COMMONWEALTH OF VIRGINIA

Meeting of the Board of Pharmacy

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

(804) 367-4456 (Tel)
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Tentative Agenda
Regulation Committee Meeting
May 11, 2015
9:00AM

TOPIC	PAGES

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

- Welcome & Introductions
- Reading of Emergency Evacuation Script
- Approval of Agenda

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.

Agenda Items

- Use of Closed System Transfer Devices to Extend Beyond Use Dates — 1-11
- Draft Emergency Regulations for Outsourcing Facilities
  - Enrolled HB 1737 — 12-20
  - Draft regulatory language for consideration — 21-24
- Draft Emergency Regulations for Permitting Dispensing Facilities for Practitioners of the Healing Arts to Sell Controlled Substances
  - HB 2192 Approved 3/16/15 — 25
  - Excerpt from Guidance Document 110-12 (Bylaws) — 26
  - Draft regulatory language for consideration — 27-32
- Regulations for PACE Facilities
  - HB 1733 Approved 3/23/15 — 33
  - Draft regulatory language for consideration — 34-39
- Possible Legislative Proposals
  - Summary of Possible Legislative Actions Needed — 40
  - Draft legislation for consideration: wholesale distributors, manufacturers, track and trace requirements — 41-50
  - Background information on VAWD — 51-60
  - Excerpt of 6/11/98 minutes re out-of-state medical equipment suppliers — 61-62
  - Draft legislation for consideration: nonresident MES — 63-64
  - Excerpt of draft 3/30/15 PMP minutes re legislative proposals — 65-67
  - Comment on draft PMP legislation — 68-71
- Consider Requirement for Pharmacy Technician Certification Board (PTCB) — 71 B-97
- Oversight of Pharmacy Benefit Managers
  - Excerpt of draft minutes and materials from 3/24/15 meeting — 98-113

Adjourn

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

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)

Originally proposed amendment to Guidance Document 110-36 as recommended by Compounding Workgroup. Full Board adopted first 3 bullets below in December 2014 and referred 4th bullet to Regulation Committee for further consideration:

from Guidance Document 110-36

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);
- A closed system transfer device (CSTD) cannot be used to extend the BUD of a single dose vial to exceed the 1 hour assigned BUD when punctured outside of an ISO Class 5 environment or the 6 hour assigned BUD when puntured within and not removed from an ISO Class 5 environment.

Sections of Law and Regulation regarding Compounding

§54.1-3410.2

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

18VAC110-20-321. Compounding.

The compounding of both sterile and non-sterile drug products shall be performed in accordance with USP-NF compounding standards and §54.1-3410.2 of the Code of Virginia.

Board staff inquiry made of USP regarding whether it addresses use of CSTDs to extend BUD of single dose vials – 4/2015

Response below per Rick Schnatz, Pharm. D., Manager, Healthcare Quality Standards & Compounding:

- Our chapter only addresses two timeframes after opening or needle-puncturing single-dose containers. Both are contained in the section titled: Single-Dose and Multiple-Dose Containers as below (yellow highlight added for emphasis).

SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS

Opened or needle-punctured single-dose containers, such as bags, bottles, syringes, and vials of sterile products and CSPs shall be used within 1 hour if opened in worse than ISO Class 5 (see *Table 1*) air quality (see *Immediate-Use CSPs*), and any remaining contents must be discarded. Single-dose vials exposed to ISO Class 5 (see *Table 1*) or cleaner air may be used up to 6 hours after initial needle puncture. Opened single-dose ampuls shall not be stored for any time period. Multiple-dose containers (e.g., vials) are formulated for removal of portions on multiple occasions because they usually contain antimicrobial preservatives. The BUD after initially entering or opening (e.g., needle-punctured) multiple-dose containers is 28 days (see *Antimicrobial Effectiveness Testing* ⟨ 51 ⟩) unless otherwise specified by the manufacturer.

Please not that these times are based on the potential risk for microbial contamination and proliferation. They are not BUDs. BUDs are based on physical and chemical stability. To determine a BUD one would need to do a full Method Development and Validation as well as forced stability studies. Here is a link that may be helpful in this arena: http://www.usp.org/sites/default/files/usp_pdf/EN/2014-01-13_strength_versus_stability_testing_for_compounded_preparations_3.pdf

The chapter does not speak to the use of CSTDs as a way to extend BUDs as it would not provide the above chemical and physical data nor forced stability studies.

- As to the chapter, we can only speak to what it says...or doesn't say. In this case we address times for SDVs in certain air quality conditions. We do not address extending those times listed based on particular devices.

KAISER PERMANENTE®
2101 East Jefferson Street
Rockville, MD 20852

December 9, 2014

Caroline D. Juran, Executive Director
Virginia Board of Pharmacy
Perimeter Center
9960 Mayland Drive, Suite 300
Henrico, VA 23233

Re: Letter of Concern for Amending Guidance Document 110-36 – Compliance with USP Standards for Compounding

Dear Ms. Juran,

Kaiser Permanente appreciates the efforts of the Virginia Board of Pharmacy to provide guidance on sterile compounding that ensures safe measures are in place to protect public interests. I understand the Board of Pharmacy is considering amending Guidance Document 110-36 on Compliance with USP Standards for Compounding. I would like to briefly comment on proposed revisions.

Kaiser Permanente asks the Board of Pharmacy to consider allowance of greater than a 6 hour BUD (Beyond Use Date) for Single-Dose vials stored outside a ISO Class 5 environment with implementation of a robust DVO (Drug Vial Optimization) program, which includes the following elements:

a. Use of a CSTD (Closed System Transfer Device), which has been recognized by the Food and Drug Administration as a true closed system, in a ISO Class 5 environment;
b. A comprehensive staff competency program and policies and procedures that validate proper aseptic technique and use of the CSTD; and
c. A continuous Quality Assurance program that monitors for pyrogen growth with appropriate sampling and monitoring frequency.

Extended BUD from a DVO program guarantees quality improvement in workplace safety and patient care, and decreases healthcare costs. For patients being treated, optimal drug therapy outcome is achieved by ensuring that the first line drug agent is always available. Therapy outcome is not compromised by having to resort to a secondary or tertiary drug agent due to drug shortage and lack of availability. A properly administered DVO program reduces healthcare costs associated with avoidable drug waste.

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Many well-known medical institutions have demonstrated that a safe DVO program can successfully be implemented with positive outcomes for patients, workers and the healthcare system.

Thank you for the opportunity to express Kaiser Permanente's concerns with proposed revisions to Guidance Document 110-36 on Compliance with USP Standards for Compounding. Should you have any questions, please do not hesitate to contact me.

Sincerely,

Kun Kim, PharmD
Manager, Regional Infusion Pharmacy Services
Office – 703-587-3657
Kun.Kim@kp.org

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BD

Helping all people
live healthy lives

Application of Closed System Transfer Devices for Appropriate Beyond Use Dating

Background

The National Institute of Occupational Safety and Health (NIOSH) define a Closed System Drug Transfer Device (CSTD) as *"device that mechanically prohibits the transfer of environmental contaminants into the system and the escape of hazardous drug or vapor concentrations outside the system."*[1] There is a significant amount of published evidence on the risk of exposure to hazardous drugs and the efficacy of the use of CSTD to eliminate or reduce exposure to hazardous drugs. In addition, the BD PhaSeal™ System [the first CSTD cleared by the Food and Drug Administration (FDA)] has been proven by independent lab and published studies that it can prevent microbial ingress.

Overview of BD PhaSeal™

BD PhaSeal™ is the first device to receive FDA 510(k) clearance as a closed-system drug transfer device.[2] To obtain this clearance, microbial-ingress testing was performed to evaluate the microbial-barrier performance of the BD PhaSeal System under simulated worst-case clinical use. A total of 280 preparations were tested and all were negative for recovered test organisms. This resulted in FDA clearance of the BD PhaSeal™ System for "preventing microbial ingress."

In a multi-center study, McMichael et al[3] studied the ability of the BD PhaSeal™ closed system drug transfer device to prevent the contamination of parenteral drug products, which could significantly reduce waste and cost of these products. A total of 1328 syringes were produced at 4 different institutions and visual, microscopic, and microbiologic subculture analyses were performed. A failure rate of 1.8% was observed, which was not greater than expected and supported the alternate hypothesis at the 99% confidence level that the BD PhaSeal™ system is capable of maintaining sterility in a controlled environment. Secondary analysis of the data was conducted based on time to failure. The analysis indicated that at the 168-hour mark there is a 98.2% probability that the vials will not be contaminated.

Carey et al undertook a non-randomized multicenter trial to assess the ability of the BD PhaSeal™ system to maintain product sterility given current US Pharmacopeia Chapter 797 and International Organization for Standardization standards for use. The results indicated that at the

[1] NIOSH Alert 2004 www.cdc.gov/niosh/topics/antineoplastic (Accessed December 2013)
[2] ONB Clearance Letter from FDA (2013)
[3] McMichael D, et al. Utility of the PhaSeal™ Closed Drug Transfer Device, Am J Pharm Benefits 2011

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168-hour mark, the probability of failure was 0.3%. The resulting failure rate of 0.3% (1 failure out of 331 samples) (99% confidence interval 0.0%-1.0%; P <.001) demonstrated that the observed failure rate was significantly different from the hypothesized rate of 2%. In other words, at 168 hours one would expect there to be a 99.7% probability that the vial would not be contaminated with bacterial growth if the same procedures were utilized under the same environmental conditions. Rowe et al conducted a study to evaluate the cost of discarding single-dose vials (SDVs) after 6 hours and to further test sterility of vials beyond this time point using BD PhaSeal™. Microbiologic testing of vial extension beyond 6 hours showed that 11 (1.86%) of 592 samples had one colony-forming unit on one of two plates. Positive plates were negative at subsequent time points, and all positives were single isolates most likely introduced during the plating process.[4]

Benefits of Appropriate Beyond Use Dating

In organized healthcare settings, prescription drugs are one of the fastest growing expense lines. Drugs routinely consume 10% to 12% of total hospital expenditures, and in some specialty hospitals such as cancer hospitals, that amount is closer to 40% to 50%[5]. Many of the newer drugs are large-molecule monoclonal antibodies. These drugs typically are parenteral medications that come in single-use non-preserved vials. Currently, across the United States significant amounts of high-cost drugs are being thrown away every year. In an audit of one of the oncology infusion clinics at Indiana University Health, the annual drug acquisition cost was approximately $15.5 million and it was estimated that more than $1 million in viable drug product was discarded[6].

The FDA makes great efforts, to address and prevent drug shortages, which can occur for many reasons, including manufacturing and quality problems, delays, and discontinuations. However, over the past few years drug shortages have occurred with regularity. In 2010, there were 178 drug shortages reported to the FDA, 132 of which involved sterile injectable drugs. In 2011, there were 251 drug shortages reported, 183 of which involved sterile injectable drugs. In 2012, there were 117 new drug shortages, 84 of which involved sterile injectable drugs. Although in 2012, there were fewer reported drug shortages. FDA continues to see shortages involving older sterile injectable drugs (see Appendix). These shortages have involved cancer drugs, anesthetics used

[4] Rowe EC, et al. Economic and Microbiologic Evaluation of Single-Dose Vial Extension for Hazardous Drugs, J Oncol Pract 2012

[5] Wilson AL, American Society for Health-System Pharmacists. Financial Management for Health-System Pharmacists. Bethesda, MD: American Society for Health-System Pharmacists; 2009

[6] McMichael D, et al. Utility of the PhaSeal™ Closed Drug Transfer Device, Am J Pharm Benefits 2011

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for patients undergoing surgery, as well as drugs needed for emergency medicine, and electrolytes needed for patients on IV feeding[7].

A 2013 national survey performed by McBride et al. to estimate the effect of shortages on cancer care revealed that delays in chemotherapy administration or changes in treatment regimens due to drug shortages were reported by 93% of survey participants; 85% of respondents reported increased costs; and 10% reported reimbursement challenges related to drug shortages. At 34% of represented institutions, at least 1000 hours of additional labor annually was needed to manage shortages. Changes in therapy leading to near-miss errors were reported by 16% of participants, with 6% reporting one or more actual medication errors attributable to a drug shortage. The oncology medications most frequently reported to be in short supply during the preceding 12 months were fluorouracil, leucovorin, liposomal doxorubicin, and paclitaxel. The conduct of clinical trials was affected by drug shortages at 44% of represented institutions[8].

In 2012 a study performed by Havrilesky et al., an estimated an additional cost of $11,168 for each patient with ovarian cancer treated with docetaxel instead of paclitaxel during a drug shortage. A drug shortage of paclitaxel that affects approximately 50% of women initiating chemotherapy would be expected to impact 779 women and cost third party payers an additional $8,699,872 monthly[9].

In 2013, Becker et al[10] assessed the impact of oncology drug shortages on patient therapy: unplanned treatment changes and found that drug shortages increased significantly between 2010 and 2011 and mandated substantial numbers of treatment changes for the first time in 2011. Surveyed physicians reported that the efficacy of the alternative regimen was equivalent to that of the unavailable medication in 69.6% of cases, and inferior in 30.4%. Physicians also reported that the toxicity of the alternative regimen was likely to be greater than that of the unavailable medication in 34.8% of the cases, likely to be less in 8.9% of cases, and likely to be equivalent in 56.5% of cases, highlighting this critical issue even further.

In 2012, an analysis of the event-free survival of children with Hodgkin's lymphoma was done in which two regimens were compared, one of which was developed at Stanford University (called the Stanford V regimen) and included mechlorethamine (nitrogen mustard) vs. an alternative

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[7] FDA. Drug Shortages: Frequently Asked Questions (Accessed January 2014)

[8] McBride A, et al. National survey on the effect of oncology drug shortages on cancer care, *Am J Health Syst Pharm* 2013

[9] Havrilesky LJ et al. Economic impact of paclitaxel shortage in patients with newly diagnosed ovarian cancer.Gynecol Oncol. 2012

[10] Becker DJ et al. Impact of oncology drug shortages on patient therapy: unplanned treatment changes. J Oncol Pract. 2013

regimen that contained cyclophosphamide in the face of shortages of mechlorethamine[11]. The 2 year event-free survival was 75% (SE, 12.5%) with the cyclophosphamide regimen vs. 88% with mechlorethamine (SE, 2.5%, p=0.01 log-rank test). Such examples indicate the detrimental impact of drug shortages may have on clinical outcomes.

Request

BD urges the Virginia Board of Pharmacy not to adopt a blanket prohibition on the appropriate use of qualified CSTDs for beyond use dating. The "6 hour rule" in United States Pharmacopeia's Chapter 797 (USP<797>)[12] allows for the use of *"technologies, techniques, materials, and procedures...proven to be equivalent or superior with statistical significance to those described."* The BD PhaSeal™ System has been proven by independent lab and published studies that it can prevent microbial ingress, therby allowing the extension of sterility of vials up to the drug expiry date or 168 hours whichever may come first. As a result, healthcare facilities across the state are sucessfully deploying the BD PhaSeal System to protect healthcare workers from hazardous drugs,while maintaing the intergrity and sterility of prepared medications for patients safety, and assisting with current drug shortages..

[11] Metzger, et al. The Impact of Drug Shortages on Children with Cancer – The Example of Mechlorethamine. New England Journal of Medicine

[12] USP 797 Guidebook to Pharmaceutical Compounding – Sterile Preparations. United States Pharmacopeial Convention 2008

References

1. NIOSH Alert 2004 www.cdc.gov/niosh/topics/antineoplastic (Accessed December 2013)
2. USP 797 Guidebook to Pharmaceutical Compounding – Sterile Preparations. United States Pharmacopeial Convention 2008
3. ONB Clearance Letter from FDA (2013)
4. McMichael D, et al. Utility of the PhaSeal™ Closed Drug Transfer Device, Am J Pharm Benefits 2011
5. Rowe EC, et al. Economic and Microbiologic Evaluation of Single-Dose Vial Extension for Hazardous Drugs, J Oncol Pract 2012
6. Wilson AL, American Society for Health-System Pharmacists. Financial Management for Health-System Pharmacists. Bethesda, MD: American Society for Health-System Pharmacists; 2009
7. McMichael D, et al. Utility of the PhaSeal™ Closed Drug Transfer Device, Am J Pharm Benefits 2011
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9. McBride A, et al. National survey on the effect of oncology drug shortages on cancer care, *Am J Health Syst Pharm* 2013
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12. Metzger, et al. The Impact of Drug Shortages on Children with Cancer – The Example of Mechlorethamine. New England Journal of Medicine
13. McMichael D, et al. Utility of the PhaSeal™ Closed Drug Transfer Device, Am J Pharm Benefits 2011
14. Vandenbroucke J, Robays H. Economic impact of the preparation scenario for cytotoxic drugs: an observational study. EJHP Practice. 2008
15. Rowe EC, et al. Economic and Microbiologic Evaluation of Single-Dose Vial Extension for Hazardous Drugs, J Oncol Pract 2012
16. Edwards MS, Solimando DA Jr et al. Cost savings realized by use of the PhaSeal(R) closed-system transfer device for preparation of antineoplastic agents. J Oncol Pharm Pract. 2013

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

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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,

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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.

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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

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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

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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.

Chapter 20
REGULATIONS GOVERNING THE PRACTICE OF PHARMACY

Part I. General Provisions

18VAC110-20-20. Fees.

A. Unless otherwise provided, fees listed in this section shall not be refundable.

B. Unless otherwise provided, any fees for taking required examinations shall be paid directly to the examination service as specified by the board.

C. Initial application fees.

1. Pharmacist license	$180
2. Pharmacy intern registration	$15
3. Pharmacy technician registration	$25
4. Pharmacy permit	$270
5. Permitted physician licensed to dispense drugs	$270
6. Medical equipment supplier permit	$180
7. Humane society permit	$20
8. Outsourcing facility permit	$270
~~8.~~9. Nonresident pharmacy registration	$270
10. Nonresident outsourcing facility registration	$270
~~9.~~11. Controlled substances registrations	$90
~~10.~~12. Innovative program approval. If the board determines that a technical consultant is required in order to make a decision on approval, any consultant fee, not to exceed the actual cost, shall also be paid by the applicant in addition to the application fee.	$250
~~11.~~13. Approval of a pharmacy technician training program	$150
~~12.~~14. Approval of a continuing education program	$100
~~13.~~15. Approval of a repackaging training program	$50

D. Annual renewal fees.

1. Pharmacist active license – due no later than December 31	$90
2. Pharmacist inactive license – due no later than December 31	$45
3. Pharmacy technician registration – due no later than December 31	$25
4. Pharmacy permit – due no later than April 30	$270
5. Physician permit to practice pharmacy – due no later than February 28	$270
6. Medical equipment supplier permit – due no later than February 28	$180
7. Humane society permit – due no later than February 28	$20
8. Outsourcing facility permit – due no later than April 30	$270
~~8.~~9. Nonresident pharmacy registration– due no later than April 30	$270
10. Nonresident outsourcing facility registration – due no later than the date of initial registration	$270 $90
~~9.~~11. Controlled substances registrations –due no later than February 28	

~~10.~~12. Innovative program continued approval based on board order not to exceed $200 per approval period.	
~~11.~~13. Approval of a pharmacy technician training program	$75 every two years
~~12.~~14. Approval of a repackaging training program	$30 every two years

E. Late fees. The following late fees shall be paid in addition to the current renewal fee to renew an expired license within one year of the expiration date or within two years in the case of a pharmacy technician training program. In addition, engaging in activities requiring a license, permit, or registration after the expiration date of such license, permit, or registration shall be grounds for disciplinary action by the board.

1. Pharmacist license	$30
2. Pharmacist inactive license	$15
3. Pharmacy technician registration	$10
4. Pharmacy permit	$90
5. Physician permit to practice pharmacy	$90
6. Medical equipment supplier permit	$60
7. Humane society permit	$5
8. Outsourcing facility permit	$90
~~8.~~9. Nonresident pharmacy registration	$90
10. Nonresident outsourcing facility registration	$90
~~9.~~11. Controlled substances registrations	$30
~~10.~~12. Approval of a pharmacy technician training program	$15
~~11.~~13. Approval of a repackaging training program	$10

F. Reinstatement fees. Any person or entity attempting to renew a license, permit, or registration more than one year after the expiration date, or more than two years after the expiration date in the case of a pharmacy technician training program, shall submit an application for reinstatement with any required fees. Reinstatement is at the discretion of the board and, except for reinstatement following license revocation or suspension, may be granted by the executive director of the board upon completion of an application and payment of any required fees.

1. Pharmacist license	$210
2. Pharmacist license after revocation or suspension	$500
3. Pharmacy technician registration	$35
4. Pharmacy technician registration after revocation or suspension	$125
5. Facilities or entities that cease operation and wish to resume shall not be eligible for reinstatement but shall apply for a new permit or registration. Facilities or entities that failed to renew and continued to operate for more than one renewal cycle shall pay the current and all back renewal fees for the years in which they were operating plus the following reinstatement fees:	
a. Pharmacy permit	$240
b. Physician permit to practice pharmacy	$240
c. Medical equipment supplier permit	$210
d. Humane society permit	$30
e. Outsourcing facility permit	$240
~~e.~~f. Nonresident pharmacy registration	$115
g. Nonresident outsourcing facility registration	$240
~~f.~~h. Controlled substances registration	$180
~~g.~~i. Approval of a pharmacy technician training program	$75

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G. Application for change or inspection fees for facilities or other entities.

1. Change of pharmacist-in-charge	$50
2. Change of ownership for any facility	$50
3. Inspection for remodeling or change of location for any facility	150
4. Reinspection of any facility	$150
5. Board-required inspection for a robotic pharmacy system	$150
6. Board-required inspection of an innovative program location	$150
7. Change of pharmacist responsible for an approved innovative program	$25

H. Miscellaneous fees.

1. Duplicate wall certificate	$25
2. Returned check	$35

Part IV. Pharmacies

18VAC110-20-215. Outsourcing facilities.

A. Any facility in the Commonwealth engaged in the sterile compounding of drugs or devices to be dispensed without a prescription for a specific patient shall obtain a permit as an outsourcing facility from the board in accordance with § 54.1-3434.05. Any outsourcing facility located outside of the Commonwealth that delivers in any manner Schedule II through VI drugs or devices into the Commonwealth without a prescription for a specific patient shall be registered with the board in accordance with § 54.1-3434.5.

B. An outsourcing facility shall comply with all provisions of this chapter relating to a pharmacy in Parts IV and VI, with the following exceptions:

1. Subsections D and E of 18VAC110-20-190, relating to dispensed prescriptions.

2. Subsection A of 18VAC110-20-200, relating to prescriptions awaiting delivery.

3. Subsections B and C of 18VAC110-20-240, relating to prescriptions and chart orders.

4. Section 18VAC110-20-250, relating to automated data processing prescription records.

5. Subsections C, D, E, and F of 18 VAC110-20-270, relating to preparation and dispensing of prescriptions.

C. In addition to applicable requirements for pharmacies, outsourcing facilities shall comply with the following:

1. Pharmacist supervision.

At all times, such facilities shall be under the supervision of a PIC who routinely practices at the location designated on the permit application. A pharmacist shall be present at all times when the facility is open for business.

2. Records.

a. All records, including the receipt and disposition of drugs or devices, shall be maintained by the facility for a period of five years and shall be available to the board upon request.

b. Compounding records shall include identification of the drugs and shall provide the active ingredient; the source of such active ingredient, including the national drug code number of the source drug or bulk active ingredient, if available; the strength of the active ingredient per unit; the dosage form and route of administration; the package description; the number of individuals units produced; and the national drug code number of the final product, if assigned.

c. Outsourcing facilities shall maintain quality control records to include stability and sterility testing for determining beyond use dating.

Renewal.

a. Upon initial application and at each renewal, outsourcing facilities shall submit to the board documentation that the facility is registered as an outsourcing facility under the Federal Food, Drug and Cosmetic Act.

b. Upon initial registration and at renewal, outsourcing facilities shall submit to the board a copy of a current inspection report consistent with § 54.1-3434.05 or § 54.1-3434.5.

c. No outsourcing facility may distribute or dispense any drug to any person pursuant to a prescription unless it is also maintains a current active pharmacy permit. The pharmacy shall comply with all state and federal laws, regulations and requirements, except it shall compound in compliance with current Good Manufacturing Practices published by the U. S. Food and Drug Administration.

d. Outsourcing facilities that fail to demonstrate that the facility is registered as an outsourcing facility under the Federal Food, Drug and Cosmetic Act or submit a copy of a current inspection report consistent with § 54.1-3434.05 or § 54.1-3434.5 shall not meet the requirements for renewal of registration.

18VAC110-20-321. Compounding.

A. The compounding of both sterile and non-sterile drug products by a pharmacy that does not share the same physical space with an outsourcing facility shall be performed in accordance with USP-NF compounding standards and §54.1-3410.2 of the Code of Virginia.

B. The compounding of sterile drug products by an outsourcing facility or by a pharmacy sharing the same physical space with an outsourcing facility shall be performed in accordance with current Good Manufacturing Practices published by the U. S. Food and Drug Administration.

VIRGINIA ACTS OF ASSEMBLY -- 2015 SESSION

CHAPTER 117

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 March 16, 2015

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.

11. The Board delegates the approval of continuing education programs to the executive director in consultation with one member of the Board.

12. The Board delegates the convening of a quorum of the Board by telephone conference call, for the purpose of considering the summary suspension of a license in accordance with § 54.1-2408.1, to the executive director or deputy executive director. The Board delegates the convening of a meeting by telephone conference call, for the purpose of considering settlement proposals in accordance with § 54.1-2400 (13), to the executive director or deputy executive director. The Board delegates the determination of probable cause for disciplinary action to a special conference committee of the Board, wherein the committee may offer a confidential consent agreement, offer a pre-hearing consent order, cause the scheduling of an informal conference, request additional information, or close the case. The Board further delegates the determination of probable cause, for the purpose of offering a confidential consent agreement or a pre-hearing consent order or for scheduling an informal conference in accordance with established Board guidelines, to the executive director or deputy executive director.

13. The Board delegates to the chairman, or the vice chairman in his absence, the approval of waivers in declared disasters or states of emergency in accordance with § 54.1-3307.3.

14. The Board delegates to the executive director, in accordance with § 54.1-3434.1(A)(2), the authority to accept an inspection report or other documentation for a non-resident pharmacy from an entity that may not be listed on the Board's guidance document, or to request an inspection by an agent of the Board.

15. The Board delegates to the executive director the authority to grant an accommodation of additional testing time, up to a maximum of double time, to candidates for Board required examinations pursuant to the Americans with Disabilities Act provided the candidate provides documentation that supports such an accommodation as required by Board regulation or guidance document. Any other requests for accommodation beyond additional testing time shall be reviewed by the Board at the next available Board meeting.

16. The Board delegates to the executive director, in consultation with the chairman, the authority to review and approve applications for limited-use practitioner of the healing arts to sell controlled substances licenses. A waiver of the square footage requirement for the controlled substances selling and storage area may be provided. Additionally, a waiver of the security system may be provided when storing and selling multiple strengths and formulations of no more than five different topical Schedule VI drugs intended for cosmetic use.

ARTICLE VI: AMENDMENTS

Amendments to these Bylaws may be proposed by a board member or staff personnel by presenting the amendment in writing to all Board members prior to any scheduled meeting of the Board. Upon favorable vote of at least two-thirds of the Board members present at said meeting, such proposed amendment shall be adopted. If notice is given to the Board members at the previously held board meeting, a favorable vote of a majority of the Board members present at the current board meeting is required to adopt the amendment.

Effective Date: July 1, 1997
Latest revision: December 9, 2014

Regulations for Implementation of HB2192

18VAC110-30-15. Fees.

A. Unless otherwise provided, fees listed in this section shall not be refundable.

B. ~~Fee for initial license for a practitioner of the healing arts to sell controlled substances.~~ Initial application fees.

~~1. The application fee for initial licensure shall be $240.~~
~~2. The application fee for reinstatement of a license that has been revoked or suspended indefinitely shall be $500.~~

1. License for practitioner of the healing arts to sell controlled substance license	$180
2. Permit for facility in which practitioners of the healing arts sell controlled substance	$240

C. ~~Renewal of license for a practitioner of the healing arts to sell controlled substances.~~ Annual renewal fees.

~~1. The annual fee for renewal of an active license shall be $90. For the annual renewal due on or before December 31, 2009, the fee shall be $50.~~
~~2. The late fee for renewal of a license within one year after the expiration date is $30 in addition to the annual renewal fee.~~

1. License for practitioner of the healing arts to sell controlled substance	$90
2. Permit for facility in which practitioners of the healing arts sell controlled substance	$120

D. Late fees.

The following late fees shall be paid in addition to the current renewal fee to renew an expired license within one year of the expiration date.

1. License for practitioner of the healing arts to sell controlled substance	$30
2. Permit for facility in which practitioners of the healing arts sell controlled substance	$40

~~3. The fee for reinstatement of a license expired for more than one year shall be $210.~~

E. Reinstatement fees.

Any person or entity attempting to renew a license or permit more than one year after the expiration date shall submit an application for reinstatement with any required fees.

1. Practitioner of the healing arts to sell controlled substance license	$150
2. Practitioner of the healing arts to sell controlled substance facility permit	$240

3. The application fee for reinstatement of a license that has been revoked or suspended indefinitely shall be $500.

F. 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 facility permit.

~~D.~~G. The fee for reinspection of any facility shall be $150.

~~E.~~H. The fee for a returned check shall be $35.

PART II. LICENSURE REQUIREMENTS.

18VAC110-30-20. Application for practitioner licensure.

A. Prior to engaging in the sale of controlled substances, a practitioner shall make application on a form provided by the board and be issued a license. The practitioner shall engage in such sale from a location that has been issued a facility permit.

B. In order to be eligible for a license to sell controlled substances, a practitioner shall possess a current, active license to practice medicine, osteopathic medicine or podiatry issued by the Virginia Board of Medicine. Any disciplinary action taken by the Board of Medicine against the practitioner's license to practice shall constitute grounds for the board to deny, restrict, or place terms on the license to sell.

18VAC110-30-21. Application for facility permit.

A. Any location at which practitioners of the healing arts sell controlled substances shall have a permit issued by the board in accordance with § 54.1-3304.1. A licensed practitioner shall make application for the facility permit on a form provided by the board.

~~C.~~B. For good cause shown, the board may issue a limited-use ~~license~~ facility permit, when the scope, degree or type of services provided to the patient is of a limited nature. The ~~license~~ permit to be issued shall be based on conditions of use requested by the applicant or imposed by the board in cases where certain requirements of regulations may be waived. The following conditions shall apply:

1. A policy and procedure manual detailing the type and volume of controlled substances to be sold and safeguards against diversion must accompany the application. The application shall list the regulatory requirements for which a waiver is requested and a brief explanation as to why each requirement should not apply to that practice; and

2. The issuance and continuation of such license shall be subject to continuing compliance with the conditions set forth by the board.

3. The executive director may grant a waiver of the security system when storing and selling multiple strengths and formulations of no more than five different topical Schedule VI drugs intended for cosmetic use.

18VAC110-30-30. Renewal of license and permit.

A. A license or facility permit so issued shall be valid until December 31 of the year of issue. Renewal of the license or facility permit shall be made on or before December 31 of each year.

B. If a practitioner fails to renew his license or facility permit to sell within the Commonwealth by the renewal date, he must pay the renewal fee plus the late fee. He may renew his license or facility permit by payment of these fees for one year from the date of expiration.

C. Failure to renew the license or facility permit to sell within one year following expiration shall cause the license or permit to lapse. The selling of controlled substances with a lapsed license or permit shall be illegal and may subject the practitioner to disciplinary action by the board. To reinstate a lapsed license or facility permit, a practitioner shall submit an application for reinstatement and pay the reinstatement fee, plus the reinspection fee if a reinspection is required as set forth in subsection D of this section. Reinstatement is at the discretion of the board and may be granted by the executive director on the board's behalf provided no grounds exist to deny said reinstatement.

D. Prior to reinstatement of a ~~license~~ facility permit that has been lapsed for more than one year, a reinspection of the storage and selling area shall be conducted ~~unless another practitioner at the same location has held an active license to sell controlled substances during that period~~. A practitioner seeking reinstatement of a facility permit shall not stock drugs until approved by the board or its authorized agent.

E. The selling of controlled substances without a current, active license or facility permit is unlawful and shall constitute grounds for disciplinary action by the board.

18VAC110-30-50. Licensees ceasing to sell controlled substances; inventory required prior to disposal.

A. Any licensee who intends to cease selling controlled substances shall notify the board 10 days prior to cessation and surrender his license, and his license will be placed on expired status. If no other practitioner of the healing arts to sell controlled substances intends to sell controlled substances from the same location, the practitioner shall also surrender the facility permit, and the permit will be placed on expired status.

B. Any Schedule II through V controlled substances shall be inventoried and may be disposed of by transferring the controlled substance stock to another licensee or other person authorized by law to possess such drugs or by destruction as set forth in this chapter.

C. The licensee or other responsible person shall inform the board of the name and address of the licensee to whom the controlled substances are transferred.

D. A licensee who has surrendered his license or facility permit pursuant to this section may request that it be made current again at anytime within the same renewal year without having to pay an additional fee, provided the licensee is selling from the same location or from another location that has been inspected and approved by the board.

18VAC110-30-70. ~~Maintenance of a common stock of controlled substances~~ Practitioner in charge in a permitted facility.

~~Any two or more licensees who elect to maintain a common stock of controlled substances for dispensing shall~~ A facility with a permit for practitioners of the healing arts to sell controlled substances shall:

1. Designate a ~~licensee~~ practitioner with a license to sell controlled substances who shall be the primary person responsible for the stock, the required inventory, the records of receipt and destruction, safeguards against diversion and compliance with this chapter;

2. Report to the board the name of the licensee and the location of the controlled substance stock on a form provided by the board;

3. Upon a change in the licensee so designated, an inventory of all Schedule II through V controlled substances shall be conducted in the manner set forth in §54.1-3404 of the Drug Control Act of the Code of Virginia and such change shall immediately be reported to the board; and

4. Nothing shall relieve the other individual licensees who sell controlled substances at the location of the responsibility for the requirements set forth in this chapter.

18VAC110-30-80. Inspection and notice required.

A. The area designated for the storage and selling of controlled substances shall be inspected by an agent of the board prior to the issuance of the ~~first license~~ facility permit to sell controlled substances from that site. Inspection prior to issuance of subsequent licenses at the same location shall be conducted at the discretion of the board.

B. Applications for ~~licenses~~ facility permits which indicate a requested inspection date, or requests which are received after the application is filed, shall be honored provided a 14-day notice to the board is allowed prior to the requested inspection date.

C. Requested inspection dates which do not allow a 14-day notice to the board may be adjusted by the board to provide 14 days for the scheduling of the inspection.

D. At the time of the inspection, the controlled substance selling and storage area shall comply with 18VAC110-30-90, 18VAC110-30-100, 18VAC110-30-110, 18VAC110-30-120 and 18VAC110-30-130.

E. If an applicant substantially fails to meet the requirements for issuance of a ~~license~~ facility permit and a reinspection is required, or if the applicant is not ready for the inspection on the established date and fails to notify the inspector or the board at least 24 hours prior to the inspection, the applicant shall pay a reinspection fee as specified in 18VAC110-30-15 prior to a reinspection being conducted.

F. No ~~license~~ or facility permit shall be issued to sell controlled substances until adequate safeguards against diversion have been provided for the controlled substance storage and selling area and approved by the inspector or board staff.

G. The licensee shall notify the board of any substantive changes to the approved selling and storage area including moving the location of the area, making structural changes to the area, or making changes to the alarm system for the area prior to the changes being made and pay a reinspection fee. An inspection shall be conducted prior to approval of the new or altered selling and storage area.

18VAC110-30-90. Physical standards.

Physical standards for the controlled substance selling and storage area:

1. The building in which the controlled substances selling and storage area is located shall be constructed of permanent and secure materials. Trailers and other movable facilities shall not be permitted;

2. There shall be an enclosed area of not less than 40 square feet that is designated as the controlled substances selling and storage area, which shall be used exclusively for the storage, preparation, and dispensing. Records related to the sale of controlled substances may be maintained outside the selling and storage area with access limited to the licensee and those persons authorized to assist in the area. The work space used in preparation of the drugs shall be contained within the enclosed area. A controlled substance selling and storage area inspected and approved prior to November 3, 1993, shall not be required to meet the size requirement of this chapter;

3. Controlled substances maintained for ultimate sale shall be maintained separately from any other controlled substances maintained for other purposes. Controlled substances maintained for other purposes such as administration or samples may be stored within the selling and storage area provided they are clearly separated from the stock maintained for sale;

4. The selling and storage area, work counter space and equipment in the area shall be maintained in a clean and orderly manner;

5. A sink with hot and cold running water shall be available within the immediate vicinity of the selling and storage area; and

6. The entire area described in this chapter shall be well lighted and ventilated; the proper storage temperature shall be maintained to meet official specifications for controlled substance storage.

18VAC110-30-100. Access to selling area.

Access to stock rooms, rest rooms, and other areas other than an office that is exclusively used by the licensee shall not be through the selling and storage area. The selling and storage area may be in an office that is exclusively used by the licensee and to which only the licensee has access provided the office is at least 40 square feet; provided the drugs are stored in a cabinet, closet or other lockable area which can be locked when the practitioner is using the office for purposes other than dispensing; and provided the office meets all other requirements of 18VAC110-30-90, 18VAC110-30-120, and 18VAC110-30-130.

18VAC110-30-120. Safeguards against diversion of controlled substances.

A. A device for the detection of breaking shall be installed in the controlled substances selling and storage area. The installation and the device shall be based on accepted burglar alarm industry standards, and shall be subject to the following conditions:

1. The device shall be a sound, microwave, photoelectric, ultrasonic, or any other generally accepted and suitable device;

2. The device shall be maintained in operating order;

3. The device shall fully protect the immediate controlled substance selling and storage areas and shall be capable of detecting breaking by any means whatsoever in the area when the area is closed;

4. The alarm system must have an auxiliary source of power;

5. The alarm system shall be capable of being activated and operated separately from any other alarm system in the area or the business in which the controlled substance selling and storage area is located;
6. The alarm system is controlled only by the licensee; and

7. An emergency key or access code to the system may be maintained as set forth in 18VAC110-30-130 B of this chapter.

B. An alarm may not be required for practitioners when storing and selling multiple strengths and formulations of no more than five different topical Schedule VI drugs intended for cosmetic use.

VIRGINIA ACTS OF ASSEMBLY -- 2015 SESSION

CHAPTER 505

An Act to amend and reenact § 54.1-3420.2 of the Code of Virginia, relating to delivery of prescription drug orders; PACE programs.

[H 1733]

Approved March 23, 2015

Be it enacted by the General Assembly of Virginia:

1. That § 54.1-3420.2 of the Code of Virginia is amended and reenacted as follows:

§ 54.1-3420.2. Delivery of prescription drug order.

A. Whenever any pharmacy permitted to operate in this Commonwealth or nonresident pharmacy registered to conduct business in the Commonwealth delivers a prescription drug order by mail, common carrier, or delivery service, when the drug order is not personally hand delivered directly, to the patient or his agent at the person's residence or other designated location, the following conditions shall be required:

1. Written notice shall be placed in each shipment alerting the consumer that under certain circumstances chemical degradation of drugs may occur; and

2. Written notice shall be placed in each shipment providing a toll-free or local consumer access telephone number which is designed to respond to consumer questions pertaining to chemical degradation of drugs.

B. If a prescription drug order for a Schedule VI controlled substance is not personally hand delivered directly to the patient or the patient's agent, or if the prescription drug order is not delivered to the residence of the patient, the delivery location shall hold a current permit, license, or registration with the Board that authorizes the possession of controlled substances at that location. The Board shall promulgate regulations related to the security, access, required records, accountability, storage, and accuracy of delivery of such drug delivery systems. Schedule II through Schedule V controlled substances shall be delivered to an alternate delivery location only if such delivery is authorized by federal law and regulations of the Board.

C. Prescription drug orders dispensed to a patient and delivered to a community services board or behavioral health authority facility licensed by the Department of Behavioral Health and Developmental Services upon the signed written request of the patient or the patient's legally authorized representative may be stored, retained, and repackaged at the facility on behalf of the patient for subsequent delivery or administration. The repackaging of a dispensed prescription drug order retained by a community services board or behavioral health authority facility for the purpose of assisting a client with self-administration pursuant to this subsection shall only be performed by a pharmacist, pharmacy technician, nurse, or other person who has successfully completed a Board-approved training program for repackaging of prescription drug orders as authorized by this subsection. The Board shall promulgate regulations relating to training, packaging, labeling, and ~~record keeping~~ *recordkeeping* for such repackaging.

D. Prescription drug orders dispensed to a patient and delivered to a Virginia Department of Health or local health department clinic upon the signed written request of a patient, a patient's legally authorized representative, or a Virginia Department of Health district director or his designee may be stored and retained at the clinic on behalf of the patient for subsequent delivery or administration.

E. Prescription drug orders dispensed to a patient and delivered to a program of all-inclusive care for the elderly (PACE) site licensed by the Department of Social Services pursuant to § 63.2-1701 and overseen by the Department of Medical Assistance Services in accordance with § 32.1-330.3 upon the signed written request of the patient or the patient's legally authorized representative may be stored, retained, and repackaged at the site on behalf of the patient for subsequent delivery or administration. The repackaging of a dispensed prescription drug order retained by the PACE site for the purpose of assisting a client with self-administration pursuant to this subsection shall only be performed by a pharmacist, pharmacy technician, nurse, or other person who has successfully completed a Board-approved training program for repackaging of prescription drug orders as authorized by this subsection. The Board shall promulgate regulations relating to training, packaging, labeling, and recordkeeping for such repackaging.

Regulations for Implementation of HB1733

Part XVI. Controlled Substances Registration for Other Persons or Entities.

18VAC110-20-685. Definitions for controlled substances registration.

For purposes of this part, the following definitions shall apply:

"BHA" means a behavioral health authority facility licensed by the Department of Behavioral Health and Developmental Services that holds a controlled substances registration issued by the board.

"CSB" means a community services board facility licensed by the Department of Behavioral Health and Developmental Services that holds a controlled substances registration issued by the board.

"PACE" means a program of all-inclusive care for the elderly licensed by the Department of Social Services pursuant to § 63.2-1701 and overseen by the Department of Medical Assistance Services in accordance with § 32.1-330.3.

18VAC110-20-700. Requirements for supervision for controlled substances registrants.

A. A practitioner licensed in Virginia shall provide supervision for all aspects of practice related to the maintenance and use of controlled substances as follows:

1. In a hospital or nursing home without an in-house pharmacy, a pharmacist shall supervise.

2. In an emergency medical services agency, the operational medical director shall supervise.

3. For any other type of applicant or registrant, a pharmacist or a prescriber whose scope of practice is consistent with the practice of the applicant or registrant and who is approved by the board may provide the required supervision.

B. The supervising practitioner shall approve the list of drugs which may be ordered by the holder of the controlled substances registration; possession of controlled substances by the entity shall be limited to such approved drugs. The list of drugs approved by the supervising practitioner shall be maintained at the address listed on the controlled substances registration.

C. Access to the controlled substances shall be limited to (i) the supervising practitioner or to those persons who are authorized by the supervising practitioner and who are authorized by law to administer drugs in Virginia, (ii) such other persons who have successfully completed a training program for repackaging of prescription drug orders in a CSB, ~~or~~ BHA, or PACE site as authorized in § 54.1-3420.2 of the Code of Virginia, or (iii) other such persons as designated by the supervising practitioner or the responsible party to have access in an emergency situation. If approved by the supervising practitioner, pharmacy technicians may have access for the purpose

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of delivering controlled substances to the registrant, stocking controlled substances in automated dispensing devices, conducting inventories, audits and other recordkeeping requirements, overseeing delivery of dispensed prescriptions at an alternate delivery site, and repackaging of prescription drug orders retained by a CSB, ~~or~~ BHA, or PACE site as authorized in § 54.1-3420.2 of the Code of Virginia. Access to stock drugs in a crisis stabilization unit shall be limited to prescribers, nurses, or pharmacists.

D. The supervising practitioner shall establish procedures for and provide training as necessary to ensure compliance with all requirements of law and regulation, including, but not limited to, storage, security, and recordkeeping.

E. Within 14 days of a change in the responsible party or supervising practitioner assigned to the registration, either the responsible party or outgoing responsible party shall inform the board and a new application shall be submitted indicating the name and license number, if applicable, of the new responsible party or supervising practitioner.

18VAC110-20-725. Repackaging by a CSB, ~~or~~ BHA, or PACE site.

A. Definition. For purposes of this section, "repackaging" shall mean removing a drug from a container already dispensed and labeled by a pharmacy or medical practitioner authorized to dispense, for a particular client of a CSB, ~~or~~ BHA, or PACE site, and placing it in a container designed for a person to be able to repackage his own dispensed prescription medications to assist with self-administration and compliance with dosage instructions. Such repackaging shall not include the preparation of a patient-specific label that includes drug name, strength, or directions for use or any other process restricted to a pharmacist or pharmacy technician under the direct supervision of a pharmacist.

B. Persons authorized to repackage. Repackaging shall be performed by a pharmacist, pharmacy technician, nurse, or such other person who has successfully completed a board-approved training program for repackaging of prescription drug orders as authorized in § 54.1-3420.2 of the Code of Virginia. A CSB, ~~or~~ BHA, or PACE site using such other person shall maintain documentation of completion of an approved training program for at least one year from date of termination of employment or cessation of repackaging activities.

C. Requirements for repackaging.

1. The repackaging of a dispensed prescription drug order pursuant to § 54.1-3420.2 of the Code of Virginia shall only be done at a CSB, ~~or~~ BHA, or PACE site.

2. The repackaging of dispensed prescription drugs shall be restricted to solid oral dosage forms and a maximum of a 14-day supply of drugs.

3. The drug container used for repackaging pursuant to this section shall bear a label containing the client's first and last name, and name and 24-hour contact information for the CSB, ~~or~~ BHA, or PACE site.

4. A clean, well-closed container that assists the client with self-administration shall be used when multiple doses of a repackaged drug are provided to the client at one time.

5. 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.

D. Written information for client. At the time a repackaged drug is initially given to a client, and upon any subsequent change in the medication order, the client shall be provided written information about the name and strength of the drug and the directions for use. Such written information shall have been prepared by a pharmacy or by a nurse at the CSB, ~~or~~ BHA, or PACE site.

E. Retention, storage, and destruction of repackaged drugs.

1. Any portion of a client's prescription drug order not placed into a container intended to assist with self-administration may be either given to the client or retained by the CSB, ~~or~~ BHA, or PACE site for subsequent repackaging. If retained by the CSB, ~~or~~ BHA, or PACE site, the remaining portion shall be stored within the board-approved drug storage location in the original labeled container, and shall only be used for the client for whom the drug was originally dispensed.

2. Any portion of a prescription drug order remaining at the CSB, ~~or~~ BHA, or PACE site 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, or PACE site 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.

F. Recordkeeping.

1. 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.

2. A record of destruction shall be made and maintained for one year for any prescription drug orders destroyed by the CSB, ~~or~~ BHA, or PACE site and shall include the following:

a. Date of destruction:
b. Name of client;
c. Prescription number of the originally dispensed prescription drug order;
d. Drug name and strength;
e. Quantity of drug destroyed; and
f. Initials of the person performing the destruction.

18VAC110-20-726. Criteria for approval of repackaging training programs.

A. Application. Any person wishing to apply for approval of a repackaging training program shall submit the application fee prescribed in 18VAC110-20-20 and an application on a form approved by the board and shall meet the criteria established in this section. The application shall name a program director who is responsible for compliance with this section.

B. Curriculum. The curriculum for a repackaging training program shall include instruction in current laws and regulations applicable to a CSB, ~~or~~ BHA, or PACE site for the purpose of assisting a client with self-administration pursuant to § 54.1-3420.2 of the Code of Virginia and in the following repackaging tasks:

1. Selection of an appropriate container;

2. Proper preparation of a container in accordance with instructions for administration;

3. Selection of the drug;

4. Counting of the drug;

5. Repackaging of the drug within the selected container;

6. Maintenance of records;

7. Proper storage of drugs;

8. Translation of medical abbreviations;

9. Review of administration records and prescriber's orders for the purpose of identifying any changes in dosage administration;

10. Reporting and recording the client's failure to take medication;

11. Identification, separation, and removal of expired or discontinued drugs; and

12. Prevention and reporting of repackaging errors.

C. Instructors and program director. Instructors for the program shall be either (i) a pharmacist with a current license in any jurisdiction and who is not currently suspended or revoked in any

jurisdiction in the United States or (ii) a pharmacy technician with at least one year of experience performing technician tasks who holds a current registration in Virginia or current PTCB certification and who is not currently suspended or revoked in any jurisdiction in the United States. The program director shall maintain a list of instructors for the program.

D. Program requirements.

1. The length of the program shall be sufficient to prepare a program participant to competently perform repackaging consistent with § 54.1-3420.2 of the Code of Virginia and 18VAC110-20-725.

2. The program shall include a post-training assessment to demonstrate the knowledge and skills necessary for repackaging with safety and accuracy.

3. A program shall provide a certificate of completion to participants who successfully complete the program and provide verification of completion of the program for a participant upon request by a CSB, BHA, PACE site, or the board.

4. The program shall maintain records of training completion by persons authorized to repackage in accordance with § 54.1-3420.2 of the Code of Virginia. Records shall be retained for two years from date of completion of training or termination of the program.

5. The program shall report within 14 days any substantive change in the program to include a change in program name, program director, name of institution or business if applicable, address, program content, length of program, or location of records.

E. Expiration and renewal of program approval. A repackaging training program approval expires after two years, after which the program may apply for renewal. For continued approval, the program shall submit the renewal application, renewal fee, and a self-evaluation report on a form provided by the board at the time of renewal notification. Renewal of a program's approval is at the discretion of the board, and the decision to renew shall be based on documentation of continued compliance with the criteria set forth in this section.

18VAC110-20-727. Pharmacists repackaging for clients of a CSB, ~~or~~ BHA, or PACE site.

A. As an alternative to repackaging as defined in 18VAC110-20-725, a pharmacist at a CSB, ~~or~~ BHA, or PACE site may repackage a client's prescription drugs that have been dispensed by another pharmacy into compliance packaging 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 shall 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, or PACE site 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, or PACE site 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.

Summary of Licensure Activities that May Need Addressing through Legislative Proposals:

- Drug Supply Chain Security Act (Title II of the DQSA) preempts state pedigree requirements; prohibits states from licensing third-party logistics providers as wholesale distributors (which has been our licensing model); and, excludes manufacturers from the definition of wholesale distributors (our model is to license out-of-state manufacturers as nonresident wholesale distributors). Therefore, consider legislative proposal to require wholesale distributors to comply with federal track and trace requirements, new licensing category for third-party logistics providers and nonresident third-party logistics providers, and new licensing category for nonresident manufacturers. (Should VAWD be considered too?)
- Consider clarifying that a manufacturer may ship product pursuant to the manufacturer permit and without needing a wholesale distributor permit.
- Do not have the ability to license out-of-state medical equipment suppliers. Board adopted legislative proposal to create this licensing category in 1998, but was not considered by the General Assembly. Board adopted stance that it would issue a medical equipment supplier permit to an out of state facility if needed for third-party reimbursement, but we could not require them to obtain licensure when shipping prescription medical devices into Virginia. Concerns resurfaced in last few years based on revised Medicaid reimbursement structure. Therefore, consider legislative proposal for new licensing category for nonresident medical equipment suppliers.
- Consider creating separate permit for those pharmacies that compound sterile drugs.

§ 54.1-3437. Permit to manufacture drugs.

It shall be lawful to manufacture, make, produce, pack, package, repackage, relabel or prepare any drug not controlled by Schedule I after first obtaining the appropriate permit from the Board. Such permits shall be subject to the Board's regulations on sanitation, equipment, and safeguards against diversion. This provision shall not apply to manufacturers or packers of medicated feeds who manufacture or package no other drugs. Such permit shall allow the distribution of the drug to anyone other than the end user without the need to obtain a wholesale distributor permit.

§ 54.1-3401

"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. This term shall also include a manufacturer's co-licensed partner or repackager.

Third-party logistics provider.--The term `third-party logistics provider' means an entity that provides or coordinates warehousing, or other logistics services of a drug or device in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of a drug or device, but does not take ownership of the product, nor has responsibility to direct the sale or disposition of the product.

"Warehouser" means any person, other than a wholesale distributor, manufacturer, manufacturer's co-licensed partner, a third-party logistics provider, or repackager 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. This term shall not include a manufacturer, a manufacturer's co-licensed partner, a third-party logistics provider, or repackager.

§ 54.1-3401.1. Practices not considered wholesale distribution.

A. Wholesale distribution, as defined in § 54.1-3401, shall not include:

1. Intracompany sales, including any transaction or transfer between any division, subsidiary, parent, and/or affiliated or related company under the common ownership and control of a corporate entity;

2. The purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a drug for its own use from the group purchasing organization or from other hospitals or health care entities that are members of such organization;

3. The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization, described in § 501 (c) (3) of the Internal Revenue Code of 1986 (26 U.S.C. § 501 (c) (3)), to a nonprofit affiliate of such organization to the extent otherwise permitted by law;

4. The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals or other health care entities that are under common control;

5. The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons;

6. The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug, or the dispensing of a drug pursuant to a prescription;

7. The distribution of drug samples by manufacturers' representatives or distributors' representatives; or

8. The sale, purchase, or trade of or the offer to sell, purchase, or trade blood and blood components intended for transfusion.

B. For the purposes of this section:

"Blood" means whole blood collected from a single donor and processed either for transfusion or further manufacturing.

"Blood component" means that part of blood separated by physical or mechanical means.

"Common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, voting rights, by contract, or otherwise.

"Drug sample" means a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug.

"Emergency medical reasons" includes transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage arising from delays in or interruptions of regular distribution schedules.

§ 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 compounded products 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.

Pharmacists 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~~ and

3. Are distributed by a licensed wholesale distributor or registered nonresident wholesale distributor, or are distributed by a supplier otherwise approved by this Board and 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.

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

It shall be unlawful for any person to engage in the wholesale distribution of prescription drugs in this 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 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 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.

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. The wholesale distributor shall comply with track and trace requirements as required in state and federal law.

(1970, c. 650, § 54-524.44; 1976, c. 614; 1980, c. 288; 1988, c. 765; 1992, c. 737; 2008, c. 320.)

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

A. Any person located outside this Commonwealth who engages in the wholesale distribution of prescription drugs into this 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 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 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. This section shall not apply to persons who distribute prescription drugs directly to a licensed wholesale distributor located within this Commonwealth.

E. The nonresident wholesale distributor shall comply with track and trace requirements as required in state and federal law.

(1994, c. 300; 2008, c. 320.)

(2003, c. 509; 2004, c. 854.)

§ 54.1-3435.1. Denial, revocation, and suspension of license as wholesale distributor, ~~or of~~ registration as a nonresident wholesale distributor, third-party logistics provider, nonresident third-party logistics provider, manufacturer, and nonresident manufacturer.

A. The Board may deny, revoke, suspend, or take other disciplinary actions against a wholesale distributor license, ~~or~~ nonresident wholesale distributor registration, third-party logistics provider,

nonresident third-party logistics provider, manufacturer, and nonresident manufacturer as provided for in § 54.1-3316 or the following:

1. Any conviction of the applicant, licensee, or registrant under federal or state laws relating to controlled substances, including, but not limited to, drug samples and wholesale or retail prescription drug distribution;

2. Violations of licensing requirements under previously held licenses;

3. Failure to maintain and make available to the Board or to federal regulatory officials those records required to be maintained by wholesale distributors of prescription drugs; or

4. Violations of the minimum requirements for qualifications, personnel, storage, and handling of prescription drugs and maintenance of prescription drug records as set forth in the federal Prescription Drug Marketing Act of 1987 (21 U.S.C. §§ 333, 353 and 381) and Part 205 of Chapter 21 of the Code of Federal Regulations.

B. Wholesale drug distributors, nonresident wholesale distributors, third-party logistics providers, nonresident third-party logistics providers, manufacturers, and nonresident manufacturers shall allow the Board or its authorized agents to enter and inspect, at reasonable times and in a reasonable manner, their premises and delivery vehicles, and to audit their records and written operating procedures. Such agents shall be required to show appropriate identification prior to being permitted access to wholesale drug distributors' premises and delivery vehicles.

§ 54.1-3307. Specific powers and duties of Board.

A. The Board shall regulate the practice of pharmacy and the manufacturing, dispensing, selling, distributing, processing, compounding, or disposal of drugs and devices. The Board shall also control the character and standard of all drugs, cosmetics and devices within the Commonwealth, investigate all complaints as to the quality and strength of all drugs, cosmetics, and devices and take such action as may be necessary to prevent the manufacturing, dispensing, selling, distributing, processing, compounding and disposal of such drugs, cosmetics and devices that do not conform to the requirements of law.

The Board's regulations shall include criteria for:

1. Maintenance of the quality, quantity, integrity, safety and efficacy of drugs or devices distributed, dispensed or administered.

2. Compliance with the prescriber's instructions regarding the drug, its quantity, quality and directions for use.

3. Controls and safeguards against diversion of drugs or devices.

4. Maintenance of the integrity of, and public confidence in, the profession and improving the delivery of quality pharmaceutical services to the citizens of Virginia.

5. Maintenance of complete records of the nature, quantity or quality of drugs or substances distributed or dispensed, and of all transactions involving controlled substances or drugs or devices so as to provide adequate information to the patient, the practitioner or the Board.

6. Control of factors contributing to abuse of legitimately obtained drugs, devices, or controlled substances.

7. Promotion of scientific or technical advances in the practice of pharmacy and the manufacture and distribution of controlled drugs, devices or substances.

8. Impact on costs to the public and within the health care industry through the modification of mandatory practices and procedures not essential to meeting the criteria set out in subdivisions 1 through 7 of this section.

9. Such other factors as may be relevant to, and consistent with, the public health and safety and the cost of rendering pharmacy services.

~~B. The Board's regulations to implement the criteria set forth in subsection A shall include, but shall not be limited to, the establishment and implementation of a pedigree system, as defined in subsection D. The Board shall structure the implementation of the pedigree with limited application to certain schedules or certain drugs, upon finding that such drugs are more subject to counterfeiting. In order to maintain a current and appropriate list of drugs susceptible to counterfeiting, the Board may amend such list in its regulations. Such amendments to the list shall be exempt from the requirements of Article 2 (§ 2.2-4006 et seq.) of the Administrative Process Act. The Board shall establish in regulation a process for amending such list that provides notice and opportunity for public comment. The Board shall limit the implementation of a pedigree system to those drugs that have left the normal distribution channel as defined in subsection D. The pedigree shall also satisfy the requirements of 21 U.S.C. § 353(e), regarding requirements for wholesale distributors of drugs in interstate commerce. The Board may provide for exceptions to the pedigree requirements of this section for emergency medical reasons as defined in regulation.~~

C. The Board may collect and examine specimens of drugs, devices and cosmetics that are manufactured, distributed, stored or dispensed in the Commonwealth.

~~D. For the purposes of this section:~~

~~"Normal distribution channel" means a chain of custody for a prescription drug from initial sale by a pharmaceutical manufacturer, through acquisition and sale by one wholesale distributor as defined in § 54.1-3401, that is not exempted pursuant to § 54.1-3401.1, until sale to a pharmacy or other person dispensing or administering the controlled substance; or a chain of custody for a prescription drug from initial sale by a pharmaceutical manufacturer, through acquisition and sale by one wholesale distributor as defined in § 54.1-3401, that is not exempted pursuant to § 54.1-3401.1, to a chain pharmacy warehouse to~~

~~its intracompany pharmacies; or a chain of custody for a prescription drug from initial sale by a pharmaceutical manufacturer to a chain pharmacy warehouse to its intracompany pharmacies.~~

~~"Pedigree" means a paper document or electronic file recording each distribution of a controlled substance from sale by a pharmaceutical manufacturer through acquisition and sale by any wholesale distributor, as defined in § 54.1-3401 and not exempted pursuant to § 54.1-3401.1, until sale to a pharmacy or other person dispensing or administering the controlled substance. Returns from a pharmacy to the originating wholesale distributor or pharmaceutical manufacturer shall not be subject to the pedigree requirements of this section.~~

§ 54.1-34 Registration of nonresident manufacturer; renewal; fee.

A. Any manufacturer, manufacturer's co-licensed partner, or repackager located outside this Commonwealth who ships prescription drugs into this Commonwealth shall be registered with the Board. The applicant for registration as a nonresident manufacturer 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 days of any substantive change in the information previously submitted to the Board; and remit a fee as established in board regulation.

B. The nonresident manufacturer shall at all times maintain a valid, unexpired license, permit, or registration in the state in which it is located or current registration as a manufacturer or repackager with the Food and Drug Administration and shall furnish proof of such upon application and at each renewal.

C. Records of prescription drugs distributed into this Commonwealth shall be maintained in such a manner that they are readily retrievable from records of shipments 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.

§ 54.1-34 Permitting of third-party logistics provider; renewal; fee.

It shall be unlawful for any person to possess or distribute prescription drugs as a third-party logistics provider in this Commonwealth without a valid unrevoked permit issued by the Board. The applicant for a permit as a third-party logistics provider in this Commonwealth shall apply to the Board for a permit, using such forms as the Board may furnish; renew such permit 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 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.

The Board may promulgate such regulations relating to the storage, handling, and distribution of prescription drugs by third-party logistics providers as it deems necessary to implement this section, to prevent diversion of prescription drugs, and to protect the public.

§ 54.1-34 Registration of nonresident third-party logistics provider; renewal; fee.

A. Any third-party logistics provider located outside this Commonwealth who ships prescription drugs into this Commonwealth shall be registered with the Board. The applicant for registration as a nonresident third-party logistics provider 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 days of any substantive change in the information previously submitted to the Board; and remit a fee as established in board regulation.

B. The nonresident third-party logistics provider shall at all times maintain a valid, unexpired license, permit, or registration in the state in which it is located or current registration as a third-party logistics provider with the Food and Drug Administration and shall furnish proof of such upon application and at each renewal.

C. Records of prescription drugs distributed into this Commonwealth shall be maintained in such a manner that they are readily retrievable from records of shipments 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.

PROGRAMS

- CPE MONITOR
- PMP INTERCONNEC
- .PHARMACY
- EXAMINATION
- ACCREDITATIO
  - DMEPOS
  - VAWD
    - Application
    - Application Instructions
    - Accreditation Process
    - Achieving Accreditation
    - Criteria
    - Fees
    - VAWD-Accredited Facilities
    - FAQs
  - VIPPS
  - Vet-VIPPS
  - e-Advertiser Approval Program
- LICENSURE

VAWD

VAWD, or Verified-Accredited Wholesale Distributors, is an accreditation for pharmaceutical wholesale distribution facilities. Those wholesale distributors that achieve accreditation are in compliance with state and federal laws and NABP's VAWD criteria and proudly display the VAWD Seal.

VAWD accreditation plays a pivotal role in preventing counterfeit drugs from entering the United States drug supply – it helps protect the public from drugs that have been contaminated, diverted, or counterfeited. The US supply of prescription drugs is produced and delivered to patients via a complex distribution path, and VAWD accreditation helps ensure that the wholesale distribution facility operates legitimately, is licensed in good standing, and is employing security and best practices for safely distributing prescription drugs from manufacturers to pharmacies and other institutions.

Wholesale distributors that display the VAWD Seal as part of their accreditation have undergone a criteria compliance review, including a rigorous review of their operating policies and procedures, licensure verification, survey of facility and operations, background checks, and screening through the NABP Clearinghouse. Accredited facilities are reviewed annually and undergo a site survey every three years.

State Efforts

The state boards of pharmacy play an important role in regulating the drug supply chain. State laws and regulations that the boards develop help protect the public from receiving medications that have been contaminated or counterfeited.

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VAWD: Helping to

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▸ CONSUMER PROTECTION
▸ MEMBER SERVICES

To aid board efforts, NABP convened a task force in 2003 on counterfeit drugs and wholesale distributers, which recommended revisions to NABP's Model Rules for the Licensure of Wholesale Distributors that would make it difficult for illegitimate wholesalers to become licensed and transact business. These Model Rules are a subset of the Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy, a document on which many states model their state pharmacy practice acts.

The task force also proposed the creation of an accreditation program and clearinghouse for wholesale distributers – a plan that was immediately supported by Food and Drug Administration – to further combat counterfeit drugs. The resulting accreditation program, VAWD, was established in 2004.

State-Specific Requirements

Twenty-one states recognize VAWD accreditation. Many of these states recognize VAWD as a means of implementing the licensing provisions of new laws, while mitigating the fiscal and operational impact on their board.

Of the 21 states that recognize VAWD, Indiana, North Dakota, and Wyoming require VAWD accreditation as a component of licensure. See the accreditation process for further information on state-specific requirements.

VAWD Accreditation Process Overview

Applicants first submit an application, supporting documentation, and pay the applicable fee.
NABP will then:

- Verify the wholesale distributor's and designated representative's licenses
- Screen the applicant against the NABP Clearinghouse for disciplinary or other actions
- Perform applicable criminal and financial background checks
- Review policies and procedures for compliance with VAWD criteria. (Applicants address policy and procedure deficiencies as directed by NABP).
- Wholesale distributor's facility is surveyed on site. (Applicants address survey deficiencies as directed by NABP).

Applicants have 90 days after receiving the Policies & Procedures Guidance Checklist to submit all documentation, including electronic copies of official policies and procedures.

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A survey will not be performed until policies and procedures and all supplemental documentation, including licensing and registration, are reviewed and proven acceptable.

PROGRAMS

- CPE MONITOR
- PMP INTERCONNEC
- .PHARMACY
- EXAMINATION
- ACCREDITATIO
  - DMEPOS
  - VAWD
    - Application
    - Application Instructions
    - Accreditation Process
    - Achieving Accreditation
    - Criteria
    - Fees
    - VAWD-Accredited Facilities
    - FAQs
  - VIPPS
  - Vet-VIPPS
  - e-Advertiser Approval Program
- LICENSURE

Accreditation Process

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IN THIS SECTION:

Application Submission
Application Review
Supplemental Documentation
Policies and Procedures
Review of Personnel
Survey
State-Specific Requirements

Application Submission

Before submitting an application for VAWD accreditation, please review the VAWD criteria. Successful applicants provide documentation addressing VAWD criteria, including information on:

- Licensure
- Facility
- Personnel
- Record keeping
- Authentication and verification
- Returned, damaged, and outdated drugs
- Policies and procedures

The application instructions can help you work your way through the online application.

Application Review

After NABP receives the application, fees, and all supplemental documentation, NABP will:

- Verify that all state wholesale distributor licenses are in good standing

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QUESTIONS? CHAT IS AVAILABLE

Recent News

RSS

Outbreak of HIV and HCV Infections in Indiana Prompts CDC Health Alert

Synthetic Cannabinoid Hospitalizations Surge in Alabama, Mississippi, and Other States

Multiple Lots of Mucinex Cold, Sinus, and Flu Medications Recalled Due to Possible Labeling Error

ADHD Stimulant Abuse Growing Among US Workers, The New York Times Reports

Opioid Dispensing and Prescription Overdose Decreased Substantially After Introduction of Abuse-Deterrent Formulation, Study Reports

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Find a VAWD Accredited Facility

VAWD: Helping to

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▸ ASSESSMENT
▸ CONSUMER PROTECTION
▸ MEMBER SERVICES

- Verify that designated representative licenses are in good standing
- Evaluate the submitted supplemental documents for compliance with the VAWD criteria
- Ensure that applicable criminal and financial background checks are performed
- Notify the applicant if discrepancies arise or clarification is needed

Supplemental Documentation

Wholesale distributors seeking accreditation will need to provide supplemental documentation that addresses the VAWD criteria. The application instructions include a list of required supplemental documents. All documents should be submitted electronically to NABP.

Policies and Procedures

Upon submitting the application, fees, and supplemental documents, NABP will provide the Policies & Procedures Guidance Checklist, which identifies documentation needed when applying to and maintaining VAWD accreditation. It should be used to prepare your facility's policies and procedures.

After receiving the Policies & Procedures Guidance Checklist, new applicants will have 90 days to prepare and submit policies and procedures to NABP for evaluation and confirmation of compliance with VAWD criteria. NABP will conduct a thorough review of your policies and procedures against the VAWD criteria and provide an opportunity to address any deficiencies found through the review.

The application instructions include further important details on submitting supplemental documentations necessary to complete your accreditation process.

Review of Personnel

As part of the VAWD accreditation process, NABP initiates background checks on some key individuals employed by the wholesale distributor. These individuals include:

- Designated representative or the most senior person responsible for facility operations, purchasing, and inventory control
- Supervisor of designated representative or most senior person referenced above
- Principals and owners who directly or indirectly own greater than 10% interest in the company, if the company is not publicly held

protect the US drug supply. Find a VAWD-accredited wholesale distributor.

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NABP's vendor, Kroll Background America, performs background checks on personnel. Records and data that will be checked include:

- Criminal records, including felony and misdemeanor convictions
- Credit history
- Bankruptcy information
- Current and previous employment (only applicable to the designated representative)

Background Checks

A few states require additional state-specific forms and/or information to be completed and submitted in order to perform criminal background checks. VAWD staff will notify the individual applicants if such forms and/or information need to be submitted.
Please refer to the Summary of Consumer Rights under the Fair Credit Reporting Act (FCRA) for more information about your rights under the federal FCRA, as well as instructions in the event that you have an inquiry regarding the accuracy or completeness of information (PDF) contained in the consumer background investigation report.

To initiate the background check, print a copy of the Notice, Authorization, and Release for the Procurement of a Consumer and/or Investigative Consumer Report form (PDF) for each person whose background must be checked.

- All sections of the authorization and release form must be completed; however, only designated representatives must complete the employer sections. The form must be reviewed, signed, and dated by the individual whose background is being checked.
- The background check costs $175 for each person whose background must be checked. This fee should be paid during the online application process. See the Fees section for more information.

NABP Clearinghouse

NABP also screens the facilities and staff of the wholesale distributor through its Clearinghouse to check for disciplinary actions levied against the distributor or the pharmacist-in-charge.

The NABP Clearinghouse is a national database of educational, competence, licensure, and disciplinary information on pharmacists practicing in NABP's active member board states and jurisdictions.

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Survey

After the documentation is evaluated and preliminarily determined to be satisfactory, an on-site survey of the wholesale distributor facility is scheduled to evaluate the operations and policies and to interview staff to determine compliance with the VAWD criteria.

NABP will send the wholesale distributor a Survey Process Guide, which includes information on what to expect during the survey.

As part of maintaining VAWD accreditation, a survey is also performed once every three years.

State-Specific Requirements

See Contact Information for Licensure Verification (PDF) for a listing of state agencies responsible for licensing wholesale distributors.

Wholesale distributors that hold licenses in Indiana and North Dakota are required to submit a photograph of the designated representative. For details on requirements see the photograph submission form (PDF).

Wholesale distributors that hold licenses in Indiana should review further state-specific requirements (PDF) to determine if their facility is exempt from the VAWD accreditation requirement.

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17. Wholesale Distributor Licensure Requirements (cont.)

State	Are Criminal History Record Checks Required for Wholesale Distributors?	Does State Recognize VAWD[8] Accreditation?
Alabama	—	No
Alaska	Yes V	No
Arizona	No	No
Arkansas	No	No
California	—	No
Colorado	Yes RRR	Yes
Connecticut	No	O
Delaware	Yes	Yes
District of Columbia	No	No
Florida	G	No
Georgia	—	No
Guam	—	—
Hawaii	No	No
Idaho	Yes RRR	Yes
Illinois	Yes SSS	No
Indiana	No	Yes
Iowa	No	Yes
Kansas	No	Yes
Kentucky	No	No
Louisiana	G	No
Maine	No OOO	NNN
Maryland	Yes RRR	Yes UU
Massachusetts	No	Yes K
Michigan	No E	No
Minnesota	No	Yes YYY
Mississippi	—	No
Missouri	Yes	No
Montana	No ZZ	Yes
Nebraska	Yes RRR	Yes
Nevada	No OOO	Yes
New Hampshire	No	Yes
New Jersey	No	K
New Mexico	No	Yes
New York	—	No
North Carolina	Yes	No
North Dakota	Yes	Yes VVV
Ohio	Yes PPP	No
Oklahoma	No	Yes
Oregon	No TTT	Yes
Pennsylvania	No	No
Puerto Rico	—	O
Rhode Island	—	No
South Carolina	No	Yes
South Dakota	No OOO	Yes
Tennessee	Yes	No
Texas	Yes G	No
Utah	Yes	Yes K
Vermont	No	Yes
Virginia	Yes	No
Washington	Yes UUU	No
West Virginia	No	No
Wisconsin	No	No
Wyoming	Yes	Yes

Colored text denotes change from 2013 edition.
— Indicates information is not available.

LEGEND

A — Full-service drug wholesaler licensure fees. Non-prescription drug wholesaler licensure fee: $500; renewal fee: $500 (biennial).
B — VAWD accreditation required for original licensure issuance and renewal.
C — Plus controlled substance registration fee. (AL – $100/yr. CT – $185/yr. Each additional location is $150. ID – $130/yr. MA – $225/yr. NM – $60/yr. NY – $1200/2 yrs. OH – $37.50/yr. OR – $50/yr. RI – $100. TN – $40/2 yrs. UT – $100/yr ($78 renewal). VA – $90/yr. For resident wholesale distributors only. WA – $115/yr ($115 renewal). WY – $275/yr.)
D — Varies. Set by Division of Professional Regulation biannually.
E — Criminal history checks are performed if applicant has a controlled substance research lab.
F — Legend drugs – state licensure fee: $200; renewal fee: $200. Over-the-counter and/or veterinary drugs – state licensure fee: $175; renewal fee: $175. Medical gases – state licensure fee: $150; renewal fee: $150. If already licensed as a pharmacy – state licensure fee: $125; renewal fee: $125.
G — Wholesalers and distributors are regulated by another state agency. (TX – Department of State Health Services.)
H — Licensed by Department of Health Services.
I — In-state wholesale distributors vary depending on GAV. GAV less than $200,000 – fee is $1,080. GAV $200,000 to less than $20 million – fee is $1,755. GAV $20 million and over – fee is $2,295. Separate fee from Texas Department of Public Safety for controlled substances. Out-of-state – GAV less than $20 million – fee is $1,300. GAV greater than $20 million – fee is $1,950.
J — License only required for distributors of products containing ephedrine and pseudoephedrine.
K — Supported but not required by current regulations.
L — The fee is $200 annually for in-state drug wholesalers and $100 annually for out-of-state wholesale distributors. There is an additional annual fee of $130 for controlled substances, where applicable.
M — However, per Board's informal interpretation, if the out-of-state wholesaler has a vendor-managed inventory system within the state, a wholesale distributor license is required.
N — $330 fee for original license and renewal.
O — Not addressed in Pharmacy Act or Board regulations.
P — However, legislation to require registration of out-of-state establishments, including the Internet, is pending.
Q — $295 – even years; $185 – odd years.
R — $270 – even years; $220 – odd years.
S — Board of Wholesale Drug Distributors.
T — Bureau of Drugs, Devices, and Cosmetics.
U — Department of Consumer Protection.
V — For facility manager.
W — Division of Occupational and Professional Licensing.
X — Department of State Health Services.
Y — However, approved subject to satisfactory inspection by the Department of Health, Food and Drug Branch.
Z — Registered, not licensed.
AA — Department of Financial and Professional Regulation.
BB — Department of Health and Human Services, Division of Public Health, Licensure Unit.
CC — Department of Health and Senior Services.
DD — Controlled substance registration required for distributing controlled substances $365.
EE — Full service wholesaler.
FF — Department of Agriculture.
GG — Yes, if located within the state. (AK, KY – No, if located out-of-state.)
HH — Licensed by Health Regulation and Licensing Administration, Pharmaceutical Control Division.
II — DHHS, Division of Public Health, Licensure Unit. However, no license is required.
JJ — Unless they also handle drugs.
KK — Plus one-time application fee of $50.
LL — Licensure required only if device contains a prescription drug.
MM — Licensed by the Ohio Respiratory Care Board (durable medical equipment products).
NN — Submit security deposit of $100,000.
OO — In most cases, this entity would apply for a "warehouse license."
PP — Licensed by the Department of State Health Services.
QQ — One location $200; two or more locations $500
RR — Registered.
SS — Have the same statute, but the manufacturers do not have VAWD, bond, or pedigree requirements.
TT — Does not include fingerprinting fee that is required if not licensed health professional or if health professional licensed prior to 2008.
UU — VAWD or location in a state with laws substantially equivalent to Maryland, required for out-of-state wholesale distributors.
VV — Instate only. Out-of-state manufacturers are registered as wholesalers. (WA – If they ship directly into Washington or are sample distributors.)
WW — Fees change annually. Contact the Board.
XX — If facility is located within state.
YY — If the medical device contains prescription medication.

Legend continued on page 61

LEGEND — cont.

ZZ — However, the entity must attest to being in good standing and submit a National Practitioner Data Bank self-query with the application. Renewal applications request attestation of disciplinary action and submission of related documentation with positive responses. See MT Reg 24.174.1202.
AAA — Department of Public Health.
BBB — Application fees are reevaluated in June of even-numbered years.
CCC — Pharmaceutical Control Division.
DDD — Medicaid.
EEE — Prescription devices only.
FFF — Department of Health and Senior Services.
GGG — Ohio Respiratory Care Board ORC 4752.01(B).
HHH — Division of Occupational and Professional Licensing.
III — If legend device sold or rented directly to patients. If legend device is distributed to persons other than consumers or patients then regulated by the Arkansas Department of Health.
JJJ — Department of Financial and Professional Regulation, Division of Professional Regulation, Home Medical Equipment and Services Board.
KKK — Licensed by the Drug Control Program only if the device contains a prescription drug.
LLL — Department of Health
MMM — Expires September 30.
NNN — Voluntary.
OOO — However, application includes criminal history questions and requires supporting documentation to be submitted. (SD – Must be confirmed via signature and notary public.)
PPP — ORC 4729.53(A)(1), ORC 4729-9-16(A)(7).
QQQ — Also AL Board for Durable Medical Device Distributors.
RRR — For designated representative. (MD – and supervising designated representative. NE – and designated representative supervisor and any owner with greater than 10% ownership.)
SSS — IL 225 ILCS 120/25 (c)(4).
TTT — However, per OAR 855-065-0006(3), the Board may require them. The Board does not require at this time though.
UUU — Criminal background questions regarding drug or controlled substance violations, moral turpitude, and professional license discipline are asked of each applicant for its partners, owners, and board of directors. If an answer is yes, an explanation must accompany the application.
VVV — Required.
WWW — §22-0102, Licensing of Medical Device Distributors and Manufacturers.
XXX — Includes $6 CURES fee, implemented on April 1, 2014.
YYY — To obtain a license, must either pass an inspection conducted by authorized representative of the board or accredited by a board-approved accreditation program. VAWD is approved by the board.

NABP*LAW Online* Search Terms

Wholesale Distributor Licensure Requirements *(type as indicated below)*

- wholesale accreditation VAWD
- wholesale criminal history
- wholesale device
- wholesale distributor fees
- wholesale license requirements
- wholesale "out-of-state" (or nonresident)
- wholesale renewal

nurses provided a needed benefit in setting up patients' medications.

Executive Session:

Ms. Chilton moved, and the Board voted 8-0 in favor of the motion, to enter into executive session pursuant to § 2.1-344.1(A)7 of the Code of Virginia for consultation with legal counsel and briefing by staff pertaining to certain legal matters requiring the provision or consideration of legal advice to discuss the interpretation of the Drug Control Act of the term "administer".

Reconvene:

Ms. Chilton moved, and the Board voted 8-0 in favor of the motion, that only public business matters lawfully exempted from open meeting requirements under Virginia law were discussed in the executive session and only public business matters as were identified in the motion convening the executive session were heard, discussed or considered by the Board.

Mr. Tiffany moved to adopt the guidance document with the second paragraph amended to read ". . ., such advance preparation shall not exceed a 14 day supply." The motioned was seconded. Mr. Ayotte moved, and the Board voted 8-0 to amend the motion, that the final paragraph be amended to read, "If the advance preparation is to assist in the administration of medications to students during a single day field trip, then such advance preparation shall not be made prior to the day before the field trip and shall not exceed a one day supply." Also insert a sentence at the end of paragraph 3 which specifies that for any field trip which is longer than one day in length, the medication should be provided by the student's parent or guardian in a properly dispensed and labeled vial and contain only enough medication for the duration of that field trip.

The Board voted 8-0 in favor of the motion as amended.

Mr. Casway reiterated that this is a guidance document and not a regulation or statute. It is the Board's interpretation of the Drug Control Act.

REQUEST FROM DMAS CONCERNING OUT-OF-STATE DME PROVIDERS:

Ms. Russell stated that the Department of Medical Assistance Services (DMAS) notifies providers that they have to hold a license with the Board of Pharmacy in order to be a provider of durable medical equipment (DME) for reimbursement by Medicaid. Calls are received from out-of-state DME providers wanting to

know how they can become licensed by the Board of Pharmacy. There is no specific statute addressing non-resident medical equipment suppliers as there is for non-resident pharmacies and wholesale distributors.

Sam Clay, Pharmacist, also has a DME company and is President of the Virginia Association of DME Companies, addressed the Board on behalf of Virginia DME providers, requesting that the Board require licensure of non-resident providers. Bobbie Terry, Virginia Association for Homecare, also addressed the Board supporting registration of out-of-state providers.

Mr. Ward moved, and the Board voted 8-0 in favor of the motion to pursue a legislative proposal to register non-resident medical equipment suppliers, but under current law to accept applications from out-of-state providers and either inspect or require other documentation of compliance with Virginia laws and regulations.

REQUEST FOR DELIVERY OF PRESCRIPTIONS TO ALTERNATE LOCATIONS

Ms. Russell stated that numerous requests have been made to allow prescriptions dispensed by a pharmacy, either in-state or out-of-state, to be delivered somewhere other than the address of the patient.

Trish Bridgers, Pharmacist-in-Charge at Virginia Commonwealth University Student Health Service, stated that MCV hospital would no longer be providing pharmacy services to MCV students and requested that the VCU pharmacy be allowed to deliver students' filled prescriptions directly to the MCV campus clinic for pick-up. She stated that because of scheduling difficulties it is not always convenient for prescriptions to be picked up by the MVC students at the VCU campus.

Executive session:

Ms. Chilton moved, and the Board voted 8-0 in favor of the motion, to enter into executive session pursuant to § 2.1-344.1(A)7 of the Code of Virginia for consultation with legal counsel and briefings by staff pertaining to certain legal matters requiring the provision or consideration of legal advice to discuss request for delivery of dispensed prescription medications.

Reconvene:

Ms. Chilton moved, and the Board voted 8-0 in favor of the motion, that only public business matters lawfully exempted from open meeting requirements under Virginia law were discussed in the executive session and only public business matters as were identified in the

Department of Health Professions
1999 Session of the General Assembly

Draft Legislation

A BILL to amend the *Code of Virginia* by adding a section numbered § 54.1-3435.2.01 and by amending and reenacting §54.1-3435.3 of pertaining to registration of medical equipment suppliers.

Be it enacted by the General Assembly of Virginia:
1. That § 54.1-3435.2.01 is enacted and that § 54.1-3435.3 of the *Code of Virginia* is amended and reenacted as follows:

§ 54.1-3435.2.01 Registration of non-resident medical equipment suppliers; renewal; fee.

A. Any person located outside this Commonwealth, with the exception of a non-resident pharmacy registered pursuant to § 54.1-3434.1, who ships, mails, or delivers to a consumer in this Commonwealth, pursuant to a lawful order of a prescriber, any hypodermic syringes and needles, medicinal oxygen, Schedule VI controlled devices, those Schedule VI controlled substances with no medicinal properties which are used for the operation and cleaning of medical equipment, or solutions for peritoneal dialysis shall be registered with the Board. The applicant for registration as a nonresident medical equipment supplier 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 or before January 1 of each year; notify the Board within thirty days of any substantive change in the information previously submitted to the Board; and remit a fee, which shall be the fee specified for medical equipment suppliers located within the Commonwealth.

B. The nonresident medical equipment supplier shall at all times maintain a valid, unexpired license, permit, or registration in the state in which it is located if required by the resident state, and shall furnish proof of such upon application and at each renewal. If the resident state does not require licensure or registration of persons engaged in direct consumer supply of the items listed in subsection A of this section, the applicant or registration holder shall furnish proof that it meets the minimum requirements of law and regulation for medical equipment suppliers in Virginia.

C. Records of distribution of any item listed in subsection A of this section into this 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.

§ 54.1-3435.3. Denial, revocation, and suspension of permit as medical equipment supplier *or registration of a non-resident medical equipment supplier.*

A. The permit as a medical equipment supplier *or the registration of a non-resident medical equipment supplier* may be denied, suspended, or revoked by the Board for any of the following:

1. Any conviction of the applicant or ~~permit~~ holder *of a permit or registration* under federal or state laws relating to wholesale or retail distribution or delivery of prescription drugs or devices or controlled substances;

2. Any felony conviction of the applicant or ~~permit~~ holder *of a permit or registration*;

3. Any misdemeanor conviction of the applicant or ~~permit~~ holder *of a permit or registration* for a crime involving moral turpitude;

4. Violations of any provision of this chapter or regulations of the Board governing medical equipment suppliers;

5. Fraud or deceit in any application for *a permit, registration or other* licensure ~~or permit~~ under this chapter; or

6. Engaging in or attempting any fraud upon the consumer, *any third-party payor, including Medicaid, any individual or group accident and sickness insurance policy or subscription contract providing coverage under a health services plan, or any health care plan, any practitioner or the Board in connection with the provision of services as a medical equipment supplier.*

B. Medical equipment suppliers shall allow the Board or its authorized agents to enter and inspect, at reasonable times and in a reasonable manner, their premises and delivery vehicles, and to audit their records and written operating procedures.

DRAFT

VIRGINIA DEPARTMENT OF HEALTH PROFESSIONS
VIRGINIA PRESCRIPTION MONITORING PROGRAM
MINUTES OF ADVISORY PANEL

Monday, March 30, 2015 — 9960 Mayland Drive, Suite 300, Henrico, Virginia 23233-1463

CALL TO ORDER:	A meeting of the advisory panel of the Prescription Monitoring Program was called to order at 1:03 p.m.
PRESIDING	Randall Clouse, Chair
MEMBERS PRESENT:	Holly Morris, RPh, Crittenden's Drug, Vice Chair Carola Bruflat, Family Nurse Practitioner Dr. Amy Tharp, Office of the Chief Medical Examiner Mellie Randall, Representative, Department of Behavioral Health and Developmental Services Brenda Clarkson, Executive Director, Virginia Association for Hospices and Palliative Care Harvey Smith, 1SG, Virginia State Police S. Hughes Melton, M.D., Mountain Valley Health
MEMBERS ABSENT:	John Barsanti, M.D., Commonwealth Pain Specialists, L.L.C.
STAFF PRESENT:	David E. Brown, D.C., Director, Department of Health Professions (DHP) James Rutkowski, Assistant Attorney General, Office of the Attorney General Elaine Yeatts, Senior Policy Analyst Ralph A. Orr, Program Director, Prescription Monitoring Program Carolyn McKann, Deputy Director, Prescription Monitoring Program
WELCOME AND INTRODUCTIONS	Mr. Clouse welcomed everyone to the meeting of the advisory panel.
APPROVAL OF MINUTES	Dr. Melton presented a motion to approve the minutes from the November 10, 2014 meeting of the PMP Advisory Panel and Ms. Bruflat seconded the motion. The minutes were approved as presented.
PUBLIC COMEDDNT:	No public comments were made.
APPROVAL OF AGENDA	The agenda was approved as presented.
DEPARTMENT OF HEALTH PROFESSIONS REPORT	Dr. Brown stated that he did not have a Department of Health Professions report but emphasized that PMPs, Virginia's included, occupy a prominent position in healthcare today.

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David E. Brown, D.C.: DEPARTMENT OF HEALTH PROFESSIONS REPORT Report on Governor's Task Force on Prescription Drug and Heroin Abuse	Dr. Brown welcomed the Panel and thanked them for taking time from their schedules. Dr. Brown discussed the Governor's Task Force on Prescription Drug and Heroin Abuse. He noted that work is being completed by five subgroups: education, treatment, data monitoring, disposal and education and that there is a lot of important work going on with respect to disposal of controlled substances and how to make the public aware of these opportunities. Dr. Brown concluded his remarks about the Governor's Task Force by acknowledging that education is an essential piece to solving this issue and that in America today, addiction usually begins with prescription drugs. Therefore, it is crucial that prescription drugs be prescribed and disposed of appropriately. Mr. Orr noted that information about the Task Force may be obtained on the DHP website by clicking on the link on the DHP home page. Mr. Orr also noted that some members present serve on Task Force committees – Ms. Randall and Dr. Melton on the Treatment Workgroup and himself on the Data-Monitoring Workgroup.
Elaine Yeatts: 2015 LEGISLATION AND DHP REGULATIONS UPDATE:	Ms. Yeatts provided on overview of bills passed during the most recent session, see pages 7 through 17 of the agenda packet. Three of the bills specifically addressed the PMP. HB1810 revised language to clearly state that data in possession of the PMP is not subject to civil subpoena in any civil proceeding. HB1841 requires all licensed dispensers (pharmacists) to be registered with the Virginia PMP. SB817 allows local parole and probation officers to have access to the Virginia PMP given that they have completed the Drug Diversion School presented each fall by NADDI and the Virginia State Police.
Ralph Orr: EXPAND ACCESS TO PMP FOR CLINICAL PHARMACISTS AND PRESCRIBERS PARTICIPATING ON HEALTHCARE TEAMS:	Mr. Orr discussed expanding access to the PMP for clinical pharmacists who are participating on healthcare teams with prescribers. He noted the draft language for a legislative proposal (Agenda Packet) for the 2016 General Assembly would allow pharmacists to access the PMP when working within their scope of care within a collaborative team. It would also allow a prescriber consulting on the care of a specific patient to use the PMP. The Panel approved a motion to support the draft legislation.
Ralph Orr: REVIEW REPORTING REQUIREMENTS TO PMP TO INCLUDE FREQUENCY OF REPORTING, SPECIES CODE AND OTHERS	Mr. Orr went over current reporting requirements and presented a legislative proposal (Agenda Packet) to reduce the reporting frequency currently in place. Mr. Orr stated that there is huge interest in shortening the time that prescription data gets reported to the PMP, not only in Virginia, but nationally. Some larger chains already report data to PMPs on a daily basis regardless of individual states' requirements. It was noted that the proposed language states that data shall be transmitted to the Department or its agent within 24 hours or the next business day whichever

	comes later since not all dispensers are open 7 days a week. Ms. Morris commented that daily reporting may be a burden on some independent pharmacies. The draft legislative proposal with respect to frequency was approved with Ms. Morris voting nay. Mr. Orr discussed language for proposed changes to program regulations (Agenda Packet) that were prompted by recommendations made by the Governor's Task Force. The primary recommendations are to add the National Provider Identifier (NPI) and the Species Code as reporting elements to support the implementation of prescriber feedback reports. Discussion by Ms. Yeatts recommended leaving the reporting frequency out of the proposal as it can be amended by an exempt action at a later date to conform to new legislation. Dr. Brown suggested deleting the language referencing the electronic reporting standard. She also noted that this legislation does not lend itself to fast-tracking, and that as a result, we are looking at a probable 2-year process. Ms. Yeatts suggested that the Panel could recommend initiating the Notice of Intended Regulatory Action without approving specific language at this time. Ms. Randall presented a motion to proceed, Ms. Bruflat seconded, and the motion was approved.
Ralph Orr: UTILIZATION OF PMP DATA: ANALYSIS OF INFORMATION HELD BY PMP	Mr. Orr told the panel that recently PMP has received an update to the software application that adds the ability to obtain de-identified data sets providing opportunities for analysis of PMP data not previously available to the program. The PMP is working on an MOU with Brandeis University under a CDC/FDA/BJA grant to provide data sets to Brandeis, which will apply 43 measures and provide a report back to PMP on these measures on a quarterly basis. There is also a current MOU with the Department of Criminal Justice Services and an MOU being developed to share de-identified data with the Department of Health. Mr. Orr noted that the Center for Disease Control just sent out an application for a grant with the enhancement of PMPs as a primary goal. A Department of Health must apply for the CDC grant, and in order to position ourselves to receive funding, we need to be able to offer de-identified data sets. The deadline to apply for this grant is early May 2015.
Ralph Orr: Guidance Related to Research Requests for PMP Data	Mr. Orr pointed the panel members to the copy of Virginia PMP's current request for research data form in the agenda packet. It is largely outdated, and Mr. Orr sought input from panel members regarding updating the form. This research form has only been utilized by the PMP program once since 2005. Panel members agreed that ideally any research must be approved by an Internal Review Board process prior to PMP approval. Also noted was that if the identity of an individual is accidentally divulged, certain actions must happen, and this form

DRAFT Legislative proposal for 2016 General Assembly

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

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

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

1. Information relevant to a specific investigation of a specific recipient or of a specific dispenser or prescriber to an agent who has completed the Virginia State Police Drug Diversion School designated by the superintendent of the Department of State Police or designated by the chief law-enforcement officer of any county, city, or town or campus police department to conduct drug diversion investigations pursuant to § 54.1-3405.

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

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

4. Information relevant to a specific investigation of a specific recipient, dispenser, or prescriber to an agent of a federal law-enforcement agency with authority to conduct drug diversion investigations.

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

1. Information in the possession of the program concerning a recipient who is over the age of 18 to that recipient. The information shall be mailed to the street or mailing address indicated on the recipient request form.

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

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

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

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

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

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

8. Information relating to prescriptions for covered substances issued by a specific prescriber, which have been dispensed and reported to the Program, to that prescriber.

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

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

F. Confidential information that has been received, maintained or developed by any board or disclosed by the board pursuant to subsection A shall not, under any circumstances, be available for discovery or court subpoena or introduced into evidence in any medical malpractice suit or other action for damages arising out of the provision of or failure to provide services. However, this subsection shall not be construed to inhibit any investigation or prosecution conducted pursuant to Article 1 (§ 18.2-247 et seq.) of Chapter 7 of Title 18.2.

DRAFT Legislation Proposal for 2016 General Assembly

§ 54.1-2521. Reporting requirements.

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

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

1. The recipient's name and address.

2. The recipient's date of birth.

3. The covered substance that was dispensed to the recipient.

4. The quantity of the covered substance that was dispensed.

5. The date of the dispensing.

6. The prescriber's identifier number.

7. The dispenser's identifier number.

8. The method of payment for the prescription.

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

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

C. Data shall be transmitted to the Department or its agent within 24 hours or the next business day whichever comes later.

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

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

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Relevant Sections of Law and Regulation for PTCB Discussion:

from *The Pharmacy Act*, July 1, 2014

§ 54.1-3321. Registration of pharmacy technicians.

A. No person shall perform the duties of a pharmacy technician without first being registered as a pharmacy technician with the Board. Upon being registered with the Board as a pharmacy technician, the following tasks may be performed:

1. The entry of prescription information and drug history into a data system or other record keeping system;

2. The preparation of prescription labels or patient information;

3. The removal of the drug to be dispensed from inventory;

4. The counting, measuring, or compounding of the drug to be dispensed;

5. The packaging and labeling of the drug to be dispensed and the repackaging thereof;

6. The stocking or loading of automated dispensing devices or other devices used in the dispensing process;

7. The acceptance of refill authorization from a prescriber or his authorized agency, so long as there is no change to the original prescription; and

8. The performance of any other task restricted to pharmacy technicians by the Board's regulations.

B. To be registered as a pharmacy technician, a person shall submit satisfactory evidence that he is of good moral character and has satisfactorily completed a training program and examination that meet the criteria approved by the Board in regulation or that he holds current certification from the Pharmacy Technician Certification Board.

C. A pharmacy intern may perform the duties set forth for pharmacy technicians in subsection A when registered with the Board for the purpose of gaining the practical experience required to apply for licensure as a pharmacist.

D. In addition, a person enrolled in an approved training program for pharmacy technicians may engage in the acts set forth in subsection A for the purpose of obtaining practical experience required for registration as a pharmacy technician, so long as such activities are directly monitored by a supervising pharmacist.

E. The Board shall promulgate regulations establishing requirements for evidence of continued competency as a condition of renewal of a registration as a pharmacy technician.

F. The Board shall waive the initial registration fee and the first examination fee for the Board-approved examination for a pharmacy technician applicant who works as a pharmacy technician exclusively in a free clinic pharmacy. If such applicant fails the examination, he shall be responsible for any subsequent fees to retake the examination. A person registered pursuant to this subsection shall be issued a limited-use registration. A pharmacy technician with a limited-use registration shall not perform pharmacy technician tasks in any setting other than a free clinic pharmacy. The Board shall also waive renewal fees for such limited-use registrations. A pharmacy technician with a limited-use registration may convert to an unlimited registration by paying the current renewal fee.

(2001, c. 317; 2004, c. 47.)

from *Regulations Governing the Practice of Pharmacy*, February 11, 2015

18VAC110-20-101. Application for registration as a pharmacy technician.

A. Any person wishing to apply for registration as a pharmacy technician shall submit the application fee and an application on a form approved by the board.

B. In order to be registered as a pharmacy technician, an applicant shall provide evidence of the following:

1. Satisfactory completion of an approved training program, and

2. A passing score on a board-approved examination.

C. In lieu of the requirements of subsection B of this section, an applicant may provide evidence of current PTCB certification.

D. A pharmacy technician trainee may perform tasks restricted to pharmacy technicians for no more than nine months without becoming registered as a pharmacy technician.

18VAC110-20-102. Criteria for approval for training programs.

A. Any person wishing to apply for approval of a pharmacy technician training program shall submit the application fee and an application on a form approved by the board and meet the criteria established in this section.

B. The curriculum of a training program for pharmacy technicians shall include instruction in applicable, current laws and regulations and in the tasks that may be performed by a pharmacy technician to include the following or any other task restricted to pharmacy technicians in regulation:

1. The entry of prescription information and drug history into a data system or other recordkeeping system;

2. The preparation of prescription labels or patient information;

3. The removal of the drug to be dispensed from inventory;

4. The counting, measuring, or compounding of the drug to be dispensed;

5. The packaging and labeling of the drug to be dispensed and the repackaging thereof;

6. The stocking or loading of automated dispensing devices or other devices used in the dispensing process; and

7. The acceptance of refill authorization from a prescriber or his authorized agent provided there is no change to the original prescription.

C. Each program shall have a program director who shall be either (i) a pharmacist with a current license in any jurisdiction and who is not currently suspended or revoked in any jurisdiction in the United States; (ii) a pharmacy technician with at least one year of experience performing technician tasks who holds a current registration in Virginia or current PTCB certification and who is not currently suspended or revoked as a pharmacy technician in any jurisdiction; or (iii) other person approved and deemed qualified by the board to be a program director.

D. Instructors for the core components listed in subsection B of this section shall meet the requirements for the program director listed in subsection C of this section. The program director may serve as an instructor.

E. The length of the program shall be sufficient to prepare a program participant to sit for the board-approved examination and demonstrate entry-level competency.

F. The program shall maintain records of program participants either on-site or at another location where the records are readily retrievable upon request for inspection. A program shall provide a certificate of completion to participants who successfully complete the program and provide verification of completion of the program for a participant upon request by the board. Records shall be maintained for two years from date of completion or termination of program.

G. The program shall report within 14 days any substantive change in the program to include a change in program name, program director, instructors, name of institution or business if applicable, address, program content, length of program, or location of records.

H. A pharmacy technician training program approval expires after two years, after which the program may apply for renewal. For continued approval, the program shall submit the renewal application, renewal fee, and a self-evaluation report on a form provided by the board at the time of renewal notification. Renewal of a program's approval is at the discretion of the board, and the decision to renew shall be based on documentation of continued compliance with the criteria set forth in this section.

18VAC110-20-103. Examination.

A. The board shall approve one or more examinations to test entry-level competency for pharmacy technicians. In order to be approved, a competency examination shall be developed in accordance with and meet the recognized acceptable test measurement standards of the Joint Technical Standards for Education and Psychological Testing (American Psychological Association, current edition), and shall be administered by an independent third party.

B. The board may contract with an examination service for the development and administration of a competency examination.

C. The board shall determine the minimum passing standard on the competency examination.

D. Any requests for testing accommodations under the Americans with Disabilities Act shall be in accordance with the provisions of 18VAC110-20-60 F.

18VAC110-20-111. Pharmacy technicians.

A. Every pharmacy that employs or uses pharmacy technicians shall maintain a site-specific training program and manual for training pharmacy technicians to work at that pharmacy. The program shall include training consistent with that specific pharmacy practice to include, but not be limited to, training in proper use of site-specific computer programs and equipment, proper use of other equipment used at the pharmacy in performing technician duties, and pharmacy calculations consistent with the duties at that pharmacy.

B. Every pharmacy shall maintain documentation of successful completion of the site specific training program for each pharmacy technician for the duration of the employment and for a period of two years from date of termination of employment. Documentation for currently employed pharmacy technicians shall be maintained on site or at another location where the records are readily retrievable upon request for inspection. After employment is terminated, such documentation may be maintained at an off-site location where it is retrievable upon request.

C. Every pharmacy that employs or uses a person enrolled in an approved pharmacy technician training program pursuant to §54.1-3321 D of the Code of Virginia shall allow such person to conduct tasks restricted to pharmacy technicians for no more than nine months without that person becoming registered as a pharmacy technician with the board as set forth in 18VAC110-20-101. Every pharmacy using such a person shall have documentation on site and available for inspection showing that the person is currently enrolled in an approved training program and the start date for each pharmacy technician in training.

Possible Questions to Consider:

1. Is the intention to require all current active pharmacy technicians and new applicants to obtain PTCB certification or will current active pharmacy technicians be grandfathered in some way?
2. Is the intention to eliminate the allowance for working for no more than 9 months without becoming registered as a pharmacy technician when enrolled in a board-approved pharmacy technician training program, i.e., person would obtain PTCB and board registration as a pharmacy technician prior to being allowed to perform duties as a pharmacy technician? Should the allowance for the board to approve pharmacy technician training programs eliminated?
3. Would a requirement for PTCB certification also apply to those practicing solely in a free clinic pharmacy? Should an allowance for a limited-use pharmacy technician registration remain?
4. ExCPT is currently a board-approved examination. Would this national certification be acceptable as well?

from *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy*, August 2014

Section 105. Definitions.

(b) "Certified Pharmacy Technician"[1] means personnel registered with the Board who have completed a certification program approved by the Board and may, under the supervision of a Pharmacist, perform certain activities involved in the Practice of Pharmacy, such as:

(1) receiving new written or electronic Prescription Drug Orders;
(2) prescription transfer;
(3) Compounding; and
(4) assisting in the Dispensing process; and
(5) performing all functions allowed to be performed by pharmacy technicians

but excluding:

(1) Drug Utilization Review (DUR);
(2) clinical conflict resolution;
(3) prescriber contact concerning Prescription Drug Order clarification or therapy modification;
(4) Patient Counseling; and
(5) Dispensing process validation.

"Pharmacy Technician"[2] means personnel registered with the Board who may, under the supervision of the pharmacist, assist in the pharmacy and perform such functions as:

(1) assisting in the Dispensing process;
(2) processing of medical coverage claims;
(3) stocking of medications; and
(4) cashiering

but excluding:

(1) Drug Utilization Review (DUR);
(2) clinical conflict resolution;
(3) prescriber contact concerning Prescription Drug Order clarification or therapy modification;
(4) Patient Counseling;
(5) Dispensing process validation;
(6) prescription transfer; and
(7) receipt of new oral Prescription Drug Orders

Section 307. Registration of Certified Pharmacy Technicians.

(a) In order to be registered as a Certified Pharmacy Technician in this State, an applicant shall:[3]

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[1] The *Model Act* defines Certified Pharmacy Technician and Pharmacy Technician separately to distinguish between the activities that can be performed. A Certified Pharmacy Technician is recognized, because of the completion of a Board-approved certification program, as having knowledge and skills that qualify them to assist the Pharmacist in the Practice of Pharmacy with limited patient care tasks that exceed routine Dispensing or Drug storage activities. Pharmacy Technicians are limited to routine Dispensing activities, Drug storage, medical coverage claims processing, and cashiering.

[2] The term Pharmacy Technician will continue to be utilized until 2015. At that time, the Model State Pharmacy Act and Model Rules will be amended to require that all Pharmacy Technicians be certified. The *Model Act* will also be amended at that time to replace the term Pharmacy Technician with the term Candidate for Certified Pharmacy Technician, which will be redefined to provide a path to certification for non-certified pharmacy technicians. A one-time renewal of the Certified Pharmacy Technician Trainee registration will be allowed.

(1) have submitted an application in the form prescribed by the Board of Pharmacy;
(2) have attained the age of _____;
(3) have good moral character;
(4) have graduated from high school or obtained a Certificate of General Educational Development (GED) or equivalent;
(5) have[4]:
  (i) graduated from a competency-based pharmacy technician education and training program approved by the Board of Pharmacy;[5] or
  (ii) been documented by the Pharmacist-in-Charge of the Pharmacy where the applicant is employed as having successfully completed a site-specific, competency-based education and training program approved by the Board of Pharmacy;[6]
(6) have successfully passed an examination developed using nationally recognized and validated psychometric and pharmacy practice standards approved by the Board of Pharmacy;
(7) have undergone a state and federal fingerprint-based criminal background check as specified by Board rule; and
(8) have paid the fees specified by the Board of Pharmacy for the examination and any related materials, and have paid for the issuance of the registration.

(b) No Pharmacist whose license has been denied, Revoked, Suspended, or restricted for disciplinary purposes shall be eligible to be registered as a Certified Pharmacy Technician.[7]

(c) The Board of Pharmacy shall, by rule, establish requirements for registration of Certified Pharmacy Technicians.

Section 308. Registration of Pharmacy Technicians.[8]

(a) In order to be registered as a Pharmacy Technician in this State, an applicant shall:

(1) have submitted an application in the form prescribed by the Board of Pharmacy;
(2) have attained the age of _____;
(3) have good moral character;
(4) have undergone a state and federal fingerprint-based criminal background check as specified by Board rule;
(5) have paid the fees specified by the Board; and

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[3] In 2015, the *Model State Pharmacy Act and Model Rules* will be amended to require persons seeking to become Certified Pharmacy Technicians to complete each of the requirements outlined in Sections 307(a)(5)(i), 307(a)(5)(ii), and 307(a)(6).

[4] Boards should avoid mention of specific examinations or other contracted services in their practice act and regulations to avoid challenges related to an unconstitutional delegation of authority. It is contemplated that Boards will utilize the Pharmacy Technician Certification Board examination as part of their assessment of technician competence to assist in the practice of pharmacy.

[5] It is recommended that states adopt this requirement, if not currently required, through a process that incorporates provisions for grandfathering.

[6] It is contemplated that Boards will approve those pharmacy technician training programs whose standards are at least equivalent to the minimum standards being developed by an accrediting organization recognized by state Boards, such as ACPE. See Comment to Section 213(a)(4) above for further discussion of the Board's proper role in the accreditation process.

[7] The Board may specifically authorize a pharmacist whose license has been disciplined to register as a Certified Pharmacy Technician or Pharmacy Technician under terms and conditions deemed appropriate.

[8] In 2015, the *Model State Pharmacy Act and Model Rules* will be amended to remove the term Pharmacy Technician and incorporate the term Candidate for Certified Pharmacy Technician, which will be redefined to provide a path to certification for non-certified pharmacy technicians. A one-time renewal of the Candidate for Certified Pharmacy Technician will be allowed.

(6) have been documented by the Pharmacist-in-Charge of the Pharmacy where the applicant is employed as having successfully completed a site-specific training program and having successfully completed an objective assessment mechanism prepared in accordance with any rules established by the Board.

(b) No Pharmacist whose license has been denied, Revoked, Suspended, or restricted for disciplinary purposes shall be eligible to be registered as a Pharmacy Technician.[9]

(c) The Board of Pharmacy shall, by rule, establish requirements for registration of Pharmacy Technicians.

Comments

Section 301(c). Comment.

Boards of Pharmacy are often confronted with the problem of preventing unlicensed individuals from engaging in one or more facets of the Practice of Pharmacy. The regulation of the Practice of Pharmacy, including the control of unlicensed practice in the profession, has a reasonable and rational relationship to public health, safety, and welfare. See, for example, *State v Wakeen*, 57 N.W.2d 364 (Wis, 1953). cf. *State v VanKeegan*, 113 A.2d 141 (Conn, 1955) and *Williamson v Lee Optical of Oklahoma*, 348 U.S. 483 (1955), concerning prohibitions on the unlicensed practice of ophthalmology. For this reason, vesting the power in the Board to regulate the illicit practice would not appear to violate the constitutional due process requirements. Monetary fines are another enforcement action Boards can utilize to protect the public health. Although monetary fines are not generally considered criminal sanctions, it can be forcibly argued that there are no constitutional barriers impeding the imposition of fines by a Board of Pharmacy. See, for example, *Helvering v Mitchell*, 303 U.S. 376 (1938); *City of Waukegan v Pollution Control Board*, 311 N.E.2d 146 (Ill, 1974); *County Council for Montgomery County v Investors Funding Corp*, 312 A.2d 225 (Md, 1973); and *Rody v Hollis*, 500 P.2d 97 (Wash, 1972).

One area that could present a serious question of law in regard to Section 301(b), however, involves the constitutional limitation on the delegation of authority to administrative agencies. It is likely that the delegation contemplated in Article III of the *Model Act* would be valid in a majority of jurisdictions. See, for example, *Jordan v Board of Insurance*, 334 S.W. 2d 278 (Tex, 1960); *Sutherland v Ferguson*, 397 P. 2d 335 (Kan, 1964); and *Kovack v Licensing Board of City of Waterville*, 173 A. 2d 554 (Me, 1961); see generally L. Davis, Administrative Law Treatise, Section 2.10 (1970 Suppl.). Be cautioned, however, that certain jurisdictions require very specific standards in a delegation of authority that could render Section 301(b) constitutionally suspect. See, for example, *People v Tibbits*, 305 N.E. 2d 152 (Ill, 1973); *Sarasota County v Barg*, 302 So. 2d 737 (Fla, 1974). In these jurisdictions, revisions of Article III may be necessary.

13. Status of Pharmacy Technicians

State	Designation	Does State: License Technicians?	Register Technicians?	Certify Technicians?	Technician Registration Fee	Registration Renewal Schedule
Alabama	Pharmacy Technician	No	Yes	No	$60	Biennial II
Alaska	Pharmacy Technician	Yes	No	No	$50 HH, UU	Biennial
— Arizona	Pharmacy Technician	Yes	No	No	B	Biennial B
Arkansas	Pharmacy Technician	No	Yes	No	$70 II; $35 YY	Biennial
California	Pharmacy Technician	Yes	Yes	No	$105	Biennial
Colorado	Unlicensed Personnel, Unlicensed Assistant	No	No	No	N/A	N/A
Connecticut	Pharmacy Technician	No	Yes	No	$100	Annual - 3/31
Delaware	Pharmacy Technician	No	No	No	None	N/A
District of Columbia	Ancillary Personnel	No BBB	Yes BBB	Yes BBB	—	—
Florida	Pharmacy Technician	No	Yes	No	$100	Biennial
Georgia	Pharmacy Technician	No	Yes	No	$100	Biennial
Guam	Pharmacy Technician	No	Yes	No	J	J
Hawaii	Pharmacy Technician	No	No	No	N/A	N/A
Idaho	Pharmacy Technician	No	Yes M	Yes M	$35	Annual
Illinois	Pharmacy Technician	No	Yes	Yes PP	$40 initial; $25 renewal	Annual
Indiana	Pharmacy Technician	Yes AAA	No	No †	$25 WW	Biennial
— Iowa	Pharmacy Technician	No	Yes	Yes H	$40, $20 trainee	Z
Kansas	Pharmacy Technician	No	Yes	No	$20	Biennial
Kentucky	Pharmacy Technician	No	Yes	No	$25	Annual
Louisiana	Pharmacy Technician	Yes	No	No	$100	Annual
Maine	Pharmacy Technician	Yes	No	No	$25	Annual
Maryland	Pharmacy Technician	No	Yes	No	$45	Biennial G
Massachusetts	Pharmacy Technician	No	Yes	No	$60	Biennial G
Michigan	Pharmacy Personnel	No	No	No	—	—
Minnesota	Pharmacy Technician	No	Yes	No	$30	Annual
Mississippi	Pharmacy Technician L	No	Yes	No	$50	Annual
Missouri	Pharmacy Technician	No	Yes	No	$35 W	Annual
— Montana	Pharmacy Technician	No	Yes	Yes AA	$60 initial; $50 renewal	Annual
Nebraska	Pharmacy Technician	No	Yes	No	$25	Biennial RR
Nevada	Pharmaceutical Technician L	No	Yes	No	$40	Biennial
— New Hampshire	Pharmacy Technician	No	Yes	Yes AA	$50	Annual
New Jersey	Pharmacy Technician	No	Yes	No	$70	Biennial
New Mexico	Pharmacy Technician N	No	Yes	No	$30	Biennial
New York	Unlicensed Person	No	No	No LL	N/A	N/A
North Carolina	Pharmacy Technician	No	Yes	No	$30	Annual
North Dakota	Registered Pharmacy Technician	No	Yes	No	$35	Annual
Ohio	Qualified Pharmacy Technician	No	No	No	N/A	N/A
Oklahoma	Pharmacy Technician	No	Yes O	No	$40	GG
— Oregon	Pharmacy Technician	Yes A	No	No	$50 VV	1 year - Sep
Pennsylvania	Pharmacy Technician	No	No	No	N/A	N/A
Puerto Rico	Pharmacy Technician	No	Yes	Yes	$50	3 years
Rhode Island	Pharmacy Technician	Yes	No	No	$25	Annual
South Carolina	Pharmacy Technician	No	Yes	Yes	$40 initial; $15 renewal	Annual
South Dakota	Pharmacy Technician	No	Yes	No	$25	Annual X
Tennessee	Pharmacy Technician	No	Yes	No	$75 biennial	Cyclical
Texas	Pharmacy Technician	No	Yes	No	$99 initial; $96 renewal	Biennial
Utah	Pharmacy Technician	Yes	No	No	$60 TT	Biennial
Vermont	Pharmacy Technician	No	Yes	No	$50	Biennial
Virginia	Pharmacy Technician	No	Yes	No	$25	Annual
Washington	Pharmacy Technician	No	No	Yes	$60 initial; $50 renewal	Annual
West Virginia	Pharmacy Technician	No	Yes	No	$25 X	Biennial
Wisconsin	Pharmacy Technician	No	No	No	—	—
Wyoming	Registered Pharmacy Technician K	Yes KK	Yes KK	No	$50	Annual

Colored text denotes change from 2014 edition.

† Other comments noted in 2014 edition no longer apply.

— Indicates information is not available.

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13. Status of Pharmacy Technicians (cont.)

State	Technician Training Requirements	Technician CPE Requirements	Technician Examination Requirement	Can Board Deny, Revoke, Suspend, or Restrict Technician Registration?	Maximum Ratio of Technician(s) to Pharmacist in an: Ambulatory Care Setting	Maximum Ratio of Technician(s) to Pharmacist in an: Institutional Care Setting
Alabama	No	3 hrs/yr MM	—	Yes	3:1*	3:1*
Alaska	Yes S	10 hrs/2 yrs	No	Yes	None	None
Arizona	Yes	NN	Yes FF	Yes	None	None
Arkansas	No	None	No	Yes	2:1	2:1
California	Yes CC	No	No CC	Yes	Varies*	2:1
Colorado	No	N/A	No	N/A	3:1	3:1
Connecticut	Yes S	No	No	Yes	2:1* or 3:1	3:1*
Delaware	Yes	N/A	No	N/A	None	None
District of Columbia	Yes BBB	—	Yes BBB	—	—	—
Florida	Yes Q	20 hrs/2 yrs	No	Yes	3:1*	3:1*
Georgia	No	None	No	N/A	3:1*	3:1*
Guam	No J	None J	No	Yes	None J	None J
Hawaii	No	No	No	No	None	None
Idaho	Yes OO	Yes	Yes	Yes	6:1*	6:1*
Illinois	Yes PP	No	Yes QQ	Yes	None	None
Indiana	Yes	No	No U	Yes	6:1*	6:1*
Iowa	Yes H	No	No	Yes	None	None
Kansas	Yes	No	Yes	Yes	2:1 or 3:1*	2:1 or 3:1*
Kentucky	No	None	No	Yes	None	None
Louisiana	No	10 hrs	Yes	Yes	3:1*	3:1*
Maine	Yes	No	No	Yes	None	None
Maryland	Yes	Yes	Yes	Yes	None	None
Massachusetts	Yes	No BB	Yes	Yes	4:1*	4:1*
Michigan	No	—	—	—	None	None
Minnesota	Yes	Yes	No	Yes	2:1*	2:1*
Mississippi	No I	No	No	Yes	2:1	2:1
Missouri	No	None	No	Yes	None*	None*
Montana	Yes** T	Yes SS	Yes AA	Yes	3:1*	3:1*
Nebraska	Yes** I	No	No	Yes	2:1	2:1
Nevada	Yes	Yes Y	No	Yes	3:1*	3:1
New Hampshire	Yes	Yes P	Yes P	Yes	None	None
New Jersey	No	No	No	Yes	Varies	Varies
New Mexico	Yes**	None	Yes AA	Yes	None	None
New York	No	No	No	No	2:1	2:1
North Carolina	Yes	None	No	Yes	2:1*	2:1*
North Dakota	Yes R	Yes 10 hrs/1 yr	Yes	Yes	3:1	4:1
Ohio	Yes	No	Yes	No	None	None
Oklahoma	Yes	None	Yes	Yes JJ	2:1	2:1
Oregon	Yes	Yes P	Yes P	Yes	None	None
Pennsylvania	Yes ZZ	None	No	N/A	None	None
Puerto Rico	Yes F	20 hrs/3 yrs	Yes	Yes	5:1	5:1
Rhode Island	Yes	Yes BB	Yes V	Yes	None	None
South Carolina	Yes DD	10 hrs/yr EE	Yes DD	Yes	3:1*	Varies*
South Dakota	Yes D †	None	Yes D	Yes	2:1*	2:1*
Tennessee	No	None	No	Yes	2:1*	2:1*
Texas	Yes C	D	Yes	Yes	3:1*	None
Utah	Yes	20 hrs/2 yrs	Yes E	Yes	*	*
Vermont	No	No	No	Yes	None	None
Virginia	Yes V	5 hrs/yr	Yes V	Yes	4:1	4:1
Washington	Yes	Yes XX	Yes AA	Yes	3:1*	3:1*
West Virginia	Yes I, K	None	Yes	Yes	4:1	4:1
Wisconsin	No	—	—	—	4:1	4:1
Wyoming	Yes	6 hrs	Yes AA	Yes	3:1	3:1

* See "Footnotes (*)" on pages 41-42.

** Contact the state board of pharmacy office to obtain requirements.

Colored text denotes change from 2014 edition.

† Other comments noted in 2014 edition no longer apply.

— Indicates information is not available.

13. Status of Pharmacy Technicians (cont.)

LEGEND

A — All new pharmacy technicians have one year after initial licensure to obtain national certification.
B — Technician trainee – $36, Technician – $72. Technician trainee may reapply for licensure not more than one time.
C — A person may be a technician trainee for no more than two years while seeking certification through PTCB. Contact the Board for specific on-site training requirements.
D — Same as PTCB requirements. (TX – One hour must be related to Texas pharmacy laws or rules.)
E — PTCB examination or the ExCPT and Utah law examination.
F — 1,000 hours of internship under direct supervision of a registered pharmacist and passing an examination prepared by the Board are required for certification. Designated pharmacy technician intern for three years maximum.
G — Biennial at birthday. (MD – First renewal 10 CE, all other renewals 20 CE.)
H — Technicians must be under the immediate and personal supervision of the pharmacist. Technician training must be documented and maintained. National certification of all technicians by nationally accredited certifying body required by December 31, 2013.
I — Training requirements developed by training pharmacies and approved by the board. (WV – PTCB or National Healthcareer Association certified pharmacy technician certification. As of July 1, 2014, technician must have graduated from a competency-based pharmacy technician training and education program or completed training requirements stated above.)
J — The Board is proposing/developing regulations.
K — Designated as a "technician-in-training" prior to meeting requirements for licensure.
L — The term "Support Personnel" is also used.
M — May register as "technician-in-training" while working towards certification. This registration is renewable twice.
N — A "Pharmacy Technician" is a subset of "Supportive Personnel."
O — Technicians are not considered "registered," but are issued a "permit."
P — Required for certified pharmacy technicians, but not pharmacy technicians.
Q — Pharmacy technicians may register in Florida if they complete a Board-approved training program.
R — Technicians must complete ASHP-accredited program.
S — On-the-job training by PIC appropriate to technician's duties.
T — Technician utilization plan filed with Board or didactic course.
U — Passage of the PTCB examination is one way to become certified as a technician in this state. Must also file application for licensure.
V — To be eligible for registration a pharmacy technician must either hold current PTCB certification or must have passed a training program and examination approved by the Board.
W — Plus a fingerprint fee paid to a contracted agency.
X — $25 initial; $30 renewal/2 years.
Y — However, technicians must complete six hours of in-service training per year and one hour of jurisprudence as do pharmacists (NV – See page 33).
Z — Biennial by birth month; trainee registration 1 year, not reusable.
AA — PTCB or ExCPT certification required. (WA – Exams administered by program accredited by NCCA.)
BB — However, "certified pharmacy technicians" must maintain certification.
CC — Educational training and/or PTCB examination are ways to qualify for technician registration.
DD — To be certified as a pharmacy technician an individual must have worked for 1,000 hours under the supervision of a licensed pharmacist as a technician and must have completed a Board of Pharmacy-approved technician course as provided for in subsection (D); a high school diploma or equivalent; and passed the National Pharmacy Technician Certification Examination or a Board of Pharmacy-approved examination and has maintained current certification; and fulfilled CE requirements as provided for in Section 40-43-130(G).
EE — As a condition of registration renewal, a registered pharmacy technician shall complete 10 hours of ACPE- or CME I-approved CE each year. A minimum of four hours of the total hours must be obtained through attendance at lectures, seminars, or workshops.
FF — Requires PTCB examination.
GG — Annual (by birth month).
HH — Plus one-time application fee of $50.
II — Odd numbered years.
JJ — Revoked 41 pharmacy technician permits, 1 probation, 0 suspensions, and 1 fine.
KK — "Technicians-in-Training" are registered until they meet the requirements for licensure. The technician-in-training permit is valid for no more than two years from date of issue.
LL — Legislation has been introduced first to register, then to certify technicians.
MM — One hour must be live CE. No carryover hours.
NN — Twenty hours, of which two hours must be pharmacy law ACPE or Board-approved providers.

Legend continued on page 41

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13. Status of Pharmacy Technicians (cont.)

LEGEND — cont.

OO — Must be 18 years of age unless waived; a high school graduate unless waived or equivalent; of good moral character; and employed.
PP — Refer to 225 ILCS 85/9.5 and 85/17.1 and 68 Illinois Administrative Code Sections 1330.210 and 1330.220.
QQ — Beginning on January 1, 2010, within two years after initial registration as a registered technician, must become certified by successfully passing the PTCB or other Board-approved examination and registering as a certified pharmacy technician with the department. Does not apply to pharmacy technicians registered prior to January 1, 2008. Refer to 225 ILCS 85/9.
RR — Biennial, January 1 of odd years.
SS — Must be PTCB-approved or ICPT-approved.
TT — Additional $40 for criminal background check.
UU — Application fees are reevaluated June of even-numbered years.
VV — Plus $52 fingerprinting fee.
WW — Indiana State Police collect an additional fee for a background check.
XX — Beginning in 2013-2014 renewal cycle. 10 hours of CE credit with one hour in law/ethics.
YY — Even numbered years.
ZZ — On-the-job training in permitted activities.
AAA — As of July 1, 2014, switched from certification. Must still hold technician-in-training permit or be PTCB or ExCPT certified prior to licensure.
BBB — D.C. Law 19-0303 "Pharmacy Technician Amendment Act of 2012."

Footnotes*

AL — 3:1 if one technician is PTCB-certified. All technicians must be at least 17.
CA — In community pharmacy, the ratio is 1:1 for the first pharmacist on duty, then 2:1 for each additional pharmacist on duty. 2:1 if pharmacy services patients of skilled nursing facilities or hospices. A pharmacist may also supervise one pharmacy technician trainee gaining required practical experience.
CT — Refer to Section 20-576-36 of the Regulations of Connecticut State Agencies. In summary, ratio not to exceed 2:1 when both technicians are registered. Ratio of 3:1 permitted when there are two registered technicians and one certified technician. However, a pharmacist is permitted to refuse the 3:1 ratio for the 2:1 ratio. In an institutional outpatient pharmacy, ratio is 2:1. The pharmacist manager may petition the Commission to increase ratio to 3:1 in a licensed or institutional outpatient pharmacy. Inpatient pharmacy ratio is 3:1 generally, but pharmacy can petition for ratio of up to 5:1; satellite pharmacy 3:1, but can petition for up to 5:1.
FL — A licensed pharmacist may not supervise more than one registered pharmacy technician unless otherwise permitted by the guidelines adopted by the Board. The Board shall establish guidelines to be followed by licensees or permittees in determining the circumstances under which a licensed pharmacist may supervise more than one but not more than three pharmacy technicians. Florida Legislature has directed the Board to come up with new guidelines. New guidelines are unavailable at this time.
GA — One of the three pharmacy technicians must be certified. Board may consider and approve an application to increase the ratio in a hospital pharmacy.
ID — Ratio includes technicians, technicians-in-training, and student pharmacists. No longer allowed cashiers/clerks in pharmacy.
IN — Technicians must be under the immediate and personal supervision of the pharmacist.
KS — The ratio may be 3:1 if at least two of the pharmacy technicians have a current certification issued by PTCB or a current certification issued by any other pharmacy technician certification organization approved by the Board.
LA — If pharmacy technician candidate is present, then maximum ratio for technicians is 2:1. If not, then maximum ratio for technicians is 3:1.

Footnotes continued on page 42

NABP*LAW* Online Search Terms

Status of Pharmacy Technicians *(type as indicated below)*

- technician certification
- technician fee
- technician license
- technician registration
- technician renewal
- technician requirements
- technician training

Note: "ancillary personnel"; "non-licensed personnel"; and "support personnel" can be substituted for "technician."

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13. Status of Pharmacy Technicians (cont.)

Footnotes (*) – cont.

MN — Specific functions are exempted from the 2:1 ratio as follows: for intravenous admixture preparation, unit-dose dispensing, prepackaging, and bulk compounding, ratio is 3:1. One additional technician per pharmacy if that technician is certified.

MO — Technician must be under the direct supervision and responsibility of a pharmacist.

MT — Ratio is 3:1. Licensee may ask Board for variance based on established criteria or greater upon Board approval.

NC — Ratio may be increased above 2:1 if additional technicians are certified and the Board approves the increase in advance.

NV — Technician to pharmacist ratio is now 3:1; however, initial prescription data input can now only be done by a registered pharmaceutical technician or a pharmacist. A clerk may enter demographic and insurance data only on new prescriptions.

SC — The PIC shall develop and implement written policies and procedures to specify the duties to be performed by pharmacy technicians. The duties and responsibilities of these personnel shall be consistent with their training and experience. These policies and procedures shall, at a minimum, specify that pharmacy technicians are to be personally supervised by a licensed pharmacist who has the ability to control and who is responsible for the activities of pharmacy technicians and that pharmacy technicians are not assigned duties that may be performed only by a licensed pharmacist. One pharmacist may not supervise more than three pharmacy technicians at a time; at least two of these three technicians must be state certified. If a pharmacist supervises only one or two pharmacy technicians, these technicians are not required to be state certified. Pharmacy technicians do not include personnel in the prescription area performing only clerical functions, including data entry up to the point of dispensing, as defined in Section 40-43-30(14).

SD — Exception to the ratio may be allowed if the specific requirements listed in administrative rule are met. See ARSD 20:51:29:19.01 and 20:51:29:19.02.

TN — Up to 4:1 if two technicians are certified.

TX — 4:1 if at least one of the technicians is not a pharmacy technician trainee.

UT — Pharmacist determined for licensed pharmacy technicians, only one technician-in-training per supervising pharmacist.

WA — A pharmacy may use more technicians than the standard 3:1 ratio if its service plan is approved by the Commission.

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Annual Progress Report

PTCB Celebrates Twentieth Anniversary

by PTCB Staff | Feb 02, 2015

WASHINGTON, DC – Saturday, January 31 marked the twentieth anniversary of the founding of the Pharmacy Technician Certification Board (PTCB). PTCB's nationally accredited Pharmacy Technician Certification and Recertification Program enables technicians to work effectively with pharmacists across all pharmacy practice settings to advance patient care and safety. As the most widely accepted national certification program for pharmacy technicians, PTCB has granted more than 550,000 certifications since its founding in 1995. In 2014 alone, 30,358 candidates earned PTCB Certification.

PTCB acknowledges and commends its founding organizations for their vision and ongoing commitment to a single national standard for certifying pharmacy technicians. PTCB was established 20 years ago by the American Pharmacists Association (APhA), American Society of Health-System Pharmacists (ASHP), Illinois Council of Health-System Pharmacists, and Michigan Pharmacists Association. In 2001, PTCB expanded its Board of Governors to include the National Association of Boards of Pharmacy (NABP).

"PTCB's 20-year anniversary represents a time to celebrate the invaluable contributions of Certified Pharmacy Technicians (CPhTs) to the pharmacy team," said PTCB Executive Director & CEO Everett B. McAllister, RPh, MPA. "PTCB applauds the nation's dedicated CPhTs, often the innovators in the pharmacy who efficiently run operations and optimize pharmacy systems, and thereby advance patient care and safety."

"A high-quality Certified Pharmacy Technician workforce is essential to optimizing patient medication safety," said Paul W. Abramowitz, PharmD, ScD (Hon), FASHP, Chair of the PTCB Board of Governors. "PTCB's twentieth anniversary is a great opportunity to raise Americans' awareness of the role of and career opportunities for the nation's many Certified Pharmacy Technicians. In honor of this milestone, PTCB renews our commitment to ensuring PTCB Certification reflects the knowledge required of CPhTs to effectively support today's pharmacists."

CPhTs play integral roles supporting pharmacists in all practice settings and carry out a variety of tasks that include entering prescription orders, operating automated dispensing systems, preparing IV admixtures, maintaining inventories, and processing insurance claims. As pharmacists become responsible for more direct patient care in such venues as pharmacy-based immunization programs and retail pharmacy clinics, CPhTs are assuming new and expanded roles in medication safety, immunization assistance, supply chain management, financial assistance, medication therapy management, transitioning patient care, inventory control, and other areas.

PTCB's achievements during the past 20 years include accreditation by the National Commission for Certifying Agencies in 2006, and transitions to computer-based testing in 2007 and year-round testing in 2009. PTCB established the Pharmacy Technician Employer and Educator Programs in 2012. In 2013, PTCB announced a series of Certification Program changes to advance CPhT qualifications by elevating PTCB's requirements. PTCB also launched a new streamlined online application process and updated its Pharmacy Technician Certification Examination that year.

Looking ahead, PTCB will continue to advocate one national standard for certification of pharmacy technicians. Establishing a national standard through PTCB is consistent with the approach used by other health professions, including the pharmacist licensure process.

By 2020, PTCB will implement further changes to strengthen its requirements, including requiring each new candidate for certification to complete an ASHP/Accreditation Council for Pharmacy Education-accredited education program. PTCB aims to provide a roadmap for CPhTs wishing to grow in their careers. To that end, PTCB is in the early stages of developing an advanced certification program to empower qualified CPhTs to assume new areas of responsibility.

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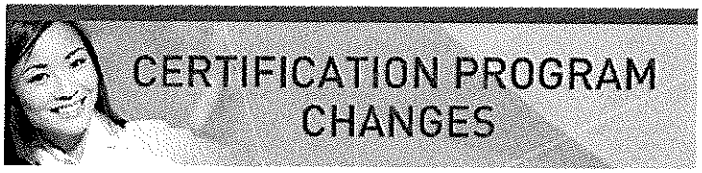

PTCB is implementing changes in the PTCB Certification Program. The new changes will advance pharmacy technician qualifications by elevating PTCB's standards for national certification and recertification. PTCB is phasing in the changes during a seven-year period through 2020. The changes include accredited education requirements and changes in acceptable continuing education (CE) programs for recertification.

Program Changes

Certification

By 2020, PTCB will require each new candidate for certification to complete an ASHP/ACPE-accredited pharmacy technician education program.

Recertification

To qualify for PTCB recertification, each Certified Pharmacy Technician (CPhT) must complete:

- One hour of patient safety CE beginning in 2014
- Twenty hours of *pharmacy technician-specific* CE beginning in 2015

The number of CE hours accepted will be modified for those earned:

- Via college/university coursework—from 15 to 10 hours beginning in 2016
- Through in-services —from 10 to 5 hours starting in 2015, and from 5 to 0 in 2018

For further information regarding the history and implementation plans for these changes, please refer to this Background Document.

Comment Period

On May 31, 2013, PTCB completed a 90-day open online comment period which allowed members of the pharmacy community to share best practices for implementing the new requirements. Procedures, guidelines, and other details will be published closer to the planned implementation dates.

Open Forums

PTCB is working closely with educators, employers, boards of pharmacy, and state/national organizations to best implement these decisions. During early 2013, PTCB asked for live feedback from pharmacy technicians and stakeholders at the following open forums across the country:

American Pharmacists Association (APhA) Annual Meeting and Exposition 2013
Session: Sunday, March 3 from 2:00-3:00 pm in room 153B, in Los Angeles, CA

California Pharmacists Association (CPhA) West Coast Pharmacy Exchange
Session: Sunday, March 17 from 5:00-6:00 pm, in Monterey, CA

South Carolina Society of Health-System Pharmacists (SCSHP) 2013 Annual Meeting
Sessions: Sunday, March 24 & Monday, March 25 from 3:30-4:30 pm, in Charleston, SC

Pharmacy Society of Wisconsin (PSW) Educational Conference
Session: Thursday, April 18 from 1:00-2:00 pm, in Madison, WI

North Dakota Pharmacists Association (NDPhA) Annual Convention
Session: Friday, April 26, in Dickinson, ND

Texas Society of Health-System Pharmacists (TSHP) 2013 Annual Meeting
Session: Saturday, April 27 in Austin, TX

C.R.E.S.T. Initiative

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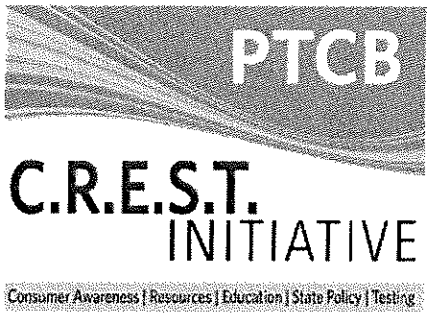

PTCB launched the C.R.E.S.T. Initiative in 2011 by hosting a summit focused on the areas of Consumer Awareness, Resources, Education, State Policy, and Testing relating to pharmacy technicians. Attendees included pharmacists, Certified Pharmacy Technicians (CPhTs), educators, major employers, State Boards of Pharmacy, as well as representatives from state and national pharmacy organizations.

During the summit, participants expressed the need for the profession to move beyond philosophical discussion and make decisions on the future of pharmacy practice and the role of pharmacy technicians.

Recommendations from the summit include eligibility requirements for the PTCB Certification Program, requirements for recertification, and the creation of new specialty certification programs.

In March 2012, the C.R.E.S.T. Initiative Steering Committee, composed of 10 leaders in pharmacy, developed and launched a profession-wide survey on the above recommendations. The survey was completed by more than 17,000 pharmacy technicians and pharmacists nationwide. Results from the survey will provide the PTCB Board of Governors and Certification Council with important input from the profession on advancing the work of pharmacy technicians and the future of the PTCB Certification Program.

C.R.E.S.T. Initiative News

PTCB 2011 C.R.E.S.T. Summit Proceedings
PTCB, June 2011

PTCB Considers Changes to Certification, Recertification
AJHP News, July 2011

Health Reform: Opening New Vistas for Pharmacists, Pharmacy Technicians
PharmacyTech News, June 2011

PTCB Hosts C.R.E.S.T. Summit
Journal of Pharmacy Technology, May/June 2011

C.R.E.S.T. Summit: Focus on Continued Innovation
Journal of the American Pharmacists Association, May 2011

C.R.E.S.T. Summit Supports Continued Innovation in Pharmacy: Consensus is Clear, Now is the Time for Change
PTCB News Release, March 2011

PTCB C.R.E.S.T. Summit Emphasized Pharmacy's Role in Health Care
DrugStore News, March 2011

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Pharmacy Technician Certification Board

Certification Program Changes

The Pharmacy Technician Certification Board (PTCB) is implementing changes to the PTCB Certification Program beginning in 2014 and continuing through 2020. These new changes advance pharmacy technician qualifications by elevating PTCB's standards for certification and recertification.

PTCB requirements have remained largely unchanged since the organization's founding in 1995. The Board of Governors decisions to implement program changes were initiated by a 2011 summit focused on five areas related to pharmacy technicians: *Consumer Awareness, Resources, Education, State Policy and Testing* (C.R.E.S.T.). Summit findings, combined with results from two profession-wide surveys, called for PTCB and the pharmacy profession to make decisive changes in certification standards.

PTCB engaged stakeholders and the pharmacy community by collecting feedback on the new requirements through May 2013.

Program Changes

Certification

To qualify for PTCB certification, each new candidate must complete a(n):

- Criminal background check by a future date to be announced*
- ASHP-accredited pharmacy technician education program by 2020

Recertification

To qualify for PTCB recertification, each Certified Pharmacy Technician (CPhT) must complete:

- One hour of medication safety continuing education (CE) by 2014
- Twenty hours of *pharmacy technician-specific* CE by 2015

The number of CE hours accepted will be modified for those earned:

- Via college/university coursework—from 15 to 10 hours by 2016
- Through in-services —from 10 to 5 hours in 2015, and from 5 to 0 in 2018

PTCB Certification Program

Criminal Background Checks*

Criminal background checks will be required for new candidates applying for PTCB certification by a future date to be announced.*

Description and Proposed Plan:

In a March 2012 survey, 88% of 17,400 respondents recommended that PTCB require background checks for technicians applying for the PTCB Certification Program. Many employers already require background checks as a condition of employment.

- Work with state boards of pharmacy and ASHP-accredited pharmacy technician education programs to determine how to synchronize existing systems and most efficiently implement background checks for new PTCB candidates.
- Collaborate with the National Association of Boards of Pharmacy (NABP) to integrate and standardize systems.
- Conduct research regarding the processing and cost implications of background checks.

UPDATE: As of December 2014, PTCB has decided not to broaden our role by requiring criminal background checks for initial applicants.

ASHP-Accredited Pharmacy Technician Education Program

Successful completion of an American Society of Health-System Pharmacists (ASHP) accredited pharmacy technician education program will become a requirement for initial PTCB certification.

Description and Proposed Plan:

Leaders in the profession have demonstrated a desire for pharmacy technicians to follow the same credentialing model as pharmacists by becoming certified and registered with the state. Pharmacists are required to graduate from an accredited pharmacy school before they sit for the NAPLEX board exam and become licensed by their state board of pharmacy.

The number of ASHP-accredited pharmacy technician education programs is growing in both community and hospital settings. ASHP-accredited programs include practical experience in addition to didactic course work, thereby providing well-rounded training for technicians. Many large employers have also begun developing their own training programs and seeking ASHP accreditation. In the March 2012 survey, 78% of respondents agreed that 2020 is a reasonable year by which to implement accredited education.

- National pharmacy technician associations will be consulted to successfully complete this transition.
- This requirement will affect new individuals applying for national certification following the implementation date. It will not affect already certified pharmacy technicians applying for PTCB recertification or reinstatement.

PTCB Recertification Program

Medication Safety CE (Equivalent to Patient Safety CE)
As part of the 20 hours of CE currently required for PTCB recertification, CPhTs will need to complete one CE hour of medication safety (equivalent to patient safety, as defined by ACPE as topic 05) by 2014, in addition to the one hour of law CE currently required.

Description and Proposed Plan:
Pharmacy technicians assist pharmacists with duties that impact patient care and safety. It is important that technicians continue to be educated on how their routine responsibilities shape the medication distribution system. By learning to identify potential errors in the system and how to report these, pharmacy technicians can affect the medication safety culture within pharmacies. 89% of respondents to the March 2012 survey supported this decision.

- Encourage pharmacy associations and other national CE providers to create patient safety CE programs specifically for pharmacy technicians.
- Highlight new patient safety CE programs on ptcb.org.

Pharmacy Technician-Specific CE
PTCB will require all CE hours to be *pharmacy technician-specific* by 2015.

Description and Proposed Plan:
It is important for pharmacy technicians to be educated through programs designed specifically to address their responsibilities and knowledge requirements in the workplace. Many CE providers currently offer pharmacy-technician specific CE, with others looking to expand their offerings.

In order to qualify for this designation, CE programs must have pharmacy technician-specific objectives written for the course. An acceptable CE program may have two sets of objectives written for it, one for pharmacists and one for pharmacy technicians.

Pharmacy technician-specific objectives will be based upon the Accreditation Council for Pharmacy Education (ACPE) CE designations; however, PTCB will not require programs to be offered only by ACPE-accredited providers.

- Work with CE providers to encourage the creation of pharmacy technician- specific objectives for all CE programs.
- Continue to feature CE programs for pharmacy technicians on ptcb.org.

Acceptable CE: College Courses
PTCB will reduce the number of CE hours that can be earned via college/university coursework from 15 to 10 by 2016.

Description and Proposed Plan:
Due to the importance of pharmacy technicians completing technician-focused CE, leaders from the pharmacy profession encouraged greater emphasis on attaining technician-specific knowledge, with less allowance for broad academic courses.

PTCB will educate technicians eligible for recertification and reinstatement prior to their certification expiration dates.

Acceptable CE: In-Service Courses

PTCB will reduce the allowable number of CE hours to be earned through in-services from 10 to 5 in 2015, and from 5 to 0 in 2018.

Description and Proposed Plan:
It is important that pharmacy technicians be educated through quality, standardized CE programs. In-service CEs will be phased out to eliminate inconsistencies.

- Work with employers through the target implementation date to standardize the information being provided through in-services.
- Educate technicians eligible for recertification and reinstatement prior to their certification expiration dates.

Online Comment Period

PTCB conducted an open comment period through May 2013, inviting members of the pharmacy community to share feedback and insight on implementing the new requirements. Visit ptcb.org for more information and access to the feedback form.

Open Forums

PTCB plans to work closely with educators, employers, boards of pharmacy, and state/national organizations to best implement these decisions. During 2013, PTCB asked for live feedback from pharmacy technicians and stakeholders at the following open forums across the country:

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About National Healthcareer Association (NHA)

Ex CPT

A story about caring and caregiving.

Like so many other companies, NHA was born out of a perceived need and a personal experience. In 1989, our founder watched as a loved one needlessly suffered in the hospital from substandard care. He was not only angry, but felt helpless having to depend on unskilled individuals to administer care.

His experience motivated him to research the education and training requirements for frontline allied health practitioners. To his disbelief, he found there were virtually no universal training or certification standards in place. In that moment, NHA's vision took root and we became a strong advocate for quality patient care delivered by certified allied health professionals.

In the last 25 years, we've certified more than 450,000 allied health professionals. Today, there's more demand than ever for highly skilled frontline practitioners. NHA is meeting that demand by offering The National Commission for Certifying Agencies (NCCA) nationally accredited certifications. It is our belief that together, NHA, schools and educators, providers and allied health practitioners can transform healthcare through education, training and certification, while consistently improving patient outcomes.

Thank you for partnering with NHA to deliver on our promise of improving the standard of patient care in the United States.

FEATURED CERTIFICATIONS

- **EKG Technician** CET
- **Pharmacy Technician** CPhT
- **Patient Care Technician** CPCT
- **Phlebotomy Technician** CPT

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NHA Certification Board

NHA has two certification boards: the NHA Certification Board and the ExCPT Certification Board.

These two entities operate independently to set policy over essential certification activities. They have the responsibility for oversight over all certification and recertification decisions, including governance, eligibility standards, and the development, administration and scoring of assessment instruments. Specifically, the certification boards are responsible for the following:

- Adopting certification program policies and procedures
- Adopting its own rules of procedure
- Approving the certification exam content outline (also known as blueprint)
- Approving appointments to the Exam Review committee and acting on its recommendations
- Appointing a Disciplinary and Appeals Committee
- Electing successors to the Board
- Appointing ad hoc committees as necessary

The certification boards represent leaders and important stakeholders in this field and have developed a Code of Ethics found here.

NHA is currently seeking new board members. Click here to learn more.

The NHA Certification Board:

- **Merrilyn Marie Barto (2015 – Chair)**
  Adjunct Faculty, Instructor of Allied Health classes
  Sinclair Community College, Dayton, Ohio
  Vocational Education Instructor - Healthcare
  ISUS Institutes, Dayton, Ohio

- **Kristi Bertrand (2013)**
  Co-Owner/Director of Education
  Medical Career & Technical College, Richmond, KY
  Paramedical Examiner, Louisville, KY

- **Joann M. Cuozzo, BS, CEHRS, CBCS, CMAA (2014)**
  Program Manager, Billing/Coding/Medical Office Programs
  Network Learning Institute, Mount Laurel, NJ

- **Terri M. Hock (2014)**
  Director of Medical Programs
  Externship Coordinator
  Allied Medical School, Laguna Hills, California

- **Shelly LaPrince, MBA, PhD (2013 – Public Member)**
  Auditor, Connolly Healthcare, Conshohocken, PA
  Adjunct Faculty – College of Nursing and Health Professions
  Drexel University, Philadelphia, PA

- **Michael A. Reynolds, CPC, CCP-P, CPMB, CBCS, OS (2014)**
  Instructor, Medical Billing and Coding and Electronic Health Records
  San Diego State University, San Diego, CA
  Co-owner, Pitt & Reynolds Coding and Consulting, San Diego, CA
  Project Manager, Sharp Healthcare's Corporate Compliance Department, San Diego, CA

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- **Marcia S. Strickland, CPC (2013)**
  Medicare Billing Compliance Auditor
  Connolly Healthcare, Philadelphia, PA

ExCPT Certification Governing Committee (CGC):

- **Timothy R. Koch, R.Ph, PD, CHC (2015 – Chair)**
  Senior Director, Corporate Compliance, Pharmacy Practice Compliance
  Walmart Health & Wellness, Bentonville, AR

- **Louis J. Chiodini, Jr., COL, PE (2015 – Public Member)**
  Retired Colonel and Professional Engineer
  St. Louis, MO

- **Judy Neville, BS, CPhT (2013 - Technician)**
  Vatterott College Pharmacy Instructor and Program Director
  Vatterott College Externship Coordinator, Omaha, NE

- **Kellina James, BS, CPhT (2015 – Technician)**
  Pharmacy Technician and Pharmacy Extern
  ShopKo Pharmacies, Boise, ID

- **Justin D. Lusk, Major-USAF, Pharm D (2014 – Pharmacist)**
  Deputy Director, Air Force pharmacy training at the Medical Education and Training Campus
  Air Force Biomedical Officer Orientation Management Course Coordinator
  Fort Sam Houston, San Antonio, TX

- **Carla Gillispie May, RPH (2015- Pharmacist)**
  Program Director, Pharmacy Technology
  Vance Granville Community College, Henderson, NC
  MTM Pharmacist, NC Check Meds Program
  Health education Evaluator, American College Evaluators
  Reviewer/Editor, F.A. Davis, Publisher & E.M.C. Paradigm, Publisher

- **Bobbi Steelman (2013 – Technician)**
  Instructor, Online Allied Health and General Education
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  Pharmacy Technician Program Manager
  Daymar Colleges Group, Bowling Green, KY
  Pharmacy Technician Department Head
  Draughons Junior College, Bowling Green, KY

- **Traci Tonhofer (2013 – Technician)**
  Program Manager and Pharmacy Technician Instructor
  Davis Applied Technology College, Kaysville, UT

- **Timaka Wilson (2014 – Technician)**
  Sr. Instructor, Everest Institute, Detroit, MI
  Pharmacy Technician Instructor, Everest Institute, Detroit MI
  Certified Pharmacy Technician, Henry Ford Medical Center, Detroit, MI

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REGULATORY ACTIONS:

- LEGISLATIVE UPDATE:

Ms. Yeatts reported that this was a busy General Assembly session. She reviewed the handout in the agenda packet and indicated that several bills submitted by DHP were passed. Ms. Yeatts also stated that the majority of the agency's bills are pharmacy-related and many will require action by the Regulation Committee. Unless otherwise authorized, bills passed will become effective July 1, 2015. Ms. Yeatts and Ms. Juran confirmed for Ms. Warriner, therefore, that the requirement to perform a perpetual inventory of hydrocodone-containing products takes effect July 1, 2015 when the State law placing hydrocodone-containing products into Schedule II becomes effective.

- REGULATION UPDATE:

Ms. Yeatts reviewed the chart of regulatory actions found in the agenda packet.

- AMENDMENT OF 18VAC 110-20-727; PHARMACISTS REPACKAGING FOR CLIENTS OF A CSB OR BHA:

Ms. Yeatts stated that staff recently identified an error in 18VAC 110-20-727 as there is no section G, H or J in 18VAC 110-20-725. She requested that the Board amend 18VAC 110-20-727 regarding pharmacists repackaging for clients of a CSB or BHA.

MOTION:

The Board voted unanimously to amend 18VAC 110-20-727 as presented regarding pharmacists repackaging for clients of a CSB or BHA. (motion by Munden, second by Allen)

NEW BUSINESS:

DISCUSS CONSTITUENT CONCERN RAISED WITH SENATOR WARNER'S OFFICE REGARDING PHARMACY BENEFIT MANAGER OVERSIGHT:

Ms. Juran provided an overview of the letter sent from Senator Mark Warner to Ms. Shinaberry requesting an appropriate response to concerns with PBMs that were expressed by John Frye, Pharmacist, Rocky Mount Family Pharmacy. In the letter, Mr. Frye states the PBM discriminates against independent pharmacies by requiring a different credentialing process than that which required for larger chain pharmacies. During the discussion, members acknowledged that not all PBM activities are within the Board's legal scope of authority. There was some focus of discussion on patient safety, security of the prescription department, and patient access to drugs. It was suggested that the NABP PBM Task Force Report be utilized as a resource. Ms. Shinaberry stated that the request for the Regulatory Committee to review this matter should be more general in nature and not limited to specific subjects.

MOTION:

The Board voted unanimously to refer the concerns of pharmacy benefit manager oversight to the Regulation Committee in May for a more thorough review. (motion by Munden, second by M. Elliott)

MARK R. WARNER
VIRGINIA

FEB 2 0 2015
DHP

COMMITTEES:
BANKING, HOUSING, AND URBAN AFFAIRS
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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Fax: (540) 857-2600

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Fax: (703) 442-0408

http://warner.senate.gov

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Mr. John W. Frye (8435778)

Contact Information

Rocky Mount Family Pharmacy 1165 Franklin Street Rocky Mount, VA 24151-1248
5404895400
familypharamcy4@embarqmail.com
familypharmacy4@embargmail.com

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

COPY

COMMONWEALTH of VIRGINIA

David E. Brown, D.C.
Director

Department of Health Professions
Perimeter Center
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Board of Pharmacy
tel (804) 367-4456
fax (804) 527-4472

February 24, 2015

Senator Mark R. Warner
United States Senate
919 East Main Street
Ste 630
Richmond, VA 23219

Dear Senator Warner:

The Virginia Board of Pharmacy is in receipt of the enclosed letter from you dated February 19, 2015 regarding a complaint against Caremark Corporation filed by John Frye. I am responding on behalf of Ellen Shinaberry, Chairman of the Board.

As I explained to Mr. Frye and a representative of the Bureau of Insurance (BOI) at the State Corporation Commission, Caremark operates both pharmacies and a pharmacy benefit manager. While the Board of Pharmacy has authority to issue pharmacy permits, it does not have the authority to specifically license pharmacy benefit managers. The concerns expressed by Mr. Frye do not appear to result from actions taken by Caremark pharmacies, but more from the pharmacy benefit manager (PBM) operated by Caremark. Therefore, the Board of Pharmacy does not have the authority to directly address the concerns expressed by Mr. Frye.

Because both the BOI and I were concerned with the complaints expressed by Mr. Frye, a representative of the BOI and I spoke directly with one another on this issue last week. I was informed that the BOI also does not have the authority to address Mr. Frye's concerns. Thus, it appears there is a possible lack of oversight in state law in regulating pharmacy benefit managers.

Please be aware that the Board of Pharmacy intends to discuss this issue at its next full board meeting on March 24th. Feel free to contact me should you have any questions.

Respectfully,

Caroline D. Juran
Executive Director
Virginia Board of Pharmacy

Cc: Ellen Shinaberry, Chairman
Kenneth J. Schrad, State Corporation Commission
Delegate Chris Jones
Delegate Keith Hodges

Enclosure

MACAULAY
& BURTCH, P.C.
ATTORNEYS AT LAW

Hunter W. Jamerson
Direct: 804.649.0985
Hunter@macbur.com
Fax: 804.649.3854

March 23, 2015

Ellen B. Shinaberry, Pharm. D.
Chair, Virginia Board of Pharmacy
Perimeter Center
9960 Mayland Drive, Suite 300
Henrico, VA 23233-1463

Re: Board of Pharmacy Consideration of Pharmacy Benefit Managers

Dear Ms. Shinaberry:

I am writing on behalf of EPIC Pharmacies ("EPIC"), a network of more than 300 community pharmacies in Virginia. Every day, EPIC members experience the situations described by Mr. Frye in his letter to Senator Warner. EPIC appreciates the opportunity to provide the Board with both written and verbal public comment on this important topic.

Presently, the Commonwealth regulates pharmacy benefit managers ("PBMs") in two limited ways. First, the Board licenses PBM mail order pharmacies and their pharmacists and technicians. Second, the State Corporation Commission's Bureau of Insurance, in connection with its licensure of commercial (but not self-insured) health plans, ensures that contracts between plans, PBMs, and pharmacies contain certain provisions. Aside from these instances, it is fair to say that PBMs are unregulated in Virginia.

The lack of regulation of PBMs manifests itself in several ways. Mr. Frye has identified one of the most challenging manifestations for community pharmacies. The credentialing requests are invasive, oppressive, and cumulative. Even if a pharmacy successfully navigates credentialing, it is then confronted with a one-sided, money losing network participation agreement. Consequently, fewer and fewer community pharmacies are able to participate in PBM networks. It is undeniable that patients suffer when community pharmacies are not available to service their needs face-to-face and on a regular basis.

We see similar pressures on community pharmacies from another widespread PBM practice. There has been a dramatic increase in the number of drugs classified as specialty tier. In many cases, these drugs do not require any special handling; they are simply expensive or subject to utilization controls. For example, simple inhalers are now in the specialty tier. PBMs then limit the dispensing of specialty tier drugs to mail-order specialty networks. Not surprisingly, these networks are frequently owned by the PBMs. The effect of these limited networks is that, again, patient access to pharmacy services is curtailed. When access is curtailed, patient safety suffers.

The above situations present good reasons for the Board to consider whether its regulatory authority should be expanded to include PBMs themselves, not just their mail order pharmacies

and staff. It is also important for the Board to consider expanded use of the tools it already has. For example: a prescription may only be dispensed when a bona fide pharmacist-physician-patient relationship exists. The Board frequency cites this requirement in disciplinary proceedings against community pharmacists, but we very rarely see it made in the case of mail-order pharmacies and pharmacists. Based on feedback from patients who have returned to community pharmacies from mail-order, this requirement is frequently ignored by mail order pharmacies. Few, if any, of our patients report an interaction with the pharmacist dispensing their mail-order prescription.

Thank you for your consideration of this agenda item and EPIC's comments this morning.

Sincerely,

Hunter W. Jamerson

HDJN

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T 804.967.9604 ▪ F 804.967.9888
www.hdjn.com

W. Scott Johnson
Ext. 416
sjohnson@hdjn.com

March 23, 2015

Hand Delivered

Ellen B. Shinaberry, PHARM.D.
Chair, Virginia Board of Pharmacy
9960 Mayland Drive, Suite 300
Henrico, VA 23233-1463

RE: **Pharmacy Benefit Managers**

Dear Ms. Shinaberry:

I trust this letter finds you doing well. I am writing as General Counsel for the Medical Society of Virginia. The Medical Society is pleased to offer comment to the Board regarding the pharmacy benefit letter submitted by Senator Mark Warner and on the agenda for the Board meeting on March 24, 2015.

The letter from Senator Warner to the Board addresses questions surrounding the credentialing process used by pharmacy benefit managers ("PBMs"). The Medical Society is aware that while the Board currently has jurisdiction to regulate pharmacists and pharmacies, current statutes do not exist to grant the Board regulatory oversight of PBMs. Likewise, it is our understanding that the Bureau of Insurance at the State Corporation Commission lacks statutory authority to license or regulate PBMs.

The Medical Society often receives feedback from its members across the state regarding PBMs and insurance carriers as it pertains to a number of issues, including prior authorization of medications. As you are aware, the Medical Society formed a taskforce which has worked over the last year on this issue and the results of that labor included the passage of House Bill 1942, patroned by Delegate Habeeb and Senate Bill 1262 patroned by Senator Newman. The Medical Society is very pleased with the protections included in this legislation to ensure patients receive access to their medications and that physicians are not unduly burdened with unnecessary red tape. However, we should note that in the legislation the Bureau of Insurance was clearly excluded from adjudicating any patient disputes or disagreements regarding denial of access to medications by carriers or the PBMs that the carriers contract with.

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Accordingly, the Board may wish to ask the Regulatory Committee of the Board to review the patient safety and access to medication issues surrounding PBMs. If it is determined that registration or licensure of PBMs is recommended, that recommendation should be made to the General Assembly.

We have also obtained a report prepared by the National Association of Boards of Pharmacies which looked at the issue of regulation of PBMs and have included the six-page report as an attachment to this letter for your review.

Thank you in advance for your cooperation. The Medical Society stands ready, willing, and able to assist the Board in its work.

Very truly yours,

W. Scott Johnson

WSJ/jpr
Enclosure
DM #703294

cc: Ms. Caroline Juran, Executive Director, Board of Pharmacy
Ms. Melina Davis-Martin, Medical Society of Virginia
Mr. Mike Jurgensen, Medical Society of Virginia
Mr. Matt Mansell, Medical Society of Virginia
Ms. Tyler S. Cox, Hancock, Daniel, Johnson & Nagle, PC

Report of the Task Force on the Regulation of Pharmacy Benefit Managers

NOTE: The NABP Executive Committee accepted all of the recommendations of this Task Force with the exception of Recommendation 5:

- **Upon review of the information pertaining to the Recommendation, the Executive Committee determined that the development of a patient reporting system for collecting consumer concerns regarding Pharmacy Benefits Managers related to the practice of pharmacy to be outside the realm of NABP and that the cost and infrastructure required for NABP to internally develop such a system is prohibitive.**

Members Present:

Patricia Donato (NY), *chair;* Buford Abeldt (TX); Julia Eaton (VT); Suzan Kedron (TX); LuGina Mendez-Harper (NM); Jeffrey Mesaros (FL); Steve Parker (MS); Richard Palombo (NJ); Laura Schwartzwald (MN); Brenda Warren (TN); Cindy Warriner (VA); Stuart Williams (MN).

Others Present:

Hal Wand, *Executive Committee liaison*; Carmen Catizone, Melissa Madigan, Eileen Lewalski, Heather McComas, Cameron Orr, *NABP staff.*

Introduction:

The Task Force on the Regulation of Pharmacy Benefit Managers met October 22-23, 2013, at NABP Headquarters. This task force was established in response to Resolution 109-3-13, Review and Revise the Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy Regarding Pharmacy Benefit Managers, which was approved by the NABP membership at the Association's 109th Annual Meeting in May 2013.

Review of the Task Force Charge:

Task force members reviewed their charge and accepted it as follows:

1. Review existing current state laws and regulations addressing the regulation of pharmacy benefit managers (PBMs).
2. Identify activities in which PBMs engage that may be construed to fall under the definition of the Practice of Pharmacy.
3. Review and, if necessary, recommend amending the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)* to address appropriate regulation of pharmacy benefit managers.

Recommendation 1: NABP Should Amend the *Model Act*

The task force recommends that NABP amend the *Model Act*. Revisions are denoted below by underlines and ~~strikethroughs~~.

Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy

...

Section 105. Definitions.

...

(x4) "Pharmacy Benefits Manager" means a Person that Administers the Prescription Drug/Device portion of health insurance plans on behalf of plan sponsors, such as self-insured employers, insurance companies, and health maintenance organizations, and that engages in or directs the Practice of Pharmacy.

(y4) "Pharmacy Benefits Processor" means a Person that Administers the Prescription Drug/Device portion of health insurance plans on behalf of plan sponsors, such as self-insured employers, insurance companies, and health maintenance organizations, but that does not engage in or direct the Practice of Pharmacy.

...

Section 105(x4) (and [y4]). Comment.

It is the performance of activities that encompass the Practice of Pharmacy that distinguishes Pharmacy Benefits Managers from Pharmacy Benefits Processors. The activities that may encompass the Practice of Pharmacy by Pharmacy Benefits Managers include, but are not limited to, the following:

- Disease state management
- Disease compliance management
- Drug adherence management
- Drug interaction management
- Drug utilization management
- Formulary management ~~intervention~~
- Generic alternative program management
- Generic incentive program management
- Medical and/or Drug data analysis
- Patient Drug Utilization Review (DUR) services
- Prior authorization services
- Provider profiling and outcomes assessment
- Refill reminder program management
- Therapy guidelines management
- Stop therapy protocol management
- Wellness management

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- Maintenance of confidential patient information
- Direction or design of the clinical programs for a pharmacy or a group of pharmacies

Background:

As a ground rule for its work, the task force agreed that all discussions and recommendations should remain within the scope of the practice of pharmacy and the protection of public health. Task force members recognized that many concerns surrounding PBMs relate to contractual issues, payment, or coverage, and as such, fall outside the purview of the boards of pharmacy. The group acknowledged the challenges involved in delineating which PBM-related issues fall strictly under the jurisdiction of the boards of pharmacy and expected that areas of ambiguity would arise in its discussions.

The task force then began addressing its charge by reviewing the reports of the 1999 Task Force on Licensing of Pharmacy Benefit Managers and the 2000 Task Force on Model Guidelines for Formulary Development. The task force discussed and ultimately agreed with the existing *Model Act* definitions for Pharmacy Benefits Managers and Pharmacy Benefits Processors that were created by the 1999 task force. The group recommended that the language in the associated Comment section be generalized to avoid the implication that the listed activities always constitute the practice of pharmacy by PBMs. After agreeing that formulary development may involveclinical decision-making and may constitute the practice of pharmacy, the task force recommended that the language related to formularies be broadened to include all aspects of formulary management, not just interventions. Finally, in recognition that many PBMs design the clinical programs for their associated mail order and/or network pharmacies, the task force recommended that direction and design of clinical programs for pharmacies be added to the list of activities that may constitute the practice of pharmacy by PBMs.

Recommendation 2: NABP Should Encourage States to Adopt Existing *Model Act* Language Pertaining to PBMs

The task force recommends that NABP encourage states to adopt existing *Model Act* language pertaining to PBMs.

Background:

After a thorough discussion of the current impact of PBM activities on the practice of pharmacy, the task force affirmed the 1999 task force's recommendation that PBMs engaged in the practice of pharmacy should be licensed and regulated by state boards of pharmacy. The task force supported the other findings and recommendations of both previous task forces.

Task force members noted that boards of pharmacy may not be aware of the work of the previous task forces or the existing provisions in the *Model Act* pertaining to the licensure of PBMs. The task force therefore agreed that NABP should remind its member boards of the existing sections of the *Model Act* addressing PBMs and encourage states that have yet to do so adopt this language in their state pharmacy practice acts.

Recommendation 3: NABP Should Monitor Member States' Initiatives to Regulate the Activities of PBMs as They Relate to the Practice of Pharmacy, Alert Members to

Available NABP Resources to Assist with Regulation Development, and Support the Creation of a State Ombudsman Position for PBM Issues

The task force recommends that NABP monitor member states' activities and initiatives to regulate PBMs in order to determine if an expansion of the boards' authority in these areas is appropriate. The task force further recommends that NABP support the expansion of the authority of state and federal agencies overseeing these activities to ensure that the health and safety of the patient is a primary consideration. Wherever possible, the task force recommends that states institute an ombudsman for PBM issues to assist patients and ensure that their interests and complaints are appropriately received and managed. The task force also recommends that member boards be alerted to the availability of NABP resources to assist in the drafting of rules/regulations pertaining to PBMs.

Background:

The task force acknowledged that the issues identified by the 1999 and 2000 task forces related to patient access, medications excluded from coverage, and formulary changes impacting patient care remain legitimate concerns and although involve payment and coverage they may also relate to the practice of pharmacy. The task force recognized that while PBM contractual and payment issues may impact patient care, they are outside the scope of authority of the boards of pharmacy. To address these continuing challenges, some states are now regulating PBMs through their boards of pharmacy. Notably, PBMs doing business in the state of Mississippi have been regulated by the Mississippi Board of Pharmacy since 2011. Under the Mississippi regulations, PBMs must obtain a license from the Board before operating in the state; the Board also coordinates financial examinations of PBMs.

Task force members discussed the many areas of uncertainty pertaining to this new regulation of PBMs by state boards of pharmacy, including issues related to the scope, purview, and authority of the boards. While it is too early to determine the ultimate outcome of these new efforts, the task force concurred that NABP should actively monitor states' efforts related to PBM regulation and, once this area is more fully evolved, determine if expansion of the boards' authority is warranted. Additionally, NABP should remind any states interested in pursuing new regulations in this area of available NABP resources and support. NABP's Government Affairs staff can assist states with drafting rules and regulations, offer support and education, and testify before legislative committees.

To address unmet patient needs in the area of PBM payment and contractual issues beyond the scope of pharmacy, the task force recommended that states appoint an ombudsman to assist consumers in resolving questions and complaints related to PBM services. Task force members agreed that an ombudsman, ideally, should be positioned within the board of pharmacy because of the board's expertise and primary mission of protecting the public health. However, the task force acknowledged that it may not always be possible to secure an ombudsman position in the board of pharmacy and did not want to exclude the creation of this position within another state agency, provided that oversight is effective.

Recommendation 4: NABP Should Acknowledge That Certain PBM Activities and Medication Therapy Decisions May Impact the Practice of Pharmacy and Require Accountability

The task force recommends that NABP acknowledge that there may be activities and medication therapy decisions implemented through pharmacy benefit plans and PBMs that impact the practice of pharmacy and require accountability.

Background:

The task force reviewed the PBM activities listed in the Comment to Sections 105(x4) and 105 (y4) of the *Model Act* and agreed that many of these examples may be the practice of pharmacy by PBMs and may impact patient care. In particular, task force members pointed to prior authorization and formulary decisions as examples of PBM activities that can affect pharmacists' ability to provide patients with needed medications and care. Given the potential effect on public health of these PBM activities, the task force recommended that NABP acknowledge the need for accountability on these issues. By encouraging states to adopt *Model Act* language regarding PBM licensure as described in Recommendation 2, NABP will be supporting accountability and increased oversight of pharmacy practice by PBMs Additionally, the data-gathering initiative described next in Resolution 5 will further NABP's efforts to protect the public health related to PBM activities.

Recommendation 5: NABP Should Collect Data on Patient, Pharmacy, and Board of Pharmacy Concerns Related to Prescription Drug Benefits Via Survey, Provide These Data to the States, and Educate Consumers and Licensees About PBMs Through the AWARxE Program

The task force recommends that NABP collect data on patient, pharmacy, and board of pharmacy concerns related to pharmacy benefits via survey and provide this information to the states. Additionally, the task force recommends that NABP utilize the AWARxE program to educate patients and licensees about PBMs and the availability of this survey tool to report applicable concerns.

Background:

The task force struggled with how to resolve the ongoing concerns regarding PBM activities within the scope of the authority of the boards of pharmacy. Task force members noted that concrete statistical data documenting consumer concerns with PBMs are necessary to convince legislators to take action on these issues and increase regulatory oversight of PBMs. There is no mechanism currently in place to collect consumer concerns regarding PBMs; therefore, the task force suggested that NABP serve as the conduit to gather this information. NABP staff indicated that there is precedence for the Association to function as a data clearinghouse, as illustrated by NABP's monitoring of rogue Internet drug outlets and collection of licensee disciplinary information. NABP's efforts to collect PBM-related data will provide weight and legitimacy to consumer concerns surrounding PBMs.

The task force discussed several important elements of the proposed data-collection initiative, which included the following:

- **Mission of the program:** The NABP program will operate exclusively as an information-gathering tool, not a dispute-resolution process, and this will need to be explicitly stated to consumers accessing the system. The program will focus solely on concerns related to the practice of pharmacy and will not address coverage or payment issues. The task force stressed that this must be clearly communicated to consumers and

suggested that NABP provide examples of the types of issues to be tracked by the system to enhance consumer understanding of the program.

- **Information sharing and confidentiality concerns:** For this program to have the greatest impact and scope, information will need to be shared between NABP and the boards of pharmacy. The task force recommended that NABP's reporting mechanism be structured to provide consumers with the option to concurrently submit their PBM-related concern to the appropriate state board of pharmacy. Similarly, task force members indicated that boards of pharmacy should share any PBM-related consumer reports with NABP. Consumers will need to authorize this information sharing, or the data will need to be appropriately de-identified prior to being shared with other organizations.
- **Data aggregation:** The program will collect and report PBM data both nationally and by state. This will allow for the identification of any state- or region-specific issues related to PBMs.
- **Participation:** To ensure that the program gathers the most robust data, all states will be highly encouraged to participate.
- **Education and Outreach:** Both NABP and the boards of pharmacy will need to publicize the PBM data reporting system to maximize its reach and utility. Boards of pharmacy will be responsible for informing licensees about the program, and licensees can then in turn communicate the information to consumers via personal interactions and signs posted in pharmacies. NABP will raise awareness about the program through multiple communication vehicles, to include newsletters, electronic news mailings, and the AWARxE Web site.
- **Data Analysis and Review:** After the collection of sufficient data, NABP should commission another task force to review and analyze the information and recommend further actions related to PBMs, if warranted.

The task force also addressed the need for education regarding PBMs among both consumers and licensees. Task force members indicated that many patients are unaware that a PBM, not their primary health insurer, administers pharmacy benefits. Additionally, consumers often do not understand their pharmacy benefits and corresponding limitations in medication coverage and access. Pharmacists and their staff also may not be fully aware of PBM operations and how plan restrictions can impact patients' access to medications.

To address these gaps in knowledge, the task force recommended that NABP create educational resources for both consumers and licensees regarding PBMs and their activities. Through the AWARxE program, NABP can increase consumers' and licensees' understanding of PBMs, as well as publicize NABP's PBM reporting system. Task force members stressed that any materials intended for a consumer audience should use simple, clear language. NABP can also use various communication outlets, including newsletters and electronic mailings, to raise awareness of the new PBM content available through the AWARxE program.