.gov/pharmacy
Click on Laws and Regulations

UNITED STATES CODE: http://www.gpoaccess.gov/uscode/index.html

CODE OF FEDERAL REGULATIONS: http://www.gpoaccess.gov/cfr/index.html

I. LICENSING, REGISTRATION, AND INSPECTION (24%)

A. Obtain, renew, and maintain pharmacist license
   1. Describe the requirements and procedures involved in obtaining and renewing a pharmacist license (54.1-3310, 54.1-3311, 54.1-3312, 54.1-3313, 54.1-3314, 18 VAC 110-20-20, 18 VAC 110-20-30, 18 VAC 110-20-40, 18 VAC 110-20-50, 18 VAC 110-20-60, 18 VAC 110-20-70, 18 VAC 110-20-80)
   2. Explain the requirements for completing continuing education and maintaining documentation (54.1-3314.1, 18 VAC 110-20-80, 18 VAC 110-20-90, 18 VAC 110-20-100)
   3. Explain dispensing activities which are restricted to pharmacists (54.1-3320,18 VAC 110-20-270)
      (a) Describe registration procedures for obtaining and renewing registration for pharmacy technicians (54.1-3321,18 VAC 110-20-101, 18 VAC 110-20-105, 18 VAC 110-20-106)
      (b) Explain authorized duties of registered pharmacy technicians (54.1-3321, 18 VAC 110-20-111, 18 VAC 110-20-270)
      (c) Explain requirements and responsibilities for supervising intern practical experience (54.1-3320 (B), 54.1-3321(C),18 VAC 110-20-40(B))
      (d) Explain scope of practice
         (i) Practice of pharmacy (54.1-3300, 54.1-3408 (I))
         (ii) Pharmacy intern (54.1-3300)
         (iii) Pharmacy technician (54.1-3300)
         (iv) Supervision, personal supervision(54.1-3300,18 VAC 110-20-10)

B. Maintain standards of legal and professional conduct
   1. Explain grounds for disciplinary action
      (a) List the grounds for revocation or suspension of a pharmacist's license or of a pharmacy permit (54.1-3315, 54.1-3316, 54.1-2408.1, 54.1-2409)
      (b) Recognize requirement to maintain patient confidentiality (32.1-127.1:03)
      (c) Describe prohibitions regarding patient's right to choose and disclosure of kickbacks, fee-splitting (18 VAC 110-20-390)
      (d) Recognize practice constituting unprofessional conduct (18VAC 110-20-25, 54.1-3316)

C. Obtain, renew, and maintain pharmacy permits
   1. Explain the requirements and procedures involved in obtaining and renewing a pharmacy permit (54.1-3434, 18 VAC 110-20-20, 18 VAC 110-20-110, 18 VAC 110-20-120)

(a) File application to open a new pharmacy, change location of an existing pharmacy, make structural changes to a prescription department, or make changes to a previously approved security system (54.1-3434, 18 VAC-110-20-140)
(b) Describe the requirements for display of pharmacy permit (54.1-3430)
(c) Describe the responsibilities for the pharmacist in charge (54.1-3432, 54.1-3434, 18 VAC 110-20-110, 18 VAC 110-20-440)

2. Meet physical requirements, restrict access and maintain proper storage and security of all Schedule II-VI controlled substances and devices
   (a) Explain the requirements for physical standards and minimum required equipment for pharmacies (18 VAC-110-20-150, 18 VAC 110-20-160, 18 VAC-110-20-170)
   (b) Explain the requirements for enclosures to the prescription department (as defined in regulation) and access to the prescription department both in the presence or absence of a pharmacist (18 VAC 110-20-10, 18 VAC 110-20-190)
   (c) Explain the requirements for an alarm system and when it should be activated (18 VAC 110-20-180)
   (d) Explain the requirements for appropriate storage for drugs, devices, controlled substances, controlled paraphernalia, and expired drugs (18-VAC 110-20-200, 54.1-3469)
   (e) Explain the requirement for drug storage and security outside the pharmacy, throughout hospitals and long term care facilities (18 VAC 110-20-420(A)(1), 18 VAC 110-20-440, 18 VAC 110-20-530 (3-6), 18 VAC 110-20-470(1))
   (f) Explain the requirements and documentation for managing after-hours access to the pharmacy in a hospital (18 VAC 110-20-450)
3. Explain the procedures for closing a pharmacy, changing hours of operation, changing ownership, and appropriate disposition of drugs and records (54.1-3434, 54.1-3434.01, 18 VAC 110-20-130, 18 VAC 110-20-135)
4. Explain the requirements for implementing a pharmacy Continuous Quality Improvement program (54.1-3434.03)

D. Comply with inspection authority of the Board of Pharmacy and the State Police
   1. Describe powers of inspection and inspection procedures and access to records by board agents and state police (54.1-3307, 54.1-3308, 54.1-3405)
   2. Describe access to prescription records during inspections (54.1-3405)

E. Comply with DEA and FDA requirements
   1. Determine the need for and describe the procedures involved in obtaining and renewing DEA registration (21 CFR 1301)
   2. Explain the regulations governing discontinuance of practice (21 CFR 1301.52, 21 CFR 1307.21)

3. Explain the requirements for registration modification and transfer (21 CFR 1301.51, 21 CFR 1301.52)
4. Describe powers of inspection, inspection procedures, access to records by DEA and FDA agents, and rights of pharmacists (21 CFR 1316, 21 USC 360(h), 21 USC 374))
5. Understand the restrictions which are imposed on the hiring of persons having access to Schedule II-V controlled substances (21 CFR 1301.76)

II. ORDERING, RECEIVING, AND MANAGING DRUG INVENTORY (20%)

A . Ordering and receiving controlled substances

1. Determine the conditions for legally transferring Schedule II-VI controlled substances between registrants (54.1-3414, 54.1-3415, 54.1-3435.02)
2. Explain the use of official DEA order forms in ordering and transferring Schedule II controlled substances (21 CFR 1305)
3. Explain the conditions under which drugs may be ordered or purchased (18-VAC 110-20-395, 21 USC 353)
4. Explain requirements for maintaining records of receipt for Schedule II-VI controlled substances (54.1-3404(C), 18 VAC 110-20-240(A), 21 CFR 1305.13)

B . Inventory

Perform inventory of Schedule II-V controlled substances, and describe the inventory requirements in terms of dates, required records, format, count requirements, filing, and newly scheduled drugs; Perform perpetual inventory of Schedule II controlled substances (54.1-3404 (A and B), 54.1-3434, 18 VAC 110-20-110(D), 18 VAC 110-20-240(A))

C . Maintain drug integrity

1. Ensure and maintain integrity of drug product
   (a) Evaluate drugs to determine whether they meet all legal requirements for selling, distributing, or dispensing and recognize the conditions under which drugs are adulterated or misbranded while being held for dispensing (54.1-3461, 54.1-3462)
   (b) Understand the use and application of the following:

(i) Storage temperature	(18 VAC 110-20-10)
(ii) Tight container	(18 VAC 110-20-10)
(iii) Unit dose container	(18 VAC 110-20-10)
(iv) Unit dose package	(18 VAC 110-20-10)
(v) Unit dose system	(18 VAC 110-20-10)
(vi) Well-closed container	(18 VAC 110-20-10)
(vii) Compliance packaging	(18 VAC 110-20-10)
(viii) Beyond-use date	(18 VAC 110-20-10)
(ix) Expiration date	(18 VAC 110-20-10)

(c) Explain the conditions under which drugs and devices previously dispensed may be accepted for return to stock for resale (54.1-3411.1, 18 VAC 110-20-400)

(d) Repackage and label prescription drugs

(i) Explain packaging and labeling requirements to include determination of appropriate expiration date for repackaged drugs (18 VAC 110-20-355(B))

(ii) Explain records required for reconstitution, bulk compounding, and repackaged drugs (18 VAC 110-20-355 (A))

(iii) Explain requirements for use of automated counting or dispensing devices (18 VAC 110-20-355(C))

D. Provide for proper disposal of drugs

1. Properly dispose of Schedule II through VI controlled substances (54.1-3417, 18 VAC 110-20-210)

(a) Identify the procedure for the destruction or disposition of unwanted Schedule II-VI controlled substances (54.1-3417, 18 VAC 110-20-210)

(b) Explain record keeping requirements (54.1-3404(D), 18 VAC 110-20-210)

2. Explain the requirements for disposition of discontinued drugs for long term care facilities, to include records (18 VAC 110-20-530(7)(A-D))

E. Report stolen or lost drugs

1. Explain the reporting requirements for theft or loss of Schedule II-V controlled substances (54.1-3404(E), 21 CFR 1301.76))
2. Explain the conditions under which an inventory needs to be taken following a drug loss (54.1-3404(E))
3. Describe record keeping requirements for loss of drugs (54.1-3404(E-F))

III. REVIEW PRESCRIPTIONS (30%)

A. Receive prescriptions and orders

1. Describe the general requirements for receipt and documentation of oral prescriptions (54.1-3320 (2), 54.1-3410(B), 54.1-3410(D), 54.1-3411, 18 VAC 110-20-290(C), 18 VAC 110-20-420(A)(2), 54.1-3408.01 (C))
2. Describe conditions under which a prescription may be faxed or electronically transmitted (18 VAC 110-20-280, 18 VAC 110-20-285) (21 CFR 1311)
3. Explain the requirements for transferring prescriptions between pharmacies (18 VAC 110-20-360)

(a) Explain the limitation for transferring a prescription for Schedule III-V controlled substances for refill purposes (21 CFR 1306.25)

4. Explain the requirements for obtaining, recording, and maintaining patient information (54.1-3319(D))

5. Explain the requirements for filling chart orders for outpatients (18VAC110-20-286)

B. Review prescriptions and orders
   1. Review prescriptions for legality
      (a) Ensure that prescriptions are written in good faith within the context of a bona fide physician-patient relationship for a medicinal or therapeutic purpose (54.1-3303(A-B), 54.1-3408)
      (b) Determine whether a prescription is written within a prescriber's authority and scope of practice (54.1-3303(A-E))
      (c) List which health care practitioners have prescriptive authority in Virginia (54.1-3303(A, D, E, F), 54.1-3401, 54.1-3408))
      (d) Describe the conditions under which an out-of-state prescription may be filled (54.1-3303(C))
      (e) Discuss the limitations upon accepting prescriptions from medical interns or residents and the purpose of the suffix assigned to the intern or resident for prescribing Schedule II-V controlled substances (18 VAC 110-20-510)
      (f) Describe the method for handling prescriptions that are declined for reasons other than nonavailability of the drug (18 VAC 110-20-270(D))
      (g) Identify the schedules of commonly used drugs as listed in Appendix A
      (h) Explain the criteria used for the general classification of Schedule I-V controlled substances (54.1-3443(A), 21 USC 811(c))
      (i) Explain the restrictions on dispensing narcotics for the purpose of maintenance or detoxification (21 CFR 1306.04-5 , 21 CFR 1306.07)
      (j) Explain the conditions under which a pharmacist may engage in generic substitution (54.1-3408.03, 54.1-3401 (Definition of therapeutically equivalent drug products))
   2. Review prescriptions for required elements
      (a) Describe the information that must appear on any prescription (54.1-3408.01, 54.1-3409, 54.1-3410)
      (b) Identify any additional information required for a valid prescription for a Schedule II-V controlled substances (54.1-3408.01(A), 21 CFR 1306.05))
   3. Conduct drug use reviews
      (a) Describe the requirements for conducting a prospective drug review prior to dispensing (54.1-3319(A))
      (b) Describe the requirements for performing monthly reviews of drug therapy for patients in a hospital or long term care facility (18 VAC 110-20-440(B), 18 VAC 110-20-530(9))

C. Explain requirements for central or remote processing of prescriptions (18 VAC 110-20-276, 18 VAC 110-20-515)

IV. DISPENSING AND DISTRIBUTION (25%)

A. Dispensing drugs pursuant to a prescription

1. Describe the appropriate terms necessary for lawful dispensing

(a)	Repackaged drug	(18 VAC 110-20-10)
(b)	Safety closure container	(18 VAC 110-20-10)
(c)	Special packaging	(18 VAC 110-20-10)
(d)	Terminally ill	(18 VAC 110-20-10)
(e)	Compounding	(54.1-3401)
(f)	Device	(54.1-3401)
(g)	Dispense	(54.1-3401)
(h)	Drug	(54.1-3401)
(i)	Administer	(54.1-3401)
(j)	Label	(54.1-3401)
(k)	Labeling	(54.1-3401)
(l)	Prescription	(54.1-3401)
(m)	Schedule VI device	(54.1-3455)
(n)	Schedule VI	(54.1-3455)
(o)	Controlled substance	(54.1-3401)
(p)	Controlled substance	(21 USC 802(6), 21 CFR 290.1))
(q)	Drug sample	(21 USC 353, 21 CFR 203.3(aa))

2. Explain the conditions under which prescriptions for Schedule II controlled substances may be filled to include time limitations, conditions for partial filling and the issuance of multiple prescriptions for the same drug (54.1-3410(A)(1-2), 54.1-3411(1), 18 VAC 110-20-290, 18 VAC 110-20-310, 21 CFR 1306.12)
3. Explain the conditions under which prescriptions for Schedule III-V controlled substances may be filled or refilled to include time limitations, restrictions, and requirements for partial filling (54.1-3410(B), 54.1-3411(2), 18 VAC 110-20-320(A,D))
4. Explain the conditions under which prescriptions for Schedule VI controlled substances may be filled or refilled to include time limitations (54.1-3410(B, C), 54.1-3411(2,3,4) 18 VAC 110-20-320(B,D))
5. Describe the records required for dispensing, refilling, or partially filling Schedule II-VI controlled substances, and required record keeping (54.1-3404 (D and F), 54.1-3410, 54.1-3411, 54.1-3412, 18 VAC 110-20-240, 18 VAC 110-20-250,18 VAC 110-20-255, 18 VAC 110-20-320))
6. Explain how to properly package prescriptions (54.1-3426, 54.1-3427, 18 VAC 110-20-340, 18 VAC 110-20-350)
7. Explain how to properly label prescriptions (54.1-3410(A)(3), 54.1-3410 (B)(2), 54.1-3463(A), 18 VAC 110-20-330))
   (a) Explain caution label requirement for Schedule II-V controlled substances (21 CFR 290.5)
8. Explain requirements for making an offer to counsel and describe the components of counseling (54.1-3319(B-E))

9. Explain requirements for compounding (54.1-3401, 54.1-3410.2, 18 VAC 110-20-321)

B . Dispensing or distributing drugs by other methods

1. Explain unit dose dispensing systems (18 VAC 110-20-420)
2. Explain procedures and required records for dispensing drugs for floor stock, licensed emergency medical services agencies, emergency drug kits, and stat drug boxes (18 VAC 110-20-460, 18 VAC 110-20-500, 18 VAC 110-20-540, 18 VAC 110-20-550, 18 VAC 110-20-560, 18 VAC 110-20-590(B))
3. Explain procedures and required records for dispensing drugs from automated dispensing devices (54.1-3434.02, 18 VAC 110-20-490, 18 VAC 110-10-555)
4. Explain procedures and required records for the use of robotic pharmacy systems (18VAC110-20-425)
5. Describe the requirements for delivery of dispensed prescriptions (54.1-3420.2, 18 VAC 110-20-275)
6. Explain the conditions under which insulin can be dispensed (54.1-3419)
7. Describe the conditions and documentation for sale of controlled paraphernalia (54.1-3467, 54.1-3468, 54.1-3469)
8. Explain the conditions and documentation for dispensing Schedule V controlled substances without a prescription (54.1-3416)

C . Prescription monitoring program

1. Describe requirements for reporting covered substances (54.1-2519, 54.1-2520, 54.1-2521, 54.1-2522, 18 VAC 76-20-30, 18 VAC 76-20-40)
2. Describe confidentiality of data and disclosure of information (54.1-2523.1, 54.1-2525,18 VAC 76-20-50, 18 VAC 76-20-60)

V. Collaborative Practice (1%)

A. Understand requirements for participation in collaborative agreements (54.1 -3300.1, 18 VAC 110-40 et.seq.)

APPENDIX A

The sections of Virginia law listing drugs within the various schedules are confusing and typically include legal or chemical names. For this reason, Appendix A was developed to assist you in studying this portion of the law for the examination. Appendix A is a listing of drug schedules and some generic and brand names of commonly dispensed drugs in each schedule in addition to some common professional suffixes. Drug names or professional suffixes included in the examination, which require or test for this knowledge, will be taken from this list.

PROFESSIONAL SUFFIXES

MD- Doctor of Medicine
OD- Doctor of Optometry
DC- Doctor of Chiropractic
DDS- Doctor of Dental Surgery
PA- Physician Assistant
RN- Registered Nurse

DPM- Doctor of Podiatric Medicine
DO- Doctor of Osteopathic Medicine
DVM- Doctor of Veterinary Medicine
DMD- Doctor of Dental Medicine
NP or LNP- Nurse Practitioner
LPN- Licensed Practical Nurse

SCHEDULE I:

Schedule I drugs are drugs which have a high potential for abuse, but which have no accepted medical use in treatment in the United Stated or which lack accepted safety for use in treatment even under medical supervision.

SCHEDULE II:

GENERIC NAME	*SOME BRAND NAMES*
meperidine	Demerol
morphine sulfate	M.S. Contin, Roxanol
oxycodone	Percodan, Percocet, Tylox, OxyContin
hydromorphone	Dilaudid
methadone	Dolophine
codeine (as a single drug entity)	
fentanyl	Sublimaze
alfentanyl	Alfenta
sufentanil	Sufenta

opium	
cocaine	
methylphenidate	Ritalin
amphetamine	Biphetamine
dextroamphetamine	Dexedrine
phenmetrazine	
methamphetamine	Desoxyn
pentobarbital (suppositories are schedule III)	Nembutal
secobarbital (suppositories are schedule III)	Seconal
amobarbital (suppositories are schedule III)	Amytal

SCHEDULE III:

GENERIC NAME	*SOME BRAND NAMES*
codeine in combination with acetaminophen	Tylenol with codeine #2, #3, #4; Phenaphen with codeine #2, #3, #4
codeine in combination with aspirin	Empirin with codeine #2, #3, #4
hydrocodone	Tussionex, Vicodin, Lorcet Plus, Lortab, Hycodan, Zydone, Anexsia
butabarbital	Butisol
butalbital (unless in combination with acetaminophen, then schedule VI)	Fiorinal, Fiorinal with codeine
thiopental sodium	Pentothal
benzphetamine	Didrex
phendimetrazine	Bontril, Prelu-2
nandrolone	Anabolin, Androlone, Deca-Durabolin, Durabolin, Hybolin, Nandrobolic
stanozolol	Winstrol
oxandrolone	Anavar
Dronabinol	Marinol

SCHEDULE IV:

GENERIC NAME	*SOME BRAND NAMES*
diazepam	Valium
lorazepam	Ativan
alprazolam	Xanax
chlordiazepoxide	Librium
oxazepam	Serax
prazepam	Centrax
triazolam	Halcion
clonazepam	Klonopin
chlorazepate	Tranxene
flurazepam	Dalmane
zolpidem	Ambien
temazepam	Restoril
phenobarbital	
pentazocine	Talwin
propoxyphene	Darvon
phentermine	Fastin, Ionamin, Adipex-P
diethylproprion	Tepanil, Tenuate
fenfluramine	Pondimin
mazindol	Sanorex

SCHEDULE V:

GENERIC NAME	*SOME BRAND NAMES*
most cough syrups containing codeine	
diphenoxylate	Lomotil

SCHEDULE VI:

All prescription drugs and devices which have not been placed in another schedule are in Schedule VI. This includes any drug or device which is not in another schedule, but which is required by federal law to bear on its label one of the following legends:

1. "Rx only" or "Caution: Federal Law Prohibits Dispensing Without Prescription"

2. "Caution: Federal Law Restricts This Device To Sales By Or Use On The Order Of A Physician"

3. "Caution: Federal Law Restricts This Drug To Use By Or On The Order Of A Veterinarian"

Schedule VI also includes any drug not listed in Schedules I - V which because of toxicity, potential for harm, method of use, or collateral measures necessary to its use is not generally recognized among experts as being safe for use except by or under the supervision of a practitioner licensed to prescribe.

GENERIC NAME	***SOME BRAND NAMES***
digoxin	Lanoxin
penicillin v.	Penicillin VK
bupropion hydrochloride	Wellbutrin
amoxicillin	Amoxil
cephalexin	Keflex
tramodol hydrochloride	Ultram

APPENDIX B

I

U.S. CODE TITLE 21 FOOD AND DRUGS
UNITED STATES CODE:
http://www.gpoaccess.gov/uscode/index.html
(Use the Browse feature)

CHAPTER 9 – FEDERAL FOOD, DRUG AND COSMETIC ACT

321	Definitions, generally
351	Adulterated drugs and devices
352	Misbranded drugs and devices
353	Exemptions and considerations for certain drugs, devices and biological products
353a	Pharmacy compounding
360	Registration of producers of drugs or devices
360c	Classification of devices intended for human use
374	Inspection

CHAPTER 13 – DRUG ABUSE PREVENTION AND CONTROL

802	Definitions
811	Authority and criteria for classification of substances
812	Schedules of controlled substances
823	Registration requirements
827	Records and reports of registrants
828	Order forms
829	Prescriptions

CODE OF FEDERAL REGULATIONS (CFR)
TITLE 21 CFR FOOD AND DRUGS
http://www.gpoaccess.gov/cfr/index.html
(Use the Browse feature)

CHAPTER 1

Part 290	Controlled drugs
Part 310	New drugs
Part 330	Over-the-counter human drugs

CHAPTER 2

Part 1301	Registration of manufacturers, distributors and dispensers of controlled substances
Part 1302	Labeling and packaging for controlled substances
Part 1304	Records and reports of registrants
Part 1305	Order forms
Part 1306	Prescriptions

Part 1307	Miscellaneous
Part 1308	Schedules of controlled substances
Part 1316	Administrative functions, practices, and procedures

THE PHARMACIST'S MANUAL
(from the United States Drug Enforcement Agency Diversion Control Program)
http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_content.htm

NAPLEX®

North American Pharmacist Licensure Examination®

MPJE®

Multistate Pharmacy Jurisprudence Examination®

2015 Candidate Registration Bulletin

Please read the *NAPLEX/MPJE Candidate Registration Bulletin* thoroughly to ensure that you understand all the policies and procedures for taking your examination. This bulletin contains information for all registrations and scheduling of NAPLEX and MPJE appointments beginning January 1, 2015.

NAPLEX®/MPJE®
Candidate Registration Bulletin

National Association of Boards of Pharmacy
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Carmen A. Catizone, MS, RPh, DPh
Executive Director/Secretary

Preamble and Mission Statement of the National Association of Boards of Pharmacy

Preamble

The National Association of Boards of Pharmacy® (NABP®) recognizes and supports pharmacists serving as the health care professionals responsible for providing patient care that ensures optimal medication therapy outcomes. NABP also recognizes the ongoing and critical need for patients' medications to be managed by a licensed pharmacist and state regulatory agencies to aggressively enforce standards of care.

NABP Mission Statement

NABP is the independent, international, and impartial Association that assists its member boards and jurisdictions for the purpose of protecting the public health.

The policies and procedures specified in the *NAPLEX/MPJE Registration Bulletin* are subject to change without notice. 01262015

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Essential Information

The information below is provided to guide you through the key steps in registering for and taking the North American Pharmacist Licensure Examination® (NAPLEX®) and the Multistate Pharmacy Jurisprudence Examination® (MPJE®) as well as obtaining score reports. It answers the most frequently asked questions about both examinations. Please read this information carefully and refer to the appropriate sections of this *Bulletin* for detailed information. If you have additional questions, refer to the "NAPLEX/MPJE Contacts" section on page 37.

Before the Examination

- **Read this *Bulletin* carefully.**
- **Know Your Licensure Requirements.** For specific requirements, contact the board of pharmacy for the jurisdiction in which you are seeking licensure.
- **Request ADA Accommodations.** If you require Americans with Disabilities Act (ADA) testing accommodations, contact your jurisdiction's board of pharmacy as early as possible for information about the necessary procedures. See page 7 for more information.
- **Create an NABP e-Profile to Register.** Create an NABP e-Profile at *https://store.nabp.net* and register for your examinations online. Make sure the name you use to register matches the two IDs you will use to check in, including middle name or middle initial. See pages 13–15 for a detailed explanation and examples.
- **Check Registration Status.** Log in to your e-Profile to check your registration status. See the glossary on pages 38-39 for further explanation of each status.
- **Schedule Testing Appointment.** After you receive your Authorization to Test (ATT) letter, visit *www.pearsonvue.com/nabp* or call Pearson VUE Customer Service at 888/709-2679 to schedule an appointment. It is important to make your appointment as soon as possible in order to ensure seating for the examination. See page 10 for further explanation.
- **Consider Taking the Pre-NAPLEX.** See page 25 for information about the Pre-NAPLEX practice exam and how to register.
- **Request an e-Profile Name Change.** If your name has changed since registering for the exam, you must submit the relevant notarized form(s) and legal documentation to NABP at least five business days prior to your examination. If you fail to meet this requirement you may not be admitted to the test center. See page 15 for instructions.

Examination Day

- **Arrive Early.** Arrive at the Pearson Professional Center at least 30 minutes prior to your testing appointment.
- **Bring Acceptable Identification.** Bring two forms of acceptable identification. Acceptable identification is defined and examples are provided beginning on page 14 of this *Bulletin*.
- **Do Not Bring Prohibited Items into Test Room.** Be aware of items that are prohibited from the testing room at the Pearson Professional Center. You may wish to leave these items at home. See page 16 for a list of prohibited items.

(Continued on the following page)

After the Examination

- **Request Score Transfers.** If you wish to participate in the NAPLEX Score Transfer Program, you must register your score transfer requests by logging in to your NABP e-Profile. Score transfer requests may be submitted online up to 90 days after taking the NAPLEX. More information on the Score Transfer Program can be found on page 35.
- **Review Your Score.** Your examination score will be provided to you by the board of pharmacy from which you are seeking licensure. If your jurisdiction's board of pharmacy participates in NABP's online score reporting, you may access your score by logging in to your e-Profile. The score will be available within seven business days of taking the exam. See page 32 for more information. Contact the board if you have questions about your examination score.

If You Miss the Examination Appointment

- **Request a Resit.** If you miss the exam or fail to cancel the appointment at least two business days in advance, you may request a resit five business days from the missed exam date. See page 6 for more information.

NAPLEX/MPJE Registration

Welcome to the NAPLEX and MPJE

The NAPLEX and MPJE are developed by NABP for use by the boards of pharmacy as part of their assessment of candidates' competence to practice pharmacy.

NAPLEX and MPJE Registration Fees

NAPLEX® North American Pharmacist Licensure Examination®	**$505** per examination
MPJE® Multistate Pharmacy Jurisprudence Examination®	**$210** per examination

Online Examination Registration Through Your NABP e-Profile

Online registration for the NAPLEX, MPJE, and NAPLEX Score Transfer can be accessed via the "Programs" page of the NABP website, available at *www.nabp.net/programs*. Click on NAPLEX or MPJE, then click the "Registering for..." link in the left navigation.

To register, you must log in to your NABP e-Profile. If you do not have an NABP e-Profile, you can create one by following the steps below.

Note: A Social Security number is required to create an e-Profile. If you do not have a Social Security number, contact NABP Customer Service Monday through Friday, 9 AM to 5 PM Central Time, at 847/391-4406, or by e-mail at custserv@nabp.net.

Candidates must provide all the requested information and pay the relevant examination fee(s) as instructed. Registration entry errors could delay your ATT.

See the "Authorization to Test" section on page 9 for more information

Creating a New e-Profile in Order to Complete the Online Examination Registration

If you already have an NABP e-Profile, skip to the "Completing the Online Examination Registration Form" section on page 4.

1. ***Visit*** https://store.nabp.net***; click on the Create an e-Profile button.***
2. ***Read and Agree to Terms of Service***

   Read the Terms of Service and select the box to acknowledge and accept the Terms of Service. You will be unable to continue without accepting these terms.
3. ***Select Products and Services***

   On the "My e-Profile" page, check the NAPLEX, NAPLEX Score Transfer, MPJE, and Score Results boxes and the corresponding boxes for any additional products or services you plan to use.
4. ***Enter Personal Information***

   Enter the correct information in the appropriate boxes. All pertinent information (maiden name, Social Security number, date of birth) must be entered.

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Name

- Enter your name, including last, first, middle name or initial, and suffixes exactly as it appears on your identification.

Important: Your name must be entered exactly as it appears on the two forms of identification you will present at the testing center. Always use the same form of your name when scheduling a testing appointment.

More information on registration and identification name matching requirements is available on pages 13–15 in the "Identification Requirements" section.

E-Mail Address and Password

- The e-mail address you enter will be the username you use to log in to your e-Profile.
- Your password must be at least six characters long and must include at least one letter and one number.

5. ***Enter Contact Information***

   Enter your home or business address, phone number(s), and other contact information. On the next screen, confirm that your contact information is correct.

6. ***Create Security Questions***

   Remember the answers to your three security questions. This information will be used to confirm your identity when you contact NABP Customer Service or if you forget your password.

Once you complete step 6, you will receive an e-mail with your e-Profile ID. Your e-Profile ID number will also appear in the upper right corner of the screen when you are logged in.

Note: To ensure timely and accurate assistance, always include your e-Profile number when contacting NABP.

Completing the Online Examination Registration Form

Log in to your NABP e-Profile to register for the NAPLEX or MPJE. Once you have logged in, you will be brought to your e-Profile Dashboard. Here you will be able to view status information on the NABP services you are utilizing (a full list of the possible statuses, including definitions, is available in Appendix A on page 36. To register for an examination, click the **NAPLEX/MPJE** link under Programs and Services (or click **Exam Services** from the navigation menu on the left side of the page), then click the **Register for** button for the test you would like to register for.

Read and Agree to Non-Disclosure Agreement

Read the terms and conditions of the NABP Non-Disclosure Agreement and select the box to acknowledge and accept. You will be unable to continue unless you accept the terms and conditions of the Non-Disclosure Agreement.

Jurisdiction and Education Information

- Select the state or jurisdiction for which you are seeking eligibility to take the NAPLEX. The state you select will be considered your primary state or jurisdiction for licensure.
- Select the country in which your school or college of pharmacy is located. Schools within the United States can be selected from a drop-down list. The schools are in alphabetical order and are preceded by their numeric code.

- If your school or college of pharmacy is located outside of the US, the code "999-other" will appear. Type the name of the school or college of pharmacy in the following field.
- Enter the date your degree was conferred as the "Date of Graduation."

Billing and Payment Information

- Select the correct "Bill To" address. If the billing address for the credit card you are using does not match the address you entered when registering, you can add it by clicking the **+Add Address** button.
- Enter credit card information.
- Payment is due at the time of registration.

Important: NABP does not accept personal checks as payment. All online payments must be made using a Visa, MasterCard, or American Express debit or credit card.

Request Testing Accommodations

If you will be contacting your board(s) of pharmacy to request testing accommodations under the ADA, select the Accommodations option. ADA accommodation requests must be made to the applicable board of pharmacy. See page 7 of this *Bulletin* for more information.

Additional Registration Options

Once registration has been successfully completed, additional NAPLEX/MPJE registration options are available through your e-Profile and are described below. Click the **NAPLEX/MPJE** link under Programs and Services (or click **Exam Services** from the navigation menu on the left side of the page), then click on the appropriate link under the Available Actions column of the Active Registrations section. If an option does not appear, you are most likely ineligible to perform that action.

Adding Score Transfers and Canceling Score Transfers

Each score transfer request requires a $75 administrative fee. NAPLEX score transfer requests may be made at the time of registration, or up to 90 days after the examination date (the day of the exam is considered day one).

To cancel a score transfer request, click the Cancel Score Transfer Request link. No refunds are issued for canceled score transfers. There is no additional charge to cancel a score transfer.

See page 35 for more details on score transfer requests.

Canceling/Withdrawing Registration

Partial refunds are issued for canceling or withdrawing a NAPLEX or MPJE registration if the action is completed before your eligibility expires.

Candidates are not permitted to register for another NAPLEX or MPJE in the same jurisdiction for five business days after canceling/withdrawing. To cancel, log into your NABP e-Profile and click **Cancel** under the Available Actions column.

Partial refunds will not be issued if a request is received:

- More than two years after the initial registration.
- After the eligibility has expired.
- If a scheduled testing appointment is missed.

Partial Refund Amounts for Examination Cancellation/Withdrawal

NAPLEX	**$360**
MPJE	**$125**

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Note: Candidates wishing to cancel/withdraw registration and who have a scheduled appointment must contact Pearson VUE to cancel the exam at least two business days before the scheduled appointment. See page 10 for more information on canceling/rescheduling appointments with PearsonVUE.

Changing Primary Jurisdiction

Changing states or jurisdictions requires a $50 administrative fee. Once the primary jurisdiction is changed, the ATT and scheduled appointment (as applicable) for the previous jurisdiction will no longer be valid.

Change of jurisdiction requests must be made at least two business days before a scheduled examination. Requests made less than two business days before a scheduled examination will not be honored and the administrative fee will be forfeited.

Resitting After a Missed/Canceled Appointment

Candidates who miss their scheduled testing appointment without following the cancellation procedure (see page 5) forfeit their testing fees. Five business days after the scheduled exam, you may pay the resitting fee and request to resit. Click the **NAPLEX/MPJE** link under Programs and Services (or click **Exam Services** from the navigation menu on the left side of the page), then click the **Resitting** link in the Available Actions column under "My Active Registrations." This option restarts the registration process.

Fees payable to NABP may be submitted via credit or debit card by selecting Resit under available actions in the online application. Once your fee has been processed, you will receive a new ATT.

Resitting Fees

NAPLEX	**$140** per missed appointment (to NABP)
MPJE	**$90** per missed appointment (to NABP)

If the **Resit** link does not appear, it may be for one of the following reasons:

- Eligibility will expire in 10 business days or less. Because NABP cannot guarantee the issuance of an ATT before eligibility has expired, the request for the resit is not permitted.
- The examination has already been taken after a no-show and was not passed. Candidates that miss an appointment, reapply, then fail the examination must register again.
- It has been less than five business days since the original exam. The link will not appear until five business days after the scheduled exam.

Obtaining Score Results

Candidates in states that participate in the NABP online score interface will typically be able to access NAPLEX and MPJE score results within seven business days of taking the examination. Log in to your NABP e-Profile and click **Exam Results.**

NAPLEX online score reports are only displayed under the state registered as your primary jurisdiction. Thus, candidates whose primary jurisdictions do not participate in online score reporting will not be able to view scores in their e-Profile, even if another state your score is reported to does participate.

A list of states that participate in the NABP online score reporting interface is available in the NAPLEX and MPJE sections of the NABP website.

Note: Only state boards of pharmacy have authority to issue a license to practice pharmacy. The posting by NABP of a passing examination score does not constitute a license to practice pharmacy. Boards will not accept online examination scores posted online by NABP for purposes of score transfer or obtaining licensure. Online reports are for candidate use only.

Note: If you are still eligible to test and would like to resit for an exam you do not need to re-register. Request a resit and pay the resitting fee online.

Note: If you have questions about obtaining your test score results, please contact the relevant board(s) of pharmacy.

Testing Accommodations

All testing accommodation requests will be evaluated by the appropriate board of pharmacy and will be forwarded to NABP for review. If more information is needed to support the testing accommodation request, NABP may contact the board of pharmacy and the candidate.

All provided information may be shared between NABP and the boards of pharmacy, including but not limited to the request, history, and nature of the accommodations requested. When all documentation is acceptable, NABP will notify the candidate and board of pharmacy and will arrange the appropriate accommodations with the testing vendor.

Accommodation request approval is current for one year from the date that the candidate and board of pharmacy are notified. After one year, the candidate must complete and submit a new set of documents.

To submit an accommodation request, please download, print, and complete the Accommodation Request Form. Submit the completed form to the board along with the required detailed documentation. The completed form should include the following:

- **Part I** – Applicant's Statement
- **Part II** – Practitioner's Statement and Diagnostic Results
- **Part III** – Academic/College Statement (as applicable)

I. *Applicant's Statement*
   a. A detailed report written by the applicant describing the disability and justification for the requested accommodations along with the completed Application for Disability Accommodation form, Part I: Applicant's Statement.
   b. A description of treatment for the disability or condition (eg, any medication management regiment, including the effect the medication has on the condition). List any physical therapy, hearing aids, magnifying equipment, or psychotherapy regimens recommended by practitioners.

II. *Practitioner's Statement and Diagnostic Results*
   a. Each provider is required to complete Part II of the ADA form "Practitioner's Statement" including the date of the initial diagnosis, date last evaluated, and the length of time as a patient.
      i. The practitioner should provide evidence that they are qualified to make the appropriate diagnosis, including licensing or certification and specialization credentials.
      ii. A statement of the specific diagnosis of the disability is required. A professionally recognized diagnosis for each category of disability is expected. The supporting written statement should explain the recommended accommodation and how the accommodation will be justified in the testing environment. The attached document should be typed on identifying letterhead and signed by the practitioner.
      iii. A written explanation should be provided if no history of accommodations were required in similar or past testing environments. The explanation should account for any disability that is not permanent or long-lasting.
      iv. Describe any treatment for the disability or condition prescribed (eg, any medication management regimens, the effect the medication has on the disability).

b. Diagnostic tests to support requests. Current diagnostic tests, as applicable, and relevant medical history should be submitted. In most cases, an evaluation should have been conducted within the past three years. Specific tests should support the diagnosis and recommendation.

III. *Academic/College Statement*

a. College Statement: Attestation from a credible source documenting accommodations afforded in a testing environment. For example, a letter from the candidate's college of pharmacy outlining the accommodations utilized in one's academic experience.

b. Provide evidence that accommodations were afforded in other testing environments, eg, academic, standardized testing.

Important: Testing accommodation requests that are unreasonable or that would fundamentally alter the nature of the examination or the security of the examination, or that would impose an undue burden to NABP or to other candidates will be subject to denial.

Scheduling With Testing Accommodations

Candidates approved for testing accommodations may not schedule examinations directly with Pearson VUE until they are instructed to do so by NABP. Once notified by NABP, candidates must schedule their testing appointment with Pearson VUE by calling their customer service number at 800/466-0450.

Your Examination Appointment

Testing Centers

The NAPLEX and MPJE are administered by Pearson VUE at its Pearson Professional Centers, which are located in all 50 of the United States, its territories, and the District of Columbia.

Jurisdictions Requiring MPJE

You must contact the board of pharmacy to confirm whether a specific jurisdiction requires the MPJE. As of June 1, 2013, 48 boards require the MPJE for initial licensure, and 48 boards require the examination for license transfer.

Eligibility Requirements

To take the NAPLEX and/or MPJE, candidates must meet the eligibility requirements of the board of pharmacy from which they are seeking licensure.

The board will determine your eligibility to take the examinations in accordance with the jurisdiction's requirements.

You may check your eligibility status by logging in to your NABP e-Profile. Click the **NAPLEX/MPJE** link under Programs and Services (or click **Exam Services** from the navigation menu on the left side of the page) under "My Active Registrations." A full list of possible statuses, including definitions, is available on page 38.

Important: If a board of pharmacy has not made a candidate eligible to test within two years of the date that the candidate initially registered with NABP, the candidate's record will be closed and all fees will be forfeited.

If you have questions concerning eligibility requirements, contact the board of pharmacy in the jurisdiction from which you are seeking licensure.

The most current listing of board of pharmacy contacts is available on NABP's website at *www.nabp.net/boards-of-pharmacy.*

Authorization to Test

After the board of pharmacy determines candidates' eligibility to take the examination, it will notify NABP. Candidates who have registered for the NAPLEX and/or MPJE will receive an ATT letter by or letter from Pearson VUE. The ATT letter includes eligibility dates during which you may take the examination, instructions for scheduling your testing appointment, and other important information.

Candidates should make sure all information in their ATT letters is correct. Check to make sure your name on the ATT letter exactly matches the two forms of identification you will bring to check into the testing center.

See "Name Matching Guidelines" on page 13 for more details.

If you do not receive or have misplaced your ATT letter, contact Pearson VUE Customer Service Monday through Friday at 888/709-2679 7 AM to 7 PM (CST). Be sure to check your spam or junk email folder before you call. ATT letters or numbers will not be issued via phone or fax.

Scheduling Your Examination Appointment

You cannot schedule your examination appointment until you receive your ATT letter.

Examination appointments are made on a first-come, first-served basis, depending on availability at the testing center. ATT letters indicate the time frame eligibility period each candidate may schedule an appointment; however, boards of pharmacy may have more stringent deadlines for completing the exam(s) as part of their requirements for licensure.

Exams must be scheduled in accordance with the board's deadline requirements.

Important: It is recommended to schedule your appointment as soon as you receive your ATT letter. Scheduling may be difficult during high-volume times of year, particularly spring and summer. Even if you do not want to test immediately, we recommend that you schedule early. Waiting to schedule your examination appointment may significantly limit the dates your preferred test center has available seating. If you wait to schedule your appointment until the end of your eligibility period, an appointment may not be available prior to the eligibility end date. If this occurs, no extensions of eligibility will be granted. You may be required to submit a new registration form and fees.

You must adhere to the procedure below when scheduling your appointment.

Scheduling

Online Scheduling: You may schedule an examination at a testing center through the Pearson VUE website (*www.pearsonvue.com/nabp*). Follow the instructions on the page to set up a Web account to select your preferred testing location, date, and time. You may also schedule an examination appointment by calling Pearson VUE Customer Service 888/709-2679 7 AM to 7 PM (CST).

Scheduling By Phone: If you choose to call Pearson VUE's Customer Service Department to schedule an appointment, you will be asked to verify your identity by stating your last name, first name, middle name or middle initial, and suffixes, along with demographic information, and to confirm which NABP examination you have been authorized to take.

The Pearson VUE Customer Service agent will search for the location closest to the address you provided on your application to your board of pharmacy, or if you have a preferred site, the agent can search that site for appointment availability. To review the locations of the testing centers, please visit *www.pearsonvue.com/nabp.*

Confirmation Message: Once your appointment has been scheduled, you will receive a confirmation email that provides the details of your examination appointment, directions to your selected test center, and instructions and policies on rescheduling and canceling your examination appointment.

Important: You must make sure all personal information is correct on your appointment confirmation email and ATT letter. For name changes and corrections, along with other demographic updates, contact NABP Customer Service at 847/391-4406 Monday to Friday, 9 AM to 5 PM CST or by email at custserv@nabp.net. Name changes and corrections must be completed at least five business days prior to the date of your scheduled exam (see page 15).

Canceling/Rescheduling Appointments

You may cancel or reschedule your examination appointment via your Pearson VUE Web account at *www.pearsonvue.com/nabp* or by calling Pearson VUE Customer Service at 888/709-2679.

Note: Candidates approved for testing accommodations must contact NABP directly to cancel or reschedule an examination appointment.

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Cancellations and rescheduled appointments must be made at least two business days prior to your scheduled appointment. For example, if you are scheduled to test at 9 AM Monday, you must call by 9 AM on the previous Thursday to cancel or reschedule. Your appointment is not canceled or rescheduled until you receive a confirmation from Pearson VUE. If you cancel without the required notice you will forfeit your testing fee.

To reschedule your appointment, you must submit the appropriate fees to Pearson VUE, either online or via their Customer Service Department. There are NO exceptions to this policy.

Rescheduling Fees

NAPLEX	**$50** per rescheduled appointment (to Pearson VUE)
MPJE	**$50** per rescheduled appointment (to Pearson VUE)

NAPLEX/MPJE Administration

On the Day of the Examination

In accordance with NABP policies and procedures, Pearson Professional Center staff will enforce the requirements explained below in order to ensure a positive testing experience and the security of the examination. Review the following information before your examination administration.

- **Arrive early.** Be at the test center at least 30 minutes before your scheduled appointment time to allow for check-in procedures. Most candidates will begin their testing session within 30 minutes after their scheduled appointment time.
  - » If circumstances cause you to wait more than 30 minutes after your scheduled appointment time, you will have the choice to continue waiting or to reschedule your appointment at no additional charge.
  - » If you arrive at the test center more than 30 minutes after your scheduled appointment, and are denied admission to sit for the examination, you will be required to forfeit your appointment. There are no refunds of testing fees for forfeited appointments. Pearson VUE will do all they can to accommodate a late arrival, however, the determination to permit you to test is solely at the discretion of the testing center staff.
- **Bring Identification.** When you arrive at the test center, you will be required to present two forms of ID: A photo ID that includes your signature and a second form of ID with a signature.

(?) See "Identification Requirements" beginning on page 13 for more information.

- **Follow Security Procedures.** All candidates will be required to have a palm vein scan, provide his or her digital signature, and have a digital photograph taken prior to being admitted to the testing room.
  - » For palm vein scans, a device will be used to digitally record the pattern of the candidate's palm veins. Candidate palm vein patterns are digitally encrypted and securely transmitted to Pearson VUE.
  - » In the event that you are physically unable to provide a digital signature or palm vein pattern, you must contact NABP at least 30 days prior to your examination date.
- **Remain Seated.** Once you have been admitted, the test center administrator will escort you to a workstation. From this point on, you must remain in your seat except when authorized to leave by a test center administrator. After being admitted, **you may not leave the testing room** without permission and **you may not leave the testing center building** for any reason until the examination is completed.

(!) **Note:** Your exam score may be invalidated or canceled, you may forfeit your appointment to test, and you may be required to reapply for the examination if:

- » You leave the testing room without permission, or
- » You leave the testing center building, regardless of reason.

There will be no refund of your testing fees in these cases.

- **Scheduled and Unscheduled Breaks.**
  - » **NAPLEX:** You will have the option of taking a 10-minute break. The computer screen will display a prompt to let you know you may take the break. You may accept or decline the option.
  - » **MPJE:** There are no scheduled breaks.

    (!) **Note:** Time used for any **unscheduled breaks** during the NAPLEX and MPJE will be subtracted from your testing time.

  - » Your palm vein pattern must be scanned to reenter the testing room after any break.

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- **Supplies Provided.** The administrator will provide you with an erasable note board and pen. You may not remove these materials from the testing room at any time. Using your own scratch paper or pen is prohibited.
  - » **NAPLEX Only:** An on-screen calculator can be activated during the examination for your use. The on-screen calculator can be used in a scientific or five function mode. Please note that many of the calculations on the NAPLEX will require the on-screen scientific calculator. A candidate requesting a handheld calculator for any reason, will be supplied a five function calculator by Pearson VUE. Personal calculators of any kind are prohibited.
- **Notify Pearson VUE Staff of Problems.** If you need help for any reason, raise your hand and notify a testing administrator. Examples include:
  - » Computer malfunctions.
  - » Note board or pen replacements.
  - » Break requests.
- **Testing Format.** The format of the examinations requires that ALL test questions be answered in the order in which they are presented. You will NOT be allowed to skip a question or return to a previous question to review your answer. Once you have confirmed an answer choice and moved on to the next question, you CANNOT return to the previous question to change your answer.
- **Completing the Exam.** When you have completed the examination and/or the end-of-examination survey, the test administrator will collect your note board and pen and assist you with the check-out process.

Identification Requirements

Admission to the testing center requires two forms of ID consisting of a primary form of ID that contains your signature with a recent photograph of you, and a secondary form of ID with your signature. Both forms of identification must adhere to the name matching guidelines below.

Important: Candidates will NOT be admitted to the examination without the proper ID, and you will NOT have an opportunity to reschedule your testing appointment at the test center. There will be no refund of your testing fee and you will be required to pay an additional fee to schedule again.

Name Matching Guidelines

The printed name on both your primary and secondary forms of ID must match the name that appears on your ATT letter. The name on your ATT letter is the same name you entered when creating your NABP e-Profile.

Important: Reference the two IDs you will use at the testing center when creating your e-Profile. Enter your name exactly as it appears on both primary and secondary IDs, including first, middle, and last names, and suffix.

Some flexibility is allowed regarding the matching of middle names and initials. It is acceptable for your ID to contain your full middle name and your ATT letter to contain only your middle initial, as long as the middle initial matches the first letter of your middle name. Similarly, if your ATT letter contains your full middle name and your ID contains only your middle initial, you will be admitted to test if the middle initial on your ID matches the first letter of the middle name on your ATT. The chart below contains examples of acceptable and unacceptable combinations.

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ATT	ID	Acceptable?
John D. Smith	John David Smith	Yes
John David Smith	John D. Smith	Yes
John D. Smith, Jr	John David Smith, Jr	Yes
John David Smith, Jr	John D. Smith, Jr	Yes
John D. Smith	John D. Smith Jr	No
John David Smith Jr	John David Smith	No
John Smith	John David Smith	No
John D. Smith	John Smith	No
John David Smith	John Smith	No

If the name on both your primary and secondary IDs does not match the name on your ATT, you must send the appropriate documentation to NABP to update your registration at least five business days prior to the date of the scheduled examination.

Important: If the name you registered with is different from the name on your IDs, you will not be admitted to the testing center. Name updates or approvals will not be completed at the testing center.

Acceptable Forms of Photo Identification.

All forms of identification must be issued by either the US/US territories or Canada.

You must present one of the following acceptable IDs, which must be current (not expired) and contain a recent recognizable photograph and your signature. The only exceptions are government-issued military IDs which may contain a signature or thumbprint.

- US/Canadian passport
- US/Canadian driver's license
- US state/Canadian province ID
- US/Canadian temporary driver's license
- US learner's permit
- US military ID
- Canadian military ID

Acceptable Forms of Secondary Identification

All forms of identification must be issued in either the US/US territories or Canada.

All secondary IDs must be current and must contain the candidate's signature. All valid debit/credit/ATM cards must be issued through Visa, Discover, MasterCard, or American Express.

- US/Canadian passport
- US/Canadian driver's license
- US state/Canadian province ID
- US/Canadian temporary driver's license
- US learner's permit
- US military ID
- Canadian military ID
- US passport card
- Valid debit/credit/ATM cards

Unacceptable Forms of Identification

Unacceptable ID documents that will not be accepted include, but are not limited to, the following:

- IDs with no photo
- Foreign passports, driver's licenses, or ID cards
- Expired US/Canadian passport
- Expired US/Canadian driver's license
- Draft classification card
- Letter of identity from a notary
- Social Security card
- Employee ID
- Green card

Temporary IDs

All candidates using forms of temporary identification must follow the same guidelines listed under the "Acceptable Forms of Photo Identification" and "Acceptable Forms of Secondary Identification" headings above and must meet the name matching guidelines.

All temporary forms of identification must be current (unexpired) and contain a recent recognizable photograph with your signature. A secondary form of identification is still required. Acceptable forms of temporary identification include only:

- State-issued temporary driver's licenses (with a photo)
- State-issued temporary ID cards (with a photo)
- State issued learner's permit (with a photo)

Legal Name Changes

Candidates who change their name after they register for an exam are required to submit legal name change documentation to the board of pharmacy and NABP. If the name with which you have registered is different from the name on your IDs, you must contact your board of pharmacy and NABP to make a legal name change at least five business days prior to your scheduled examination.

See the "Frequently Asked Questions" page (NAPLEX/MPJE Online Registration Assistance, question 3) on the NABP website for links to the required forms and other more detailed instructions.

The only acceptable forms of legal documentation are marriage licenses, divorce decrees, and/or court action legal name change documents. All documents must be in English, or accompanied by a certified translation. Photographs of original documents may be submitted.

If the name with which you have registered is different from the name on your IDs, you will not be permitted to test. Name changes cannot be completed at the test center and documentation brought to the test center confirming your name change will not be accepted.

Test Center Restrictions

To ensure that examination results for all candidates are earned under comparable conditions and represent fair and accurate measurement of each candidate's individual knowledge and skills, it is necessary to maintain a standardized and secure testing environment. All candidates must adhere to the following policies:

- No reference, study, or other materials or devices may be brought into the testing center.
- Candidates will not be allowed to take anything into the testing room at the Pearson Professional Center other than those items given to them by the test center administrator and their ID documents (eg, passport, driver's license).

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- Prohibited items will not be allowed into the testing room. Prohibited items include, but are not limited to, the following:
  - Beverages
  - Books
  - Book bags or backpacks
  - Briefcases
  - Calculators
  - Cell phones
  - Computers/tablets
  - Computer bags
  - Contents of pockets
  - Food
  - Handbags/purses
  - Other electronic or digital devices (watches, PDAs)
  - Outerwear (coats, hats)
  - Pagers
  - Photographic devices
  - Recording devices
  - Wallets
  - Weapons
- Secure storage located outside the testing room will be provided for personal items, but space is limited. Test centers assume no responsibility for candidates' personal belongings.
- Even if no secure storage is available, you will be required to leave all other personal belongings, including prohibited items, outside the testing room.

Note: Candidates may have access to some personal items, including beverages, food, handbags/purses, and wallets, while outside the testing room during scheduled or unscheduled breaks.

- Use of tobacco is not allowed in the testing room or in the testing center.
- Friends or relatives who accompany you will not be permitted to wait in the test center or test room during your admission process or during your examination.
- Candidates may not leave the test center building during the examination. If you leave the testing room without permission or the testing center building at any time during an examination appointment, you may be suspended from the test administration and your score may be invalidated.

Security Measures

The NAPLEX and MPJE are the property of NABP and are confidential examinations that are protected by trade secret law, copyright law, and other applicable state and federal laws and regulations. The NAPLEX and/or MPJE will be made available to the examination candidate solely for the purpose of determining eligibility for licensure in the field of pharmacy.

- Examination candidates are expressly prohibited, at all times, from offering, disclosing, reproducing, transmitting, receiving, utilizing, or making available the NAPLEX or MPJE including, but not limited to, examination question format, questions, profiles, answers, and scenarios, in whole or in part, in any form and by any means, whether verbal, written, electronic, or mechanical, for any purpose.
- Numerous security measures will be enforced during the test administration to ensure the integrity of the examination programs.
- Be aware that you will be observed at all times while taking the examination. This observation may include direct observation by test center staff, as well as video and audio recordings of your testing session.

Misconduct

Individuals are prohibited from engaging in misconduct in connection with the NAPLEX or MPJE at all times, including during an examination appointment session as described in this *Bulletin*. Misconduct includes, but is not limited to, misconduct during the examination appointment session (see next paragraph) or offering, disclosing copying, reproducing, transmitting, receiving, utilizing, or making available any portion of the NAPLEX or MPJE in any form to or from individuals, study groups, organizations, entities, or the like, or attempting or arranging to have an individual take the examination for you.

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Misconduct during the Examination

Individuals who engage in any of the following misconduct or who exhibit any of the following behaviors during their examination appointment session may be subject to one or more of the actions listed in the "Actions" subsection of this *Bulletin*, below. The examination appointment session begins when the candidate is checked in to the test center, and includes scheduled and non-scheduled beaks, and ends when the candidate is dismissed from the center.

Examples of misconduct during the examination appointment include but are not limited to:

- Attempting to take the examination for someone else or taking the examination for someone else
- Attempting to have someone else take the examination for you or having someone else taking the examination for you
- Taking the examination for any purpose other than determining the eligibility for licensure, unless otherwise approved by NABP and the board(s) of pharmacy
- Accessing a cell phone or any other electronic communications devices
- Using notes, books, reference material, or other aids
- Attempting to aid an individual or receive aid to complete the examination
- Bringing any materials, devices, or items to the examination appointment session that may compromise the security or validity of the administration
- Failing to follow an administrator's instructions
- Creating a disturbance of any kind
- Removing or attempting to remove from the test center scratch paper, note boards, writing materials, or the like
- Copying or memorizing examination questions, answers, or any other examination content and/or removing this information
- Tampering with the operation of the computer or attempts to use it for any function other than taking the examination
- Leaving the testing room without permission
- Leaving the testing center building for any reason
- Offering, disclosing, copying, reproducing, transmitting, receiving, utilizing, or making available any portion of the NAPLEX or MPJE in any form

Actions

If NABP obtains information that an individual has engaged in any misconduct, as defined in the *Bulletin*, NABP, in its sole discretion, may take one or more actions including but not limited to:

- Suspension of the test administration
- Forfeiture of all testing fees
- Termination of the test administration
- Withholding the reporting of the examination score while NABP reviews the matter
- Invalidation/Cancellation of an examination score
- Notification to one or more boards of pharmacy or state or federal law enforcement agencies
- Initiation of civil, criminal, and/or administrative proceedings against the candidate that may result in civil penalties, criminal punishments, and/or disciplinary action including denial of licensure or licensure revocation by one or more board(s) of pharmacy

Important: NABP reserves the right to share information concerning the cancellation or invalidation of a candidate's NAPLEX and/or MPJE score or candidates' misconduct with boards of pharmacy or law enforcement authorities as applicable.

Individual or Group Irregularities

Unlike cases of individual candidate misconduct, occasional testing irregularities occur that affect an individual or a group of test takers. Such problems include, without limitation, administrative errors, defective equipment or materials, as well as other disruptions of test administrations (eg, natural disasters and other emergencies). When testing irregularities occur, Pearson VUE will conduct an investigation to provide information to NABP. Based on this information, NABP, at its sole discretion, may not score the test, may withhold the reporting of a score while NABP reviews the matter, or may cancel or invalidate the test score. If NABP deems it appropriate to do so, NABP will work with Pearson VUE to give affected candidates the opportunity to retake the test as soon as possible, at no additional cost. Affected test takers will be notified of the reasons for the cancellation and their options for retaking the test. The appeal process does not apply to testing irregularities.

NAPLEX and MPJE Score Withholding, Cancellation, or Invalidation

NABP reserves the right to determine, in its sole discretion and at any time, whether to withhold the reporting of an examination score so it can review a matter involving irregularities or misconduct, or to cancel or invalidate one or more examination scores. NABP may cancel or invalidate an examination score regardless of whether there is evidence of a candidate's personal involvement in group or individual irregular activities.

The bases for withholding, cancelling or invalidating individual or group examination scores may occur prior to, during, or after examination administration and include, but are not limited to, the following: examination administration errors; equipment malfunction; candidate misconduct, noncompliance with policies; observed irregular behavior; discrepancy/falsification of an examinee's identification; impersonating an examinee or allowing an unauthorized person to take the exam; unusual answer patterns; unusual or large score variances among a candidate's examinations; leaving a testing center facility; accessing exam content prior to taking the exam; stealing exam content; communicating with other test-takers during an examination appointment session, disclosing, publishing, reproducing, or transmitting an exam, in whole or in part, in any form or by any means, verbal or written, or electronic or mechanical, for any purpose. NABP's right to determine whether to withhold, cancel or invalidate an examination score is not in any way waived or modified because NABP processed an examination registration form, authorized a candidate to sit for an examination, scored an examination, or reported an examination result.

Inclement Weather

In the event of a testing center closing due to inclement weather, Pearson VUE will attempt to contact the candidate to reschedule the appointment; however, it is the responsibility of the individual candidate to contact Pearson VUE to determine if the test center is open and/or to reschedule his or her appointment.

If the Pearson Professional Center where the candidate is scheduled to test is open and the candidate does not keep his or her scheduled appointment, the candidate forfeits all fees and no portion of the examination fee will be refunded. Resitting fees apply (see page 6).

Technical Difficulties

On rare occasions, technical difficulties occur at testing centers. If you experience a computer-related technical problem, notify the test center administrator immediately. Every effort will be made to correct any difficulties as soon as possible. Should the testing center experience a loss of power, backup systems are in place, and every reasonable effort will be made to retrieve testing data.

Once power is restored, candidates will be able to continue their testing sessions from the point at which they were interrupted.

If technical issues cause you to wait more than 30 minutes after your scheduled appointment time, or a restart delay lasts longer than 30 minutes, you will be given the choice of waiting to continue the exam or rescheduling your appointment with no additional fee.

If you choose not to reschedule, but rather to continue testing after a delay, you will have no other options and your testing results will be considered valid. If you choose to reschedule your appointment or the technical issue cannot be resolved, you will be allowed to test at a later date, at no additional charge and without a required waiting period.

MPJE

What is the MPJE?

The MPJE is a 90-question computer-based examination that uses adaptive technology to deliver selected-response test questions. Of the 90 delivered questions, 75 are operational and will be used to calculate your score. The remaining 15 questions are pretest questions and will not count toward your MPJE score. Pretest questions are included on all MPJE examinations and are administered to evaluate their appropriateness for possible inclusion in future examinations. The pretest questions are dispersed throughout the examination and cannot be identified by the candidate. The total testing time for the MPJE is two hours.

In cooperation with participating state boards of pharmacy, the MPJE is uniformly developed, administered, and scored under policies and procedures developed by NABP. The content of the MPJE is approved by boards of pharmacy, practitioners, and educators from around the country through their service as MPJE Review Committee members, item writers, and board of pharmacy representatives.

All candidates are tested on their mastery of pharmacy law as outlined in the MPJE Competency Statements. Each participating state board of pharmacy approves those questions that are specific to the federal and state laws of the jurisdictions in which candidates are seeking licensure. Candidates must take a separate examination for each state or jurisdiction in which they are seeking licensure.

The MPJE Test Design

The examination is assembled as you answer questions, using information recorded and completed during the examination to influence the composition of the remainder of the examination.

When you respond to computer-selected MPJE questions, the adaptive technology will assess your answers and use that information to select your next test question. The computer will then select a question suited to your estimated ability level from the test's question pool. Your ability level will be estimated from a combination of your responses (right and wrong answers) and the attributes of the questions that you were assigned. The passing scaled score for MPJE is 75. The minimum scaled score you can earn is zero and the maximum is 100.

See page 32 for more information on score results.

Note: You cannot change an answer once you have confirmed an answer choice or go back and review a question once you have moved on to the next question.

You must answer all questions in the order in which they are presented, and you may NOT skip a question.

MPJE Competency Statements

The MPJE Competency Statements provide a blueprint of the topics covered on the examination. They offer important information about the knowledge, judgment, and skills you are expected to demonstrate while taking the MPJE. A strong understanding of the Competency Statements will aid you in your preparation to take the examination.

Your formal education, training, practical experience, and self-study prepare you for the MPJE. The MPJE has been designed to assess how well you apply your knowledge, skills, and abilities to evaluate situations involving the applicable federal and state laws and regulations that govern the practice of pharmacy in the state in which you are seeking licensure. Additional information may also be obtained from the state board of pharmacy where you are seeking licensure.

Note: No distinction is made in the examination between federal and state jurisprudence questions. You are required to answer each question in terms of the prevailing laws of the state in which you are seeking licensure.

Area 1 Pharmacy Practice
(Approximately 84% of Test)

1.01.00 Identify the legal responsibilities of the pharmacist and other pharmacy personnel.

1.01.01 Identify the unique legal responsibilities of the pharmacist-in-charge (or equivalent), pharmacists, interns, and the owner of a pharmacy such as, the theft and/or loss of prescription drugs; the destruction/ disposal of prescription drugs; and the precedence of state, federal, or local requirements.

1.01.02 Identify the qualifications, scope of duties, and conditions for practice of pharmacy technicians and all other non-pharmacist personnel, including such topics as personnel ratios and duties.

1.02.00 Identify the requirements for the acquisition and distribution of pharmaceutical products, including samples.

1.02.01 Identify the requirements for ordering or obtaining pharmaceuticals, including controlled substances, from a supplier of pharmaceuticals or other sources, including the content and maintenance of records of acquisition in pedigrees.

1.02.02 Identify the requirements for distributing a pharmaceutical product, including the content and maintenance of records of distribution. This addresses who may legally possess pharmaceutical products, (including drug samples), product labeling, packaging, repackaging, compounding, and sales to practitioners.

1.03.00 Identify the legal requirements that must be observed in the issuance of a prescription/drug order.

1.03.01 Identify those pharmaceutical products for which a prescription/drug order is required and the limitations on their respective therapeutic uses.

1.03.02 Identify the scope of authority, scope of practice, and valid registration of all practitioners who are authorized under law to prescribe, dispense, or administer pharmaceutical products, including controlled substances. This addresses, but is not limited to federal and state registrations; methadone programs; office-based opioid treatment programs; regulations related to retired or deceased prescribers; Internet prescribing; limits on jurisdictional prescribing; and prescriber/patient relationships.

1.03.03 Identify the conditions under which the pharmacist participates in the administration of pharmaceutical products, or in the management of patients' drug therapy, which may include prescriptive authority, collaborative practice, consulting, counseling, and vaccine administration.

1.03.04 Identify the requirements for issuing a prescription/drug order, including content and format for written; telephonic voice transmission; electronic facsimile; computer and Internet; during emergency conditions and via tamper-resistant prescription forms.

1.03.05 Identify special requirements for the issuance of controlled substance prescriptions/drug orders, including content and format for written; telephonic voice transmission; electronic facsimile; computerized and Internet; during emergency conditions; conditions for changing a prescription; time limits for dispensing initial prescriptions/drug orders; and requirements for multiple Schedule II prescription orders.

1.03.06 Identify the limits of a practitioner's authority to authorize refills of a pharmaceutical product, including controlled substances.

1.04.00 Identify the procedures necessary to properly dispense a pharmaceutical product, including controlled substances, pursuant to a prescription/drug order.

1.04.01 Identify responsibilities for determining whether prescriptions/drug orders were issued for a legitimate medical purpose and within all applicable legal restrictions, addressing such issues as corresponding responsibility; maximum quantities; and restricted distribution systems.

1.04.02 Identify the requirements for the transfer of existing prescription/drug order information from one pharmacist to another.

1.04.03 Identify the conditions under which a prescription/drug order may be filled or refilled. This includes but is not limited to emergency fills or refills; partial dispensing of controlled substances; declarations of disaster or emergency; patient identification; requirements for death with dignity; medical marijuana; and conscience/moral circumstances.

1.04.04 Identify the conditions under which prospective drug use review is conducted prior to dispensing a prescribed pharmaceutical product for appropriate patients. This includes the requirements for documentation, such as those for patient profiles.

1.04.05 Identify the conditions under which drug product selection is permitted or mandated; addressing consent of the patient and/or prescriber; passing on of cost savings; and documentation of the product dispensed.

1.04.06 Identify the requirements for the labeling of pharmaceutical products dispensed pursuant to a prescription/drug order, including such things as generic and therapeutic equivalency; formulary use; auxiliary labels; patient package inserts; Food and Drug Administration medication guides; and written drug information.

1.04.07 Identify the requirements for the appropriate packaging of pharmaceutical products dispensed pursuant to a prescription/drug order, including such things as child-resistant and customized patient medication packaging.

1.04.08 Identify the conditions under which a pharmaceutical product could not be dispensed, including conditions as in adulteration; misbranding; and dating.

1.04.09 Identify the requirements for compounding pharmaceutical products.

1.04.10 Identify the requirements for emergency kits, including such things as supplying; maintenance; access; security; and inventory.

1.04.11 Identify the regulations regarding the return and/or reuse of pharmaceutical products, addressing such issues as charitable programs; cancer or other repository programs; previously dispensed; and from "will call" areas of pharmacies.

1.04.12 Identify procedures and requirements for systems or processes whereby a non-pharmacist may obtain pharmaceutical products, addressing such issues as Pyxis (vending); after hour's access; telepharmacies; and secure automated patient drug retrieval centers.

1.04.13 Identify procedures and requirements for establishing and operating central processing and central fill pharmacies, addressing, among other things, remote order verification.

1.05.00 Identify the conditions for making an offer to counsel or counseling appropriate patients, including the requirements for documentation.

1.05.01 Identify the requirements to counsel or make an offer to counsel.

1.05.02 Identify the requirements to maintain documentation of counseling.

1.06.00 Identify the requirements for the distribution and/or dispensing of nonprescription pharmaceutical products, including controlled substances.

1.06.01 Identify the requirements for the labeling of nonprescription pharmaceutical products.

1.06.02 Identify the requirements for the packaging and repackaging of nonprescription pharmaceutical products.

1.06.03 Identify the requirements for the distribution and/or dispensing of poisons, restricted, nonprescription pharmaceutical products, and other restricted materials or devices including but not limited to pseudoephedrine, dextromethorphan, emergency contraception, and behind the counter products as appropriate.

1.07.00 Identify the proper procedures for keeping records of information related to pharmacy practice, pharmaceutical products and patients, including requirements for protecting patient confidentiality.

1.07.01 Identify the requirements pertaining to controlled substance inventories.

1.07.02 Identify the content, maintenance, storage, and reporting requirements for records required in the operation of a pharmacy, including, but not limited to, prescription filing systems; computer systems and backups; and prescription monitoring programs.

1.07.03 Identify requirements for protecting patient confidentiality, including Health Insurance Portability and Accountability Act requirements.

Area 2 Licensure, Registration, Certification, and Operational Requirements (Approximately 13% of Test)

2.01.00 Identify the qualifications, application procedure, necessary examinations, and internship requirements for licensure, registration, or certification of individuals engaged in the storage, distribution, and/or dispensing of pharmaceutical products (prescription and nonprescription).

2.01.01 Identify the requirements for special or restricted licenses, registrations, authorizations, or certificates for pharmacists, pharmacist preceptors, pharmacy interns, pharmacy technicians, controlled substance registrants, and under specialty pharmacist licenses (nuclear, consultant, etc).

2.01.02 Identify the standards of practice for the practice of pharmacy, including, but not limited to quality assurance programs, including peer review; changing dosage forms; therapeutic substitution; error reporting; public health reporting requirements, such as notification of potential terrorist event, physical abuse, and treatment for tuberculosis; and issues of conscience and maintaining competency.

2.01.03 Identify notification requirements pertaining to their license to practice pharmacy.

2.01.04 Identify the requirements for the renewal or reinstatement of an individual's licensure, registration, or certification.

2.01.05 Identify the reasons for classifications and processes of disciplinary actions that may be taken against a registered, licensed, certified, or permitted individual.

2.01.06 Identify the requirements for reporting to, and participating in, programs addressing the inability of an individual licensed, registered, or certified by the board to engage in the practice of pharmacy with reasonable skill and safety, by reason of impairment caused by the use of alcohol, drugs, chemicals, or other materials or mental, physical, or psychological conditions.

2.02.00 *Identify the requirements and application procedure for the registration, licensure, certification, or permitting of a practice setting or business entity.*

2.02.01 Identify the requirements for registration, license, certification, or permitting of a practice setting, including but not limited to, in-state pharmacies; out-of-state pharmacies; specialty pharmacies; controlled substance registrants; wholesalers; distributors; manufacturers/repackagers; computer services providers; and Internet pharmacies.

2.02.02 Identify the operational and notification requirements for changes to the facility or changes in the application for licensure, registration, certification, or permit of a practice setting such as in remodeling; renaming; change of ownership; moving; and closing.

2.02.03 Identify the requirements for an inspection of a licensed, registered, certified, or permitted practice setting.

2.02.04 Identify the requirements for the renewal or reinstatement of a license, registration, certificate, or permit of a practice setting.

2.02.05 Identify the reasons for classifications and processes of disciplinary actions that may be taken against a registered, licensed, certified, or permitted practice setting.

2.03.00 *Identify the operational requirements for a registered, licensed, certified, or permitted practice setting.*

2.03.01 Identify the requirements for the operation of a pharmacy or practice setting that are not directly related to the dispensing of pharmaceutical products. This includes, but is not limited to, issues related to space; equipment; advertising and signage; security, including temporary absences of the pharmacist; policies and procedures; libraries; and the display of licenses.

2.03.02 Identify the requirements for the possession, storage, and handling of pharmaceutical products, including controlled substances. This includes, but is not limited to, investigational new drugs; repackaged or resold drugs; sample pharmaceuticals; recalls; and outdated pharmaceutical products.

2.03.03 Identify the requirements for delivery of pharmaceutical products, including controlled substances. This includes, but is not limited to, issues related to identification of the person accepting delivery of a drug; use of the mail; contract delivery; use of couriers; use of pharmacy employees; use of kiosks, secure mail boxes, and script centers; use of vacuum tubes; and use of drive-up windows.

Area 3 Regulatory Structure and Terms (Approximately 3% of Test)

3.01.00 *Identify the purpose of, and the terms and conditions found in, the laws and rules that regulate or affect the manufacture, storage, distribution, and dispensing of pharmaceutical products (prescription and nonprescription), including controlled substances.*

This includes such things as the Food, Drug, and Cosmetic Act(s) and Regulations; the Controlled Substances Act(s) and Regulations; OBRA 90's Title IV Requirements; Practice Acts and Rules; other statutes and regulations, including but not limited to, dispensing of methadone, child-resistant packaging, tamper-resistant packaging, drug paraphernalia, drug samples, pharmacist responsibilities in Medicare-certified skilled-nursing facilities; National Drug Code numbers; and schedules of controlled substances.

3.02.00 *Identify the authority, responsibilities, and operation of the agencies or entities that enforce the laws and rules that regulate or affect the manufacture, storage, distribution, and dispensing of pharmaceutical products (prescription and nonprescription), including controlled substances.*

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MPJE Sample Questions

The following are examples of question types that examinees may encounter when taking the MPJE. These questions are presented as examples to familiarize examinees with their formats and are not intended to represent content areas on the MPJE. Every examinee is presented with the opportunity to take a tutorial at the testing center, prior to initiating the MPJE. The tutorial instructs examinees on how to respond to all of the types of questions that could be presented on the examination. NABP strongly encourages each examinee to take the tutorial in order to become familiar with how to submit responses in the computer-based examination.

Multiple-Choice Question Format

How many total continuing pharmacy education hours are required to be completed upon the second renewal of a pharmacist's license in this jurisdiction?

A. 15
B. 20
C. 25
D. 30
E. 40

Multiple-Response Question Format

Which of the following medications are classified as Schedule II controlled substances in this jurisdiction?

(Select **ALL** that apply.)

A. Strattera
B. Lisdexamfetamine
C. Meprobamate
D. Amphetamine
E. Dexmethylphenidate

Ordered-Response Question Format

Place the following in the order in which they would expire according to federal regulations, starting with the earliest.

(**ALL** options must be used.)

Left-click the mouse to highlight, drag, and order the answer options.

Unordered Options	Ordered Response
A partially filled methylphenidate prescription for a patient not in a long-term care facility	
A phoned-in, emergency oxycodone prescription	
A written bupropion prescription	
An electronic pemoline prescription	
A partially filled morphine prescription for a patient in a long-term care facility	

NAPLEX/MPJE Score Results

NAPLEX Score Results

The NAPLEX is the means by which boards of pharmacy assess the competence of candidates for licensure. Any other use of individual NAPLEX scores is inappropriate and is not condoned by NABP. By applying to take the NAPLEX, you authorize NABP to release your test scores to your designated board of pharmacy. NABP will forward your NAPLEX score to the board(s) of pharmacy from which you are seeking licensure, as well as to any state that you have requested receive your scores by score transfer, unless NABP has withheld, invalidated, or cancelled your NAPLEX score, as described in the *Bulletin*.

The minimum acceptable passing score on the NAPLEX scale is 75. The passing score reported is NOT a percentage value.

To receive a test score, you must have completed at least 162 questions on the examination. Candidates completing less than 162 questions will NOT have their scores reported. Candidates who complete at least 162 questions, but fewer than 185 questions, will have a penalty applied and their scores adjusted to reflect the number of questions that remained unanswered. Therefore, it is in the candidate's best interest to answer all questions presented.

NABP uses a mathematically based weighted scoring system to calculate an ability measure for each examinee. These ability measures are transformed to a reporting scale that ranges from 0 to 150. Scaled scores do NOT represent the raw number of correct answers and should not be interpreted as such.

The score is calculated by first determining the candidate's ability level on the NAPLEX and then whether the score has met the minimum passing standard established for the NAPLEX.

The passing standard has been established by a panel of pharmacy experts, and the ability level that defines the passing standard is the same for all NAPLEX administrations.

Failed Attempts

Official score reports for candidates who receive a failing score on the NAPLEX will include a diagnostic section which indicates their relative performance in each major competency area. Because of the secure nature of the NAPLEX, no review of the test questions is allowed. Scores are submitted to the boards of pharmacy on a daily basis. Candidates will receive scores or an official score report for the NAPLEX directly from their boards of pharmacy.

MPJE Score Results

The MPJE is the means by which boards of pharmacy assess pharmacist licensure candidates' knowledge of pharmacy jurisprudence. Any other use of individual MPJE scores is inappropriate and is not condoned by NABP. By applying to take the MPJE, you authorize NABP to release your test scores to the designated boards of pharmacy. NABP will forward your MPJE score to the board of pharmacy from which you are seeking licensure unless NABP has withheld, invalidated, or cancelled your MPJE score, as described in this *Bulletin*.

By applying to take the MPJE, you authorize NABP to release your test scores to the designated boards of pharmacy.

To receive an MPJE test score, you must have completed at least 80 questions on the examination. Candidates completing fewer than 80 questions will NOT have their scores reported. Candidates who complete at least 80 questions, but fewer than 90 questions, will have a penalty applied and their scores adjusted to reflect the number of questions that remained unanswered. Therefore, it is in the candidate's best interest to

answer all questions presented. The minimum acceptable passing score on the MPJE scale is 75. The passing score reported is NOT a percentage value.

NABP uses a mathematically based weighted scoring system to calculate an ability measure for each examinee. These ability measures are transformed to a reporting scale that ranges from 0 to 100. Scaled scores do NOT represent the raw number of correct answers and should not be interpreted as such.

The score is calculated by first determining the candidate's ability level on the MPJE and then determining whether the score has met the MPJE passing standard. The passing standard has been established by a panel of pharmacy experts and is the same for all candidates for licensure. Candidates will receive a score or an official score report for the MPJE directly from their boards of pharmacy. Because the MPJE is unique to the state or jurisdiction in which you seek licensure, it is not possible to transfer your MPJE score to another state.

Note: Only the individual boards of pharmacy have the authority to issue a license to practice pharmacy. The posting by NABP of a passing score on an examination does not constitute a license to practice pharmacy. Boards will not accept examination scores posted online by NABP for purposes of score transfer or obtaining licensure. Online score reports are for candidate use only.

NAPLEX and MPJE Score Review

On occasion, a candidate may believe that the score reported is not accurate. Please note that prior to the release of NAPLEX or MPJE scores to the boards of pharmacy, all scores are carefully verified with an independent scoring tool to ensure the validity of the score. It is extremely unlikely that a score will be changed through the review process. However, should a candidate request to have a NAPLEX or MPJE score reviewed, they must do so within 60 days of the date that scores are released to the respective board of pharmacy. The request must be submitted in writing and be accompanied by the score review fee. In your written request you must include your name, NABP e-Profile number, address, and phone number. You will be informed in writing of the score review results within two to four weeks. The fee for the NAPLEX or MPJE score review is $100 per examination. The fee must be submitted in the form of a money order, bank draft, or a certified check payable to the National Association of Boards of Pharmacy or NABP.

Score Holds/Psychometric review process

On occasion, a candidate's score will be placed on hold for further evaluation. Test scores may be subject to a hold as part of NABP's routine quality control and assurances processes. Tests are evaluated to ensure compliance with delivery and scoring models. Test scores may also be held as a result of an incident reported at the testing center or an observed difference in a candidate's performance on two or more examination attempts. In the event of a score hold, NABP will notify the respective board of pharmacy and the candidate within seven business days. Should you receive notification of a score hold, there will be explicit instructions regarding the action that you need to take in order to respond to NABP's inquiries. All inquiries regarding score holds should be addressed to NABP_comp_assess@nabp.net.

Retake Policy

Effective March 1, 2013, candidates will be limited to five attempts to pass the NAPLEX and MPJE. Candidates who have attempted to pass the exams five or more times by March 1, 2013, will be permitted one more opportunity to pass the examinations upon approval from a board of pharmacy. Candidates who have attempted to pass the exams fewer than five times by March 1, 2013, will be subject to the new five-attempt limit. Failure to finish an exam is counted as an attempt.

MPJE candidates will have five chances per jurisdiction or state to pass the exam. For example, a candidate may attempt to pass the MPJE in State A five times and will also have five attempts for State B.

Some exceptions may apply, as NABP member boards retain the authority to determine the number of attempts per candidate in their jurisdiction. If you have any questions, or require more information about the five-attempt limit, please contact NABP Customer Service, Monday through Friday, 9 AM to 5 PM Central Time, at 847/391-4406, or by email at custserv@nabp.net.

See page 18 for more information on score cancellations.

Waiting Periods

Candidates who fail or do not complete the NAPLEX must wait 91 days before another attempt. For the MPJE the waiting period is 30 days between attempts.

Waiting periods also apply for both examinations after a missed appointment.

Contact the state board of pharmacy for which you are seeking licensure regarding additional waiting periods.

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NAPLEX/MPJE Contacts

Contacts for Your Questions

The following table provides you with contact information in the event you have questions about the examination programs or procedures.

Questions About:	Contact:
• Eligibility to take the NAPLEX/MPJE • ADA accommodations • Examination results	The board of pharmacy in the state(s) in which you are seeking licensure. The most current listing of board of pharmacy contacts is available on NABP's website at *www.nabp.net/boards-of-pharmacy.*
• Scheduling, rescheduling, or canceling your testing appointment • Test center directions	Pearson VUE Customer Service at 888/709-2679, or visit the website at *www.pearsonvue.com.*
• Misplaced ATT letter	Pearson VUE Customer Service at 888/709-2679, or visit the website at *www.pearsonvue.com.*
• Questions about the content of the NAPLEX/MPJE • General comments about the test center • General NAPLEX/MPJE information • Score transfer	**Mail:** NABP Customer Service 1600 Feehanville Dr Mount Prospect, IL 60056 **Phone:** 847/391-4406 **Fax:** 847/391-4502 **Website**: *www.nabp.net* **Email:** custserv@nabp.net **Hours**: Monday to Friday, 9 AM to 5 PM Central Time
• Name or address changes and corrections.	NABP and the board(s) of pharmacy in the state(s) in which you are seeking licensure.

Candidate Comments

NABP constantly evaluates the examinations and, therefore, is open to and appreciative of your constructive comments. Immediately after your examination ends, any comment or complaint about any matter related to the examinations can be made in the comment section of the exit survey.

You may also send your comments about the test center or questions on your examination via mail to NABP at 1600 Feehanville Dr, Mount Prospect, IL 60056, or via e-mail at custserv@nabp.net.

Report Exam Irregularities

NABP examinations are administered under strict security measures, and information on suspected examination irregularities, acts of unethical behavior, and breaches of security can be reported to NABP through the website or by contacting Customer Service at 847/391-4406.

Incidents that compromise the content of any NABP examinations can be submitted anonymously, or, to further discuss the incident with NABP staff, include personal contact information when submitting the report. Reports of suspected irregularities are treated confidentially and are investigated fully in support of NABP's commitment to ensuring the integrity and reliability of its examinations.

MARK R. WARNER
VIRGINIA

FEB 2 0 2015
DHP

COMMITTEES:
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COMMERCE, SCIENCE, AND TRANSPORTATION
BUDGET
RULES AND ADMINISTRATION
INTELLIGENCE
JOINT ECONOMIC COMMITTEE

United States Senate

WASHINGTON, DC 20510–4606

February 19, 2015

Ms. Ellen B. Shinaberry
Chair
Virginia Board of Pharmacy
9960 Mayland Drive, Suite 300
Henrico, VA 23233-1485

Dear Ms. Shinaberry,

I have recently been contacted by Mr. John W. Frye of Rocky Mount. Attached please find a copy of that correspondence. I would appreciate it if you could look into this matter and provide me with an appropriate response. Thank you.

Sincerely,

Mark R Warner

MARK R. WARNER
United States Senator

MRW/kp
Enclosure

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Mr. John W. Frye (8435778)

Contact Information:

Rocky Mount Family Pharmacy 1165 Franklin Street Rocky Mount, VA 24151-1248
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Incoming Message:

Date: 2/9/2015

I am trying to get this issue addressed as and independent pharmacist. I have sent to the SCC, Board of Pharmacy, and NCPA. Can you help us address this issue, and the issue of Pharmacy Benefit Manager oversight? Please help Mom and Pop drugstores survive. Caremark, Express Scripts, Optum Rx, Humana, Aetna, and the like are killing us. We just want a level playing field to compete and we have no where to turn. This email was turned down by the Virginia Corporation commision and insurance bureau as not having the authority to act. The Virginia Board of Pharmacy also refuses to get involved with PBM ovesight although they license them. The National Community Pharmacist's association is involved but needs help on a Federal and State level. Please help us.

thanks,

John W. Frye R.Ph.

----- Original Message -----

From: Familypharmacy4

To: sccinfo@scc.virginia.gov

Cc: Stuart Family Pharmacy ; Rick McKaig ; Family Stanleytown ; Chris Jones ; keithhodges98@gmail.com

Sent: Wednesday, February 04, 2015 12:28 PM

Subject: Complaint against Caremark Corporatiion

Dear Sirs,

My name is John W. Frye R.Ph. and I represent Family Discount Pharmacy LLC, which is a registered corporation in VA and owns 5 pharmacies in Southwestern Virginia. I need your help in filing a complaint against Caremark involving discrimination in their credentialing and re-credentialing practices involving what information they require for independent pharmacies versus the chain pharmacies such as CVS, Walgreen's, Wal-Mart, and Rite Aid, etc. They will terminate our contracts for payment of prescriptions if we do not comply. The point of the complaint is that they are requiring documentation of items for independent pharmacies that they do not require for other contractors and are thus discriminatory in their practices which is unlawful.

Here are examples of required information in a recent credentialing application for one of our pharmacies.

1. Photographs and detailed floor plans of our pharmacies stating what each area is used for and what type of individuals occupy that space and what they do in those areas.
2. Evidence of Prescription Monitoring Program submissions for the last 30 days (this is a violation of our agreement with the state.)
3. All Board of Pharmacy inspection reports for the previous 24 months.
4. Policies of compounding of prescriptions with 3 or more ingredients.
5. List of API approved vendors with copies of the last 30 days invoices.
6. Polices of Anti Kick Back statue policies

7. Disclosure of all owners, investors, and shareholders of our corporation with corresponding percentage of ownership and personal information such as birth certificate, social security number, and address and phone numbers.

Caremark and other Pharmacy Benefit Managers commit discriminatory practices as a regular business practice and we want them to cease doing so, as it is a threat to our ability to conduct normal business. The threat of termination of our contracts with them should not be allowed if we do not provide the above information.

Please help us file this complaint and contact Caremark to end this blatant violation of our rights of privacy regarding the business practices of our corporation.

Thank you for your considerations and assistance,

John W. Frye R.Ph.

Rocky Mount Family Pharmacy
1165 Franklin St.
Rocky Mount, VA 24151
540-489-5400

Virginia Board of Pharmacy

COMPLIANCE WITH USP STANDARDS FOR COMPOUNDING

§54.1-3410.2 requires pharmacies performing sterile or non-sterile compounding to comply with USP Standards. USP standards for sterile and non-sterile compounding may be found in the current editions of the USP-NF. In accordance with 18VAC110-20-170, the Board requires a pharmacy to maintain references consistent with the pharmacy's scope of practice and with public safety.

USP Chapter 795 lists the requirements for non-sterile compounding including information about the compounding environment, equipment, stability criteria and beyond-use dating and records. USP Chapter 797 lists requirements for policies and procedures, training and evaluation of personnel performing sterile compounding, determining risk levels and the physical standards for the sterile compounding area. The Board expects that the requirements of Chapters 795 and 797 will be found in compliance at time of inspection.

The terms "annually" and "semiannually" as used in USP Chapters 795 and 797 are defined to mean every 12 months and every 6 months, respectively. Records associated with annual and semiannual requirements shall be maintained in accordance with USP standards. Such records may be maintained as an electronic image that provides an exact image of the document that is clearly legible provided such electronic image is retrievable and made available at the time of inspection or audit by the Board or an authorized agent.

1. ***Where may information regarding USP-NF standards for compounding be located?***

   A subscription to the current version of "USP on Compounding: A Guide for the Compounding Practitioner" may be purchased at http://www.usp.org/store/products-services/usp-compounding This guide provides access to all compounding-related General Chapters from the USP-NF and is updated with the release of each new USP-NF edition and supplement. The latest edition, USP 36- NF 31, published on November 1, 2012 becomes official May 1, 2013.

2. ***Does the law require compliance only with Chapter <797>?***

   No, the law requires compliance with all applicable chapters within USP-NF. Regarding sterile compounding, pharmacists should pay particularly close attention to General Chapters: <1> Injections, <71> Sterility Testing, <85> Bacterial Endotoxin Testing, and <797> Pharmaceutical Compounding- Sterile Preparations.

3. ***Are there specific educational and training requirements regarding personnel?***

Yes. In USP chapter <797>, compounding personnel are required to be adequately skilled, educated, instructed, and trained to correctly perform and document the following activities in their sterile compounding duties: perform aseptic hand cleansing and disinfection of nonsterile compounding surfaces; select and apropriately don protective garb; maintain or achieve sterility of compounded sterile products in ISO class 5 environments; identify, weigh, and measure ingredients; manipulate sterile products aseptically; sterilize high-risk level compounded sterile products and label; and, inspect the quality of compounded sterile products. Personnel must also sucessfully complete a site-specific training program as required in Regulation 18VAC110-20-111.

3. ***In the absence of sterility testing, what beyond use dates (BUDs) must be used?***

When sterility testing has not been performed, the assigned BUD must not exceed the following allowances:

	Controlled Room Temperature	Refrigerator	Freezer
Low-risk	48 hours	14 days	45 days
Medium-risk	30 hours	9 days	45 days
High-risk	24 hours	3 days	45 days

4. ***What BUD must be assigned to a single dose vial used in preparing a compounded sterile product?***

- If the single dose vial is punctured outside of an ISO Class 5 environment, the assigned BUD shall not exceed 1 hour, unless specified otherwise by the manufacturer;
- If the single dose vial is puntured within and stored within an ISO Class 5 environment, the assigned BUD shall not exceed 6 hours;
- A puntured single dose vial that is removed from the ISO Class 5 environment such as for final verification purposes shall not exceed 1 hour from being removed from the ISO Class 5 environment or the originally assigned BUD of 6 hours within the ISO Class 5 environment, whichever is shorter (reference the Center For Disease Control (CDC) and USP Appendix);

5. ***Is it appropriate to assign a BUD of 90 days in the absence of sterility testing if there is literature indicating the stability of the drug is assured for 90 days?***

No, it is inappropriate and a violation of law to assign a BUD which exceeds the USP default BUDs in the absence of sterility testing. Drug stability should not be confused with drug sterility.

6. ***How may stability information be taken into consideration when assigning a BUD?***

Stability information for multiple drugs may be considered when combining the drugs in a compound, assuming the shortest BUD is used to assign stability to the compound. Peer-review or reference source literature shall be consulted and the professional judgement of the pharmacist exercised when assigning the BUD of a compound containing multiple drugs. Any extended BUD must also comply with the applicable USP Chapter <795> or <797>.

7. ***What concepts, at a minimum, should be taken into consideration when determining drug stability?***

Pharmacists should use professional judgment to determine appropriate references of chemical stability information and note that sterile and non-sterile drug stability is formulation specific. Existing stability information may only be used when the compound has been prepared using the same formulation (USP-NF equivalent ingredients) as used in either at least one peer-reviewed article or other reliable reference source. The process used by the pharmacist to determine drug stability should be well-documented and maintained for inspector review.

Additionally, stability may be estimated for an aqueous or non-aqueous compound under the following conditions:

- Stability information exists in peer-reviewed articles or reference sources indicating stability at a low concentration and high concentration and therefore, stability for concentrations in-between could be estimated;
- Stability of the drug is not concentration-dependent; and,
- The drug is compounded using the same formulation (USP-NF equivalent ingredients) as used in the peer-reviewed articles or reference sources.

8. ***What is skip lot testing and may skip lot testing be used to perform sterility testing of compounded sterile products?***

Skip lot testing is a process that only tests a fraction of the drugs compounded. It is NOT appropriate for sterility testing. It may only be used for ensuring consistency and drug strength (potency). Because skip lot testing is complex and requires a robust program, it may not be possible for a pharmacy to properly implement. Information regarding skip lot testing may be accessed at http://www.itl.nist.gov/div898/handbook/pmc/section2/pmc27.htm

9. ***How may a hospital pharmacy "batch-producing" limited quantity of CSPs for IN-HOUSE use extend the BUD past the default dating in Chapter <797>?***

EACH BATCH must undergo sterility testing in accordance with USP Chapter <71> in order to extend the BUD past the default dating in Chapter <797> and the appropriate documentation to support an extended BUD must be kept on file for presentation upon inspection.

10. ***Do batches less than 25 require sterility testing to be performed?***

No, however, the batches may not be assigned a BUD which exceeds the default BUDs in USP Chapter <797>. The chapter requires sterility testing according to USP <71> before CSPs are dispensed or administered when:

- high-risk level CSPs that are prepared in groups of more than 25 identical individual single-dose packages (e.g., ampuls, bags, syringes, vials) or
- in multiple-dose vials (MDVs) for administration to multiple patients or
- CSPs that are exposed longer than 12 hours at 2 to 8 C and longer than 6 hours at warmer than 8 C before they are sterilized.

11. How often must the primary engineering control, e.g., laminar airflow workbench and secondary engineering control, e.g., ante and buffer rooms be certified?

Certification of the primary and secondary engineering controls shall be performed no less than every six months and whenever the device or room is relocated, altered, or major service to the facility is performed. The certification must be performed no later than *the last day of the sixth month*, following the previous certification.
***Note- this guidance reflects a change to Major Deficiencies 22 and 23 in Guidance Document 110-9 which was amended at the March 2013 full board meeting.

12. Must compounding personnel who work in multiple pharmacies, to include pharmacy interns on rotations, pass a media-fill test at each pharmacy where they will prepare CSPs?

Yes, all compounding personnel working in multiple pharmacies, to include pharmacy interns on rotations, must pass a media-fill test at each pharmacy prior to performing sterile compounding.

13. How often must media-fill testing be performed?

Media-fill testing of all compounding personnel shall be performed initially prior to beginning sterile compounding and at least annually thereafter for low and medium-risk compounding, and semiannually for high-risk level compounding. ***Note - the terms "annually" and "semi-annually" are defined within this guidance document to mean every 12 months and every 6 months, respectively. Annual media-fill testing must be performed no later than the last day of the twelfth month from the date the previous media-fill test was initiated. Semiannual media-fill testing must be performed no later than the last day of the sixth month from the date the previous media-fill test was initiated.

14. If compounding personnel fail a media-fill test, may they continue preparing compounded sterile products?

No, compounding personnel who failed a media-fill test may not be allowed to prepare compounded sterile products (low, medium, or high-risk) prior to retraining and receipt of a passing media-fill test. ***Note- this guidance reflects a change to Major Deficiency 26a in Guidance Document 110-9 which was amended at the March 2013 full board meeting.

15. Because batches less than 25 do not require sterility testing to be performed, may the CSP which may have been autoclaved be assigned an extended BUD based on stability data?

Yes, sterility tests for autoclaved CSPs are not required unless they are prepared in batches of more than 25 units. The board would expect to see that biological indicators are used with each autoclave batch and that the cycle time and temperature were recorded on a log or printer tape directly from the autoclave.

16. Does USP-NF address how long a CSP may hang for infusion?

No, USP-NF does not address how long a CSP may hang for infusion. Refer to facility policy on this issue. USP-NF, however, does require the administration of CSPs to begin prior to the assigned BUD.

17. May a pharmacist repackage Avastin for office administration not pursuant to a patient-specific prescription?

No. While pharmacists may repackage a drug product when dispensing a drug pursuant to patient-specific prescription, a pharmacist may not repackage a drug for another entity. The board has historically interpreted the repackaging of a drug for distribution purposes as an act restricted to a manufacturer, defined in Va Code §54.1-3401. This interpretation appears consistent with recent warning letters from the US Food and Drug Administration (FDA). The allowance in Va Code §54.1-3401 for a pharmacist to provide compounded drugs to a physician for office administration does not apply. Repackaging Avastin does not constitute compounding as it does not involve the mixing of two of more substances.

18. May a pharmacist repackage Avastin pursuant to a patient-specific prescription?

Yes, a pharmacist may repackage a drug as part of the dispensing process pursuant to a patient-specific prescription.

19. What concepts, at a minimum, should be taken into consideration when performing sterility testing of CSPs?

- Maintain a written policy and procedure manual clearly identifying sterility testing procedures used by the pharmacy and processes for assigning BUDs.
- Prior to using an outside testing company to perform sterility testing, evaluate the company to determine if it performs testing in full compliance with USP Chapter <71>. This may be done by reviewing 483 reports issued by the FDA to the testing company and which may be available on the FDA website. Alternatively, request copies of the 483 reports directly from the testing company. The observed deficiencies noted on the 483 reports will assist the pharmacist in evaluating the testing company's level of compliance. Also, request written documentation from the testing company which explains the sterility testing processes used and how it complies with USP Chapter <71> in its totality. This documentation should contain, at a minimum, specific details regarding the method of testing, method suitability associated with each sterility testing process to ensure the drug being tested will not interfere with the test, identification of testing method (membrane filtration is the preferred method of testing), two growth media, and number of days of incubation. Have this documentation readily available for inspector review.
- When performing sterility testing in-house, document in the written policy and procedure manual, at a minimum, specific details regarding the method of testing, method suitability associated with each sterility testing process to ensure the drug being tested will not interfere with the test, identification of two growth media, and number of days of incubation.

- Vendors providing products for in-house testing must describe all conditions and limitations to their testing products. Ensure the appropriate filtration volume and sample size is being tested.
- When determining an appropriate sterility testing process, note that the preferred method per USP is membrane filtration. The Board strongly recommends that written documentation justifying the use of direct inoculation be available for inspection
- Ensure the sterility testing incorporates two media for growth.
- The sample size used for testing must comply with USP Chapter <71>, tables 2 and 3.
- Maintain robust recordkeeping, e.g., chart the dates, temperatures, growth associated with the two media incubations, and employee signatures. Do not simply indicate "no growth" without indicating which growth media was used and the number of days incubated.

20. Must sterility testing be performed on all batches of CSPs?

Sterility testing is not required of low and medium-risk level batched CSPs if the BUDs do not exceed the default BUDs found in USP Chapter <797>. If the low or medium-risk level batched CSP is to be assigned an extended BUD, then sterility testing must be performed. Sterility testing must always be performed of high-risk level CSPs in batches greater than 25. See Response to Q#7

21. What is the definition of a "batch"?

USP does not currently define the term "batch". In 21CFR210.3, FDA defines "batch" to mean a specific quantity of a drug or other material that is intended to have uniform character and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of manufacture.

22. How should a dilution or stock bag for pediatrics be treated?

USP does not currently address this issue, however, the Board advises that the dilution or stock bag should be treated as a single dose container/vial with the remains being discarded within 6 hours of compounding.

23. What are some important considerations regarding membrane filtration and filter integrity testing, aka bubble point testing?

Membrane filtration may be accomplished using a 0.22 micron filter. It is important to note that sterility testing cannot be accomplished by simply performing membrane filtration. Filter integrity testing, also known as a bubble point test, must be performed to verify that the filter was successful in its application. Smaller disc filters may have filter volume limitations which must be taken into consideration. Because it is known that filtration has not always been successful in preventing the passing through of microorganisms, pharmacists must always build quality processes into their sterile compounding to minimize the risk and the introduction of contamination.

24. What are some best practices for performing required media fill testing and gloved fingertip sampling?

Persons performing high-risk level CSPs must successfully pass media-fill testing prior to initially compounding sterile products and semi-annually (within 6 months of the last testing). Persons performing low or medium-risk level CSPs must successfully pass media-fill testing prior to initially compounding sterile products and annually (within 12 months of the last testing). Persons who fail a media-fill test may not perform sterile compounding prior to retraining and receipt of a passing media-fill test.

Media fill testing should mimic the most challenging sterile compounding activity performed by those persons. Robust documentation regarding the media-fill testing process and individual testing must be maintained which documents, at a minimum, the media growth to include lot and expiration date, number of days in incubator, incubator temperature, name of person being tested, dates testing performed, results of growth. Blanks in the form used to document media fill testing should be evaluated and corrected to ensure an accurate testing process.

Glove finger tip testing verifies the person can properly don gloves without contaminating them and is routinely disinfecting them. To improve compliance with required testing, pharmacists should consider performing media-fill testing and glove finger tip testing around the same time that environments are being certified. Employees who use isolators must also perform gloved fingertip sampling by donning sterile gloves within the ISO Class 5 main chamber and testing those gloves.

25. How often must air and surface sampling be performed?

USP requires air ~~and surface~~ sampling to be performed ~~"periodically"~~ at least every 6 months. ~~The Board advises that air and surface sampling should be performed at least quarterly annually.~~ Air sampling shall be conducted using volumetric air sampling equipment and the appropriate media (bacterial sampling for all risk levels and fungi sampling for high-risk level compounding operations). ~~It may be performed by pharmacy personnel or outsourced.~~

USP requires surface sampling to be performed "periodically". The Board advises that surface sampling should be performed at least quarterly. It may be performed by pharmacy personnel or outsourced.

26. What minimally should be taken into consideration when having primary and secondary engineering controls certified?

Certification and testing of primary (LAFWs, BSCs, CAIs and CACIs) and secondary engineering controls (buffer and ante areas) shall be performed by a qualified individual no less than every six months and whenever the device or room is relocated, altered, or major service to the facility is performed. Certification procedures such as those outlined in the CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006) shall be used. Pharmacists shall request written documentation from the certifying company explaining how the company's certifying processes fully comply with these standards. This shall include

written acknowledgement that certification testing will be performed under dynamic conditions. Certifications issued shall specifically indicate the ISO standard for each primary and secondary engineering control and not simply indicate "passed".

27. What minimally should be taken into consideration when compounding multidose vials?

Currently USP Chapter <797> does not contain specific requirements for compounding multiple-dose containers, such as the need for a preservative, nor requirements for testing, labeling, and container closures for compounded multiple-dose containers. Chapter <797> references Chapter <51> for informational purposes as the source of the 28-day BUD after initially entering or opening a multiple-dose container, unless otherwise specified by the manufacturer.

28. What BUDs are recommended for non-sterile compounded products?

USP Chapter <795> makes the following recommendations for assigned BUDs of non-sterile compounded products:

Nonaqueous formulations - The BUD is not later than the time remaining until the earliest expiration date of any API or 6 months, whichever is earlier.
Water-Containing Oral Formulations - The BUD is not later than 14 days when stored at controlled cold temperatures.
Water-Containing Topical/Dermal and Mucosal Liquid and Semisolid Formulations – The BUD is not later than 30 days.

These maximum BUDs are recommended for nonsterile compounded drug preparations in the absence of stability information that is applicable to a specific drug or preparation. The BUD shall not be later than the expiration date on the container of any component.

29. May a non-sterile compounded product be assigned an extended BUD beyond the recommendations in USP Chapter <795>?

The Board advises that non-sterile compounded products should not be assigned an extended BUD unless the pharmacist maintains full documentation to justify the appropriateness of the extended BUD.

30. Under what conditions may a glove box be used to perform sterile compounding?

The glove box, referred to as an isolator (CAI/CACI) in Chapter <797>, must be placed in an ISO 7 buffer area UNLESS it meets all of the following conditions listed in USP Chapter 797:

- The isolator shall provide isolation from the room and maintain ISO Class 5 during dynamic operating conditions, including transferring ingredients, components, and devices into and out of the isolator and during preparation of CSPs.
- Particle counts sampled approximately 6 to 12 inches upstream of the critical exposure site shall maintain ISO Class 5 levels during compounding operations.

- Not more than 3520 particles (0.5 µm and larger) per m^3 shall be counted during material transfer, with the particle counter probe located as near to the transfer door as possible without obstructing the transfer.[8]

It is incumbent upon the compounding personnel to obtain documentation from the manufacturer that the CAI/CACI will meet this standard when located in environments where the background particle counts exceed ISO Class 8 for 0.5-µm and larger particles. When isolators are used for sterile compounding, the recovery time to achieve ISO Class 5 air quality shall be documented and internal procedures developed to ensure that adequate recovery time is allowed after material transfer before and during compounding operations.

If the primary engineering control (PEC) is a CAI or CACI that does not meet the requirements above or is a LAFW or BSC that cannot be located within an ISO Class 7 buffer area, then only low-risk level nonhazardous and radiopharmaceutical CSPs pursuant to a physician order for a specific patient may be prepared, and administration of the CSP shall commence within 12 hours of preparation or as recommended in the manufacturer's package insert, whichever is less.

The weighing of chemicals must occur in at least ISO Class 8 conditions. An isolator used to compound hazardous drugs (with exception of "low volume") must be located in a separate negative pressure room and exhausted outside.

31. May hazardous sterile products be compounded in the same hood as non-hazardous sterile drugs?

No. Hazardous sterile products may not be compounded in the same hood as non-hazardous CSPs.

32. Under what conditions may hazardous drugs be compounded in a cleanroom with positive air pressure?

USP allows a "low volume" of hazardous CSPs to be compounded in a cleanroom with positive air pressure, however, USP does not currently define the term "low volume". The "low volume" hazardous CSPs must be compounded under two tiers of containment, the isolator or biologic safety cabinet and closed system transfer device.

33. Must a compounding pharmacy using Schedule II powders comply with the perpetual inventory requirements of Regulation 18VAC110-20-240?

Yes.

34. Must bladder irrigation fluids and irrigations for wounds be prepared in a sterile manner in compliance with USP-NF requirements?

Yes.

35. In addition to bladder irrigation and irrigations for wounds, what other types of drugs must be prepared in a sterile manner in compliance with USP-NF requirements?

USP Chapter <797> states that for the purposes of the chapter, a compounded sterile product includes any of the following: compounded biologics, diagnostics, drugs, nutrients, and radiopharmaceuticals, including but not limited to the following dosage forms that must be sterile when they are administered to patients: aqueous bronchial and nasal inhalations for the lungs, baths and soaks for live organs and tissues, injections (e.g., colloidal dispersions, emulsions, solutions, suspensions), irrigations for wounds and body cavities, ophthalmic drops and ointments, and tissue implants. Note: Nasal sprays and irrigations for the nasal passages may be prepared as non-sterile compounds.

36. May a pharmacist provide a compounded drug to another pharmacy or veterinarian who will then dispense the drug to his client?

No. Va Code §54.1-3410.2 indicates pharmacists shall not distribute compounded drug products for subsequent distribution or sale to other persons or to commercial entities, including distribution to pharmacies or other entities under common ownership or control with the facility in which such compounding takes place.

VA Code §54.1-3410.2 does authorize pharmacists to provide compounded drug to practitioners of medicine, osteopathy, podiatry, dentistry, or veterinary medicine to administer to their patients in the course of their professional practice, either personally or under their direct and immediate supervision. The compounded drug must be labeled with (i) the statement "For Administering in Prescriber Practice Location Only"; (ii) the name and strength of the compounded medication or list of the active ingredients and strengths; (iii) the facility's control number; (iv) an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding; and (v) quantity.

37. May a prescriber or patient obtain a compounded sterile product from an out-of-state pharmacy that is not registered by the Virginia Board of Pharmacy as a nonresident pharmacy?

No, only nonresident pharmacies registered by the Virginia Board of Pharmacy may ship compounded sterile products into Virginia. Verification of registration may be determined at https://secure01.virginiainteractive.org/dhp/cgi-bin/search_publicdb.cgi by searching the business name and choosing the occupation of "non-resident pharmacy".

38. What risk-level is associated with repackaging an undiluted multi-dose vial?

The repackaging of an undiluted multi-dose vial, e.g., insulin, into multiple syringes is a medium-risk level manipulation when puncturing the vial more than 3 times. Note: this guidance addresses repackaging, not administration.

> No unlabeled containers—continued from page 1

tragic story was featured in our short documentary film, *Beyond Blame* (www.ismp.org/sc?id=440), which describes how medication errors affect practitioners and patients alike. One of the film's stand-out scenes features the anesthesiologist present during the event saying, "Now I will bet any dollar that I have, that this has happened before, multiple times, same type of scenario, and I'll bet it's going to happen again." Well, he was right! Since then, ISMP and others have repeatedly published cases of mix-ups between unlabeled solutions or medications on the sterile field, including but not limited to the following examples:

- A woman was injected with hydrogen peroxide instead of lidocaine 1% for local anesthesia when both were on the sterile field in unlabeled cups. The patient suffered no adverse reaction (www.ismp.org/sc?id=443).
- A man was injected with lidocaine 2% instead of contrast media during angiography; both were on the sterile field in unlabeled syringes. He suffered a grand mal seizure but recovered (www.ismp.org/sc?id=443).
- A caustic germicidal solution (pH of 13) was mistakenly applied to the genitals of a 37-year-old male patient instead of vinegar during surgical removal of genital warts, causing severe burns (www.ismp.org/sc?id=443).
- A patient's face was injected with ethyl alcohol instead of lidocaine prior to a surgical procedure. Both of the clear solutions were in unlabeled basins. The patient suffered partial facial paralysis (www.ismp.org/sc?id=445).
- A patient had an injection site infiltrated with contrast media from an unlabeled basin instead of lidocaine for local anesthesia prior to angiography. Local tissue damage resulted (www.ismp.org/sc?id=443).
- A 60-year-old woman undergoing coil placement via cerebral angiography to repair a brain aneurysm was accidentally injected with the skin prep solution, chlorhexidine, instead of contrast media. Both clear solutions were on the sterile field in unlabeled basins. Severe chemical injury to the injection site in the patient's groin led to leg amputation, which resulted in a stroke, organ failure, and death (www.ismp.org/sc?id=444).
- A patient under general anesthesia had his knee injected with **EPINEPH**rine found in an unlabeled syringe on an OR prep table, which was mistaken for bupivacaine. The patient experienced a heart attack, pulmonary edema, and died (www.ismp.org/sc?id=441).

High-profile cases like these and the national attention given to unlabeled medication and solution containers by The Joint Commission, the Centers for Medicare & Medicaid Services, the US Food and Drug Administration, ISMP, and others suggest that most healthcare professionals have basic knowledge of the risks associated with unlabeled containers. Thus, repetition of this error suggests that healthcare providers have lost the perception of risk associated with unlabeled products, mistakenly believe the risk is insignificant or justified, or have forgotten to implement effective prevention strategies in all procedural areas. First, *normalcy bias* may cause some to falsely believe that an error would never happen to them. This leads to the mistaken belief that labeling is not always necessary or the rationalization of faulty strategies. These faulty strategies may include identifying products by where they

continued on page 3—No unlabeled containers >

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Propylene glycol is a clear, colorless, odorless, and tasteless product used as a stabilizer, thickener, and texturizer. The above product contains 103.6 g/100 mL of propylene glycol. The infant received 600,000 units of vitamin D_2, equivalent to 75 mL of solution or 77.7 g of propylene glycol. According to the World Health Organization, this far exceeds the maximum tolerable amount of 25 mg/kg/day (or 227.5 mg for the baby in this event). In fact, the baby was exposed to 340 times the maximum amount, which led to acute renal failure. The infant's serum creatinine rose from 0.22 mg/dL to 3 mg/dL. Fortunately, the child survived. Renal toxicity has occurred in neonates who were given HIV medications such as **KALETRA** (lopinavir/ritonavir) oral solution, which also uses propylene glycol as a carrier given the lack of better alternatives for solubility of this drug (www.ismp.org/sc?id=442).

As a dietary supplement, vitamins are regulated by the US Food and Drug Administration (FDA) Center for Food Safety and Applied Nutrition (CFSAN). FDA, which received this error report, should require manufacturers to state the propylene glycol ingredient more prominently on the label, including the amount in the container. Since all liquid vitamin D_2 products have propylene glycol, consider preparing an approximate dose for stoss therapy from vitamin D_2 liquid filled capsules that do not contain propylene glycol. Computer systems should warn staff about excessive propylene glycol and the potential for renal toxicity with pediatric patients.

State drug tracking database helps prevent an error. Many states have been working to reduce prescription drug abuse, overdose, and misuse by enacting legislation to set up scheduled drug electronic tracking programs. Doctors and pharmacists can access the program database to prevent an individual from going from doctor to doctor to obtain controlled drugs. A report we received recently shows how these systems can also protect patients against medication errors.

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are placed on the sterile field and overreliance on immediate use before the container leaves one's hands. Or, unlabeled containers may be considered "*someone else's problem,*" a phenomenon similar to *bystander apathy* that causes people to ignore a problem because they believe it is not relevant to them, unlikely to happen, something they can't fix, or someone else's responsibility to fix. Additionally, some may believe they have implemented the perfect labeling procedures only to find partial compliance because the task is tedious, error-prone, or impractical without system changes.

Results from the **2011 ISMP Medication Safety Self Assessment for Hospitals** (N = 1,310 hospitals) showed that 1% of participating hospitals **never** labeled containers of solutions or medications on the sterile field; 24% labeled containers **inconsistently**; and only 73% reported **full compliance** with this important safety practice. Compliance may not be significantly better today, 3 years later.

Safe Practice Recommendations: Will the next victim be in your hospital? Or, will you improve your labeling practices? While you may not have experienced a serious sentinel event despite poor labeling practices, you shouldn't wait until a patient is harmed in your facility to take action. Consider the following:

Provide labels. Make labeling easy by purchasing sterile markers, blank labels, and preprinted labels prepared by the facility or a commercial vendor that can be opened onto the sterile field during all procedures in all areas and used effectively on syringes, basins, bowls, and cups. To minimize staff time, prepare surgical packs ahead of time with sterile markers, blank labels, and preprinted labels for all anticipated medications and solutions that will be needed for the case.

Require labels. In **all** patient care areas, require labels on **all** medications, medication containers (e.g., syringes, medicine cups, basins), and other solutions on (and off) the sterile field, even if there is only one medication or solution involved. Also require labels on all solutions, chemicals, and reagents (e.g., formalin, saline, Lugol's solution, radiocontrast media) that are used in perioperative and procedural units, or in other units where procedures might be performed.

Differentiate look-alike names and products. If drug or solution names are similar, use tall man lettering on the labels to differentiate them, or highlight/circle the distinguishing information on the label. When possible, purchase skin antiseptic products in prepackaged swabs or sponges to clearly differentiate them from medications or other solutions.

Label one at a time. Individually verify each medication and complete its preparation for administration, delivery to the sterile field, and labeling on the field at the time of preparation, **before** another medication is prepared.

Confirm medications and labels. Before preparing a medication or solution listed on a physician's preference list, verify with the physician that it will be required for the procedure and needed on the sterile field. When preparing the medication or solutions for the procedure, require the scrub person, the circulating nurse, or a second practitioner involved in the procedure to concurrently verify all medications/solutions visually and verbally by reading the product name, strength, and dosage from the labels. (If there is no scrub person, the circulating nurse or other nurse should verify the medication/solution with the licensed professional performing the procedure.) During the procedure, when passing a medication to the licensed professional per-

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A patient admitted during the night through the emergency department (ED) had a home medication list that included a **DURAGESIC** (fenta**NYL**) 100 mcg patch, which was circled to be continued on admission. Upon checking the state prescription database to verify that the patient was receiving 100 mcg regularly, the pharmacist noticed that the patient hadn't filled a prescription for the patches in the past 4 months. After confirming with the ED nurse that the patient was not currently wearing a patch, the pharmacist did not feel comfortable dispensing the pain medication when it hadn't been used in months, meaning the patient was essentially opioid naïve by then. The pharmacist entered a note to "clarify home med," and the hospitalist discontinued the order for the patch. Of note, the patient went to surgery the next day and the home medication list was printed. Unfortunately, the pharmacist and hospitalist who knew the fenta**NYL** patch was not a recent home medication did not delete or clarify the entry on the home medication list. The surgeon circled Duragesic patch on the home medication list to continue its use. The same pharmacist happened to receive the postoperative orders and, again, did not dispense the patch. The Duragesic patch was not continued upon discharge.

This is a great illustration of the safety potential in reviewing a state scheduled drug database when a new patient is admitted with a controlled substance prescription. This enabled the pharmacist to detect a potentially dangerous medication error.

Where did *this* come from? A hospital reported several occurrences in which medications not purchased or provided by the pharmacy made their way into the hospital supply, including on pharmacy shelves and in automated dispensing cabinets (ADCs). Recent examples include lidocaine ampuls that came from an IV line insertion kit and a heparin flush syringe brought in from home by a patient's family. Likewise, doctors sometimes bring unauthorized medications into the hospital to use for a patient.

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