



Virginia Department of
Health Professions

Virginia Board of Pharmacy Law Update

Virginia Pharmacists Association
Annual Convention

September 7, 2018

Caroline D. Juran, Executive Director



Virginia Department of
Health Professions

- No financial interests or conflicts of interest to declare.



Objectives

- Summarize select pharmacy-related bills passed by the 2018 General Assembly
- Describe recent Board of Pharmacy action related to regulations and board guidance
- Review ongoing and upcoming projects related to pharmaceutical processors, e-prescribing, routine pharmacy inspections, and PMP-related subjects

Pre-Test Questions

- 1) According to State law, CBD oil may only be used to treat intractable epilepsy. True or False

Pre-Test Questions

- 2) When must you comply with USP Chapter <800>?
- a) July 1, 2018
 - b) December 1, 2018
 - c) December 1, 2019



Department of Health Profession Mission

- To ensure safe and competent patient care by licensing health professionals, enforcing standards of practice, and providing information to health care practitioners and the public.



Virginia Department of
Health Professions

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Virginia Department of
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Legislation



HB313/SB728

- Amended §54.1-2523.1
- Requires DHP Director, in consultation with Advisory Panel, to review controlled substances prescribing and dispensing patterns using PMP
- Panel includes reps from Boards of Medicine & Pharmacy, VDH, DMAS, DBHDS
- Report findings and best practices to Joint Commission on Health Care annually



HB501

- Amended §32.1-162.5:1 and §54.1-3411.2
- Requires hospice programs to develop policies for disposal of unwanted drug
- Disposal shall be (i) performed by a nurse, PA, or physician employed by or contracted with the hospice program; (ii) witnessed by member of patient's family or second hospice employee licensed by DHP; and (iii) documented in the patient's medical record.



HB520

- Amended §54.1-3435.1 and added §54.1-3435.4:01 and §54.1-3435.4:2
- Created licensing category for nonresident warehousemen and nonresident third party logistics providers that ship prescription drugs and devices into Virginia
- Regulatory amendments adopted in June 2018.
- OAG indicated it must proceed as a fast-track action, not an exempt action.



HB793

- Amended multiple sections of law.
- Eliminates need for nurse practitioner to have practice agreement with patient care team physician if:
 - 5+ years clinical experience
 - Physician submits attestation
 - Consult, collaborate, and develop plan for referral to physician of complex cases or emergencies
 - Boards of Medicine & Nursing developing joint regulations



HB842

- Amended §54.1-3466 (F) and §54.1-3467 (C)
- Authorizes REVIVE! Trainers dispensing naloxone pursuant to §54.1-3408(Y) to dispense hypodermic needles and syringes for administering naloxone;
- Guidance Document 110-45 amended to include board protocol for issuance of standing order;
- DBHDS-approved trainer must first complete DBHDS-approved training on proper administration of injectable naloxone and disposal of needles and syringes;



HB842, cont.

- Standing order must be issued to organization on whose behalf trainer is acting;
- Standing order must include allowance to dispense
 - #2 single-use 1ml naloxone vials, and
 - #2 (3ml) syringe with 23-25 gauge 1-1.5 inch IM needles



HB878/SB413

- Amended §54.1-3401
 - Definitions of “deliver” and “wholesale distribution”
- Created new section §54.1-3415.1
- Authorizes manufacturers, wholesale distributors, 3PLs, warehouse users to deliver CVI prescription devices directly to ultimate user if:
 - agreement entered with medical equipment supplier who has received valid order; or,



HB878/SB413, cont.

- Agreement entered with medical director of home health, nursing home, ALF, or hospice and he/she has directed devices to be distributed directly to patient's residence and administered to patient.
- Board adopted emergency regulations and a NOIRA in June 2018.
- Currently under Administrative Review at the Department of Planning and Budget.



HB1173/SB632

- Amended §54.1- 2522.1
- Eliminated exception for a prescriber to check the PMP when issuing opioid prescription for up to 14 days if for treatment of surgical or invasive procedure.
- Now must check PMP if opioid Rx anticipated to last more than 7 consecutive days.



HB1251/SB726

- Amended §§ 18.2-250.1, 54.1-3408.3, 54.1-3442.5, and 54.1-3442.7
- Expands treatment with CBD or THC-A oil to treatment of any disease or condition as determined by physician
- Expands allowance from 30-day supply to 90-day supply
- Recommendations of JCHC



SB330

- Amended §§ 54.1-2519, 54.1-2521, 54.1-2522.1, 54.1-3442.6, and 54.1-3442.7
- Requires dispensing of CBD and THC-A oil to be reported to PMP
- Requires physician to query PMP prior to issuing written certification
- Requires FBI criminal background check of pharmaceutical processor applicant



SB330, cont.

- Requires processor to establish stability testing to ensure percentage of THC in THC-A oil on-site remains within 10% of level measured when labeled



HB1556/SB832

- Amended §§ 54.1-2519 and 54.1-2520
- Requires reporting of naloxone and Schedule V drugs dispensed pursuant to a prescription to the PMP



SB544

- Amended § 54.1-3411.1
- Further clarifies donation of unwanted drugs for redispensing as means of increasing participation in current program
- Refer to Regulations 18VAC110-20-740 through 18VAC110-20-800



SB882

- Amended § 54.1-3303
- Provides prescriber may authorize nurse to approve additional refills for CVI drug for no more than 90 days if:
 - No changes to drug
 - Prescriber has current written protocol identifying when nurse may approve additional refills
 - Nurse documents in patient chart
 - Additional refills transmitted to pharmacy orally or by facsimile

SB226

- Exempts veterinarian dispensing from being reported to the PMP when course of treatment is to last 7 days or less.
- If veterinarian does not wish to report to the PMP, then may issue prescription to be dispensed at a pharmacy.

SB226, cont.

- **NOTE:** § 54.1-3410 requires prescription label to contain the “name of the patient or, if the patient is an animal, the name of the owner of the animal and the species of the animal”



Virginia Department of
Health Professions

Other Actions related to *PENDING* Regulations and Board Guidance



E-Profile ID

- March 2018 – Board adopted proposed regulations requiring pharmacists, pharmacy technicians, and pharmacy interns to provide board with E-profile ID when applying for new license or renewing
- Free of charge from NABP and most already have one
- Will facilitate exchange of information between board and NABP
- Governor approved proposed regs on 8/15
- Public comment period 9/17/18 -11/16/18



Increase in Fees

- March 2018 – Board adopted proposed regulations to increase licensure fees
- First increase since 2002
- Note: Two fee reductions since 2002
- 2002 license count approximately 12,000; currently approximately 35,000
- Proposed regulations in Secretary's office



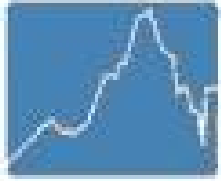
Brown Bagging/White Bagging

- NOIRA adopted
- Public comment on NOIRA ended 9/5/18
- Board will consider regulations for:
 - Brown bagging of drugs requiring special storage, reconstitution or compounding prior to administration
 - Requiring specialty pharmacies to notify receiving pharmacy of shipment to ensure coordination of patient care
 - Providing estimated arrival date and exact address where product has been shipped



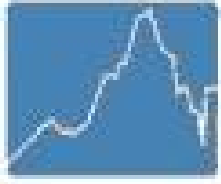
Periodic Regulatory Review

- Chapters 20 and 50
- Board adopted proposed amendments in three parts – December '16, March '17, & June '17
- Refer to agenda packets and minutes on board website for proposed language
- Once Governor approves publishing of proposed regulations, a 60-day comment will open.



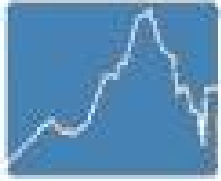
Periodic Regulatory Review – *Proposed* Amendments, *cont.*

- Examples of proposed amendments:
- Regulations for individuals (pharmacists, pharmacy technicians, interns) would be moved to new Chapter 21
- Regulations for facilities (pharmacies, medical equipment supplies) would remain in Chapter 20
- Would place language from guidance documents into regulation



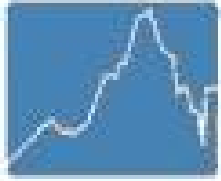
Periodic Regulatory Review – *Proposed* Amendments, *cont.*

- 18VAC110-20-90, Continuing education:
 - Would require at least 5 hours in live or real-time interactive CE which may include:
 - 1 hour attendance at board meeting;
 - 1 hour serving as preceptor for pharmacy student or resident in accredited school or program.



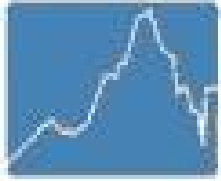
Periodic Regulatory Review – *Proposed* Amendments, *cont.*

- 18VAC110-20-110, PIC eligibility:
 - Would require minimum two years experience practicing as pharmacist in VA or another state;
 - Board could grant exception for good cause shown.
- 18VAC110-20-140, New pharmacies
 - Would state if pharmacy not operational within 90 days from date permit issued, board shall rescind permit unless extension granted for good cause shown.



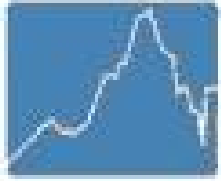
Periodic Regulatory Review – *Proposed* Amendments, *cont.*

- 18VAC110-20-150, Physical standards
 - Would state pharmacies stocking drugs requiring cold storage temperature shall record temperature daily and adjust temperature as necessary;
 - Would require record to be maintained manually or electronically for two years.



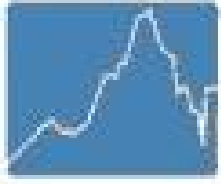
Periodic Regulatory Review – *Proposed* Amendments, *cont.*

- 18VAC110-20-530, Long Term Care
 - Would allow pharmacy to share copy of CVI prescription or order with another pharmacy for immediately dispensing up to 7-day supply without transferring prescription if:
 - Have written contract in place with other pharmacy outlining services, recordkeeping, and responsibilities of each pharmacy



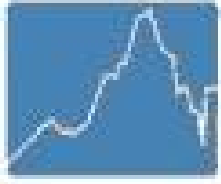
Periodic Regulatory Review – *Proposed* Amendments, *cont.*

- 18VAC110-20-550, Stat-drug box
 - Would allow one unit of liquid, not to exceed 30ml, to be substituted for a solid dosage unit in each drug schedule



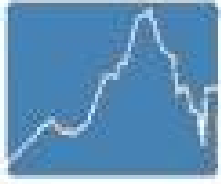
Pharmaceutical Processors

- Board adopted revised emergency regulations in June 2018 based on recent statutory changes.
- General Notice for accepting public comment was open 7/3/18 - 8/22/18.
- Board will adopt permanent replacement regulations on September 25, 2018.



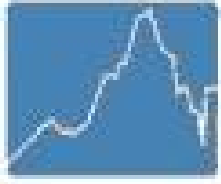
USP <800>

- Guidance Document 110-36 amended December 2017.
- Practice and quality standards for handling hazardous drugs to promote patient safety, worker safety, and environmental protection
- <800> first published in 2014. Published as an official standard in February 2016 with a delayed implementation date of July 1, 2018.
- Delayed to December 1, 2019 to align with next revision of <797>.



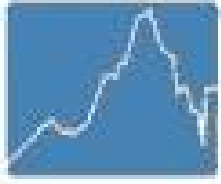
Other Guidance Documents Recently Amended

- 110-2 Pharmacist Licensure
- 110-4 Continuing Education
- 110-5 Theft and Loss
- 110-46 Delivery of Drugs
- 110-47 Counseling regarding Disposal



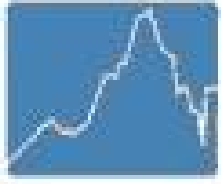
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Ongoing and Upcoming Projects



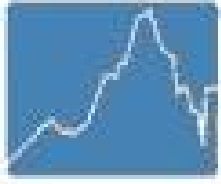
Pharmaceutical Processors

- RFA for conditional approval of permits
 - Ad hoc committee met September 4, 2018 to evaluate 51 applications
 - Board will consider committee's recommendations on September 25, 2018 and identify which applicants will potentially receive conditional approval
 - Identified applicants must obtain criminal background checks
 - Board will consider background information and finalize awarding conditional approval on either October 25, 2018 or November 28, 2018



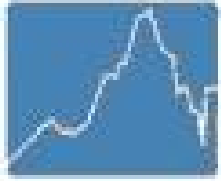
Pharmaceutical Processors

- Began registering physicians, patients, parents/guardians on July 30, 2018
- Approximately 106 registered physicians in-state and 17 out-of-state



Revised Routine Pharmacy Inspection Report

- April 2018 - Convened meeting with pharmacist inspectors
 - Comprehensive review of inspection report
 - pros/cons to current version
- June 2018 - Convened ad hoc committee of board
 - Revised & shortened inspection report
 - Added educational items on chapter <800>



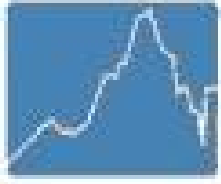
Amended Guidance Document 110-9

- Effective July 1, 2018
- Identified 10 deficiencies that if cited will no longer result in an automatic monetary penalty, but must still correct deficiency.
- If “repeat deficiency” during the next subsequent routine or focused inspection, then will result in monetary penalty.
- Refer to guidance document or September e-newsletter



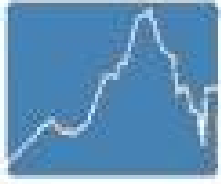
E-prescribing Work Group

- HB2165 (2017) mandates e-prescribing of opiates, effective July 1, 2020
- 2017 Work Group Interim Report available at - <https://rga.lis.virginia.gov/Published/2017/RD431/PDF>
- Work group met August 29, 2018 to discuss 2019 legislation
- Final report due in November 2018



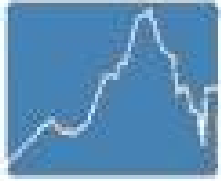
E-prescribing Work Group, cont.

- 2019 Legislative proposal will:
 - 1) set out 10 exceptions;
 - 2) require licensing boards to promulgate emergency regulations for a temporary waiver based on financial hardship;
 - 3) authorize a pharmacy to dispense a valid prescription transmitted by other means; and



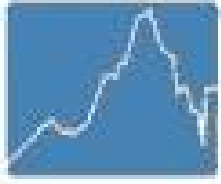
E-prescribing Work Group, cont.

- Legislative proposal will:
 - 4) require the convening of a workgroup to identify successes and challenges with the mandate, and offer possible recommendations for increasing the electronic prescribing of controlled substances by November 1, 2022.



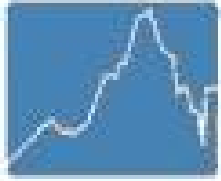
Other Possible 2019 Legislative Proposals

- Proposal to clarify authority of the Board or law enforcement to seize drugs and the process to be followed if drugs are placed under seal, forfeited and destroyed.



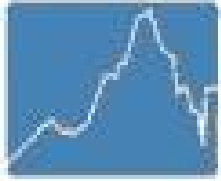
Other Possible 2019 Legislative Bills, cont.

- Proposal to:
 - amend language for mandatory suspensions to avoid cyclical action, and
 - amend provision in Pharmacy law for holding a hearing for a nonresident pharmacy after a mandatory suspension that is inconsistent with the law for all boards and is unrealistic.



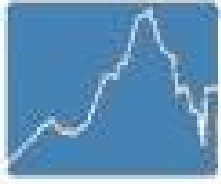
Other Possible 2019 Legislative Bills, cont.

- Proposal to:
 - 1) allow Governor to extend the four-year term of a member on a health regulatory board for an additional one or two years for the purpose of staggering the expiration of terms and maintaining valuable board experience and knowledge; and
 - 2) re-designate membership on the Boards of Nursing and Psychology.



Paperless Licensing Initiative

- Agency moving away from issuing licenses with an expiration date.
- Verify status of license on Board's website via *License Lookup* feature.
- Paper will have enhanced security features.
- Unsure if process will be in place prior to December 31st renewals.
- Ensure board has current email address on file!



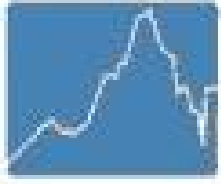
Annual Healthcare Workforce Survey

- 2017 Pharmacist and Pharmacy Technician Workforce Survey Reports

<https://www.dhp.virginia.gov/hwdc/findings.htm#Pharm>

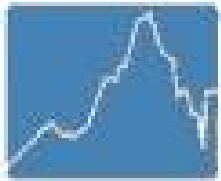
- Trends in Full Time Equivalency

<http://vahwdc.tumblr.com/Full%20Time%20Equivalency>



Prescription Monitoring Program

- Ongoing efforts to identify optimal criteria to identify unusual patterns of dispensing or prescribing
- Implementation of NarxCare



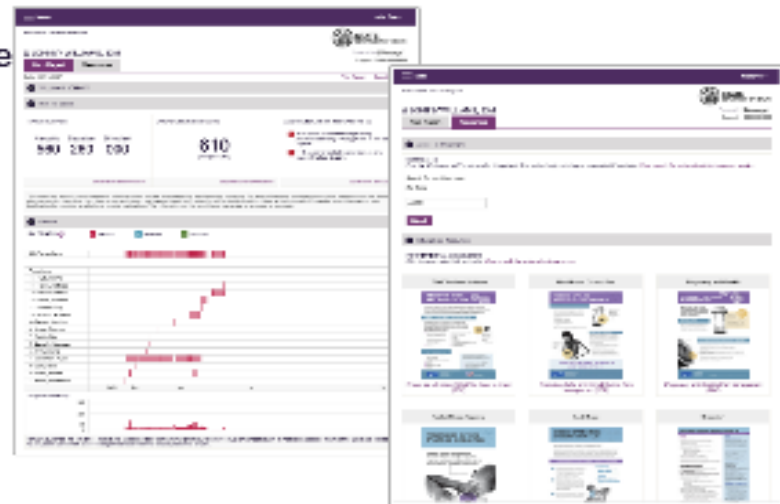
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Welcome to NarxCare!



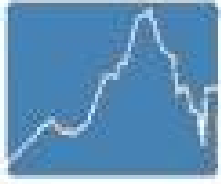
Beginning July 30, 2018, the Virginia PMP has delivered expanded functionality and intelligence within the PDMP called NarxCare.

NarxCare helps providers make better-informed decisions when it comes to **identifying**, **preventing**, and **managing** substance use disorders.



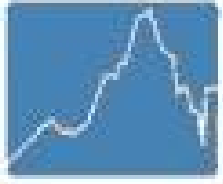
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NarxCare

- Assigns patient a score based on risk factors:
 - Number of prescribers
 - Number of pharmacies
 - Amount of medication
 - Overlapping prescriptions of similar type from different prescribers
- Takes time into consideration, i.e., 1,000MME filled last month = greater score than if filled last year.

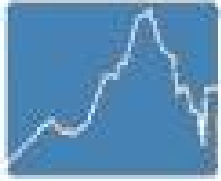


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NarxCare

- Video user tutorials

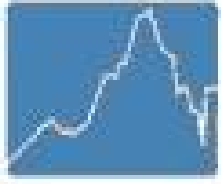
http://www.dhp.virginia.gov/dhp_programs/pmp/default.asp



NarxCare

Narx Scores:

- 75% score less than 200
 - 5% score more than 500
 - 1% score more than 650
-
- 3 categories: narcotics, sedatives stimulants



Department of Health Professions

Welcome to NarxCare!



Scores and Indicators

Narx Scores, an Overdose Risk Score, and Red Flag indicators are all presented below the header. A brief explanation of each score and flag is available by selecting the "Explanation and Guidance" links.

Risk Indicators

NARX SCORES			OVERDOSE RISK SCORE	ADDITIONAL RISK INDICATORS (2)
Narcotic	Sedative	Stimulant	600 (Range 000-999)	<ul style="list-style-type: none">>= 4 op ioid or sedative dispensing pharmacies in any 90-day period in the last 2 years.>= 5 op ioid or sedative providers in any year in the last 2 years.
280	130	000		
Explanation and Guidance	Explanation and Guidance	Explanation and Guidance	Explanation and Guidance	Explanation and Guidance

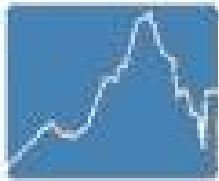
This NarxCare report is based on search criteria supplied and the data entered by the dispensing pharmacy. For more information about any prescription, please contact the dispensing pharmacy or the prescriber. NarxCare scores and reports are intended to aid, not replace, medical decisionmaking. None of the information presented should be used as sole justification for providing or refusing to provide medical care. The information on this report is not warranted as accurate or complete.



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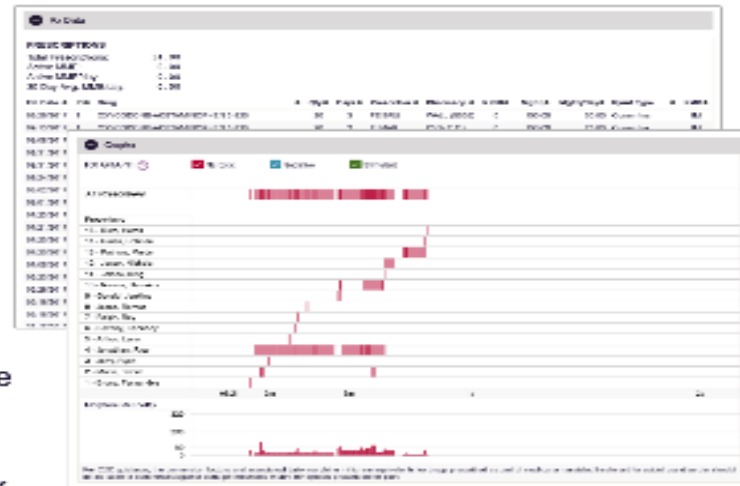
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Welcome to NarxCare!



Graphs and Full Prescription Detail

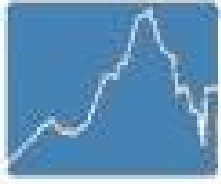
- Graphs are provided to reveal important details of prescription use.
- Providers are listed on the left, and color-coded prescriptions are graphed in reverse time order.
- The Rx Graph is interactive. You may click on a prescription or drag over several to see additional detail.
- Full prescription detail is listed below the Rx Graphs.



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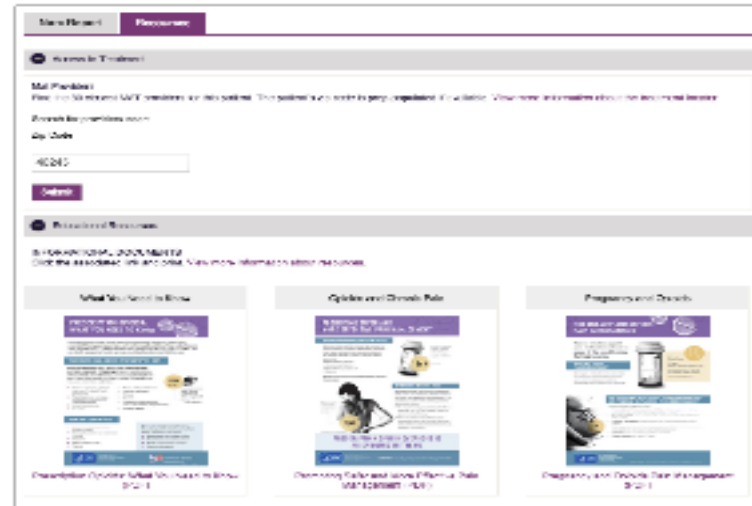
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Welcome to NarxCare!



MAT and CDC Resources are accessible from the header by clicking on the Resources tab.

- A SAMHSA supported Buprenorphine Treatment Locator is available.
- The patient's zip code is pre-populated but can be edited if needed.
- Selecting submit will generate a document listing the 30 providers found that are closest to the patient.
- Printable CDC pamphlets are also available.



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Post-Test Questions

- 1) According to State law, CBD oil may only be used to treat intractable epilepsy. True or False



Post-Test Questions

1) False. CBD oil may now be used to treat any disease or condition identified by the physician to benefit the patient.

Post-Test Questions

- 2) When must you comply with USP Chapter <800>?
- a) July 1, 2018
 - b) December 1, 2018
 - c) December 1, 2019

Post-Test Questions

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Resources

Board website: www.dhp.virginia.gov

Regulatory Town Hall:

Become registered user –

<http://townhall.virginia.gov/L/Register.cfm>

Actions underway -

<http://townhall.virginia.gov/L/NowInProgress.cfm>

Charts for Regulatory Actions-

<http://townhall.virginia.gov/UM/charts.cfm>

DEA website: <https://www.dea diversion.usdoj.gov/>



Virginia Department of
Health Professions

Contact Information

Department of Health Professions
Virginia Board of Pharmacy
Perimeter Center
9960 Mayland Drive, Suite 300
Henrico, VA 23233

(804) 367-4456

pharmbd@dhp.virginia.gov

www.dhp.virginia.gov