# COMMONWEALTH OF VIRGINIA
# Meeting of the Board of Pharmacy

**Perimeter Center, 9960 Mayland Drive, Third Floor** **(804) 367-4456 (Tel)**
**Henrico, Virginia 23233** **(804) 527-4472(Fax)**


## Tentative Agenda of Public Hearing and Full Board Meeting
***March 30, 2021 Meeting***
**9AM**
*******Refer to the Third Page of Agenda for Meeting Access Information*******

**TOPIC** **PAGES**

**Call to Order of Public Hearings:** Kris Ratliff, Chairman
- Welcome & Introductions

**Public Hearing:**
- Registered agents and wholesale distribution of cannabis oil **1-17**
- Placement of chemicals into Schedule I **18-19**

**Adjournment of Public Hearing**

**Call to Order of Full Board Meeting:** Kris Ratliff, Chairman
- Approval of Agenda

**20-41**

**Approval of Previous Board Meeting Minutes:**
- December 9, 2020, Special Conference Committee
- December 10, 2020, Full Board Meeting
- December 10, 2020, Public Hearing to Schedule Certain Chemicals
- December 10, 2020, Public Hearing to Deschedule Epidiolex
- January 12, 2021, Special Conference Committee
- January 26, 2021, Special Conference Committee
- February 23, 2021, Formal Hearing

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

**DHP Director's Report:** David Brown, DC

**Legislative/Regulatory/Guidance:**
- Report of 2021 General Assembly – Elaine Yeatts, Dr. Brown **42-50**
- Chart of Regulatory Actions – Elaine Yeatts **51-52**
- Adoption of Exempt Regulations to Place Certain Chemicals into Schedule I **53-66**
- Adoption of Proposed Regulations for Pharmacists to Initiate Treatment **67-72**
- Adoption of Proposed Regulations for Pharmacist Technician Trainee Registration and Training **73-89**
- Adoption of Proposed Regulations for Limited Licenses for Dispensing Schedule VI Drugs from a Non-profit Facility **90-97**
- Guidance Documents: **98-110**
  - Amend 110-27
  - Amend 110-31

- Amend 110-33
- Repeal 110-20
- Readopt 110-38

**Old Business:**

**New Business:** Caroline D. Juran

- Discuss Signing of FDA MOU for Compounding **111-133**
- Amend Pharmacist Workforce Survey to Include Question about Statewide Protocols **134**
- Recognition of Former Board Members Warriner, Thornbury, and Boone

**Reports:**

- Chairman's Report – Kris Ratliff
- Report on Board of Health Professions – Ryan Logan
- Report on Licensure Program – Beth O'Halloran **135-146**
- Report on Inspection Program – Beth O'Halloran
- Report on Pharmaceutical Processors – Annette Kelley **147**
- Report on Disciplinary Program – Ellen B. Shinaberry **148**
- Executive Director's Report – Caroline D. Juran **149**

**Consideration of consent orders, summary suspensions, or summary restrictions, if any.**

**Adjourn**

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

*****A panel of the Board will tentatively convene at 1:00pm or immediately following adjournment of the board meeting, whichever is later.*****

# Virginia Board of Pharmacy

## Instructions for Accessing March 30, 2021 Virtual Public Hearing/Full Board Meeting and Providing Public Comment

- **Access:** Perimeter Center building access remains restricted to the public due to the COVID-19 pandemic. To observe this virtual meeting, use one of the options below. Participation capacity is limited and is on a first come, first serve basis due to the capacity of CISCO WebEx technology.
- **Public comment:** Comments will be received during the public hearings and during the full board meeting from those persons who have submitted an email to caroline.juran@dhp.virginia.gov **no later than 8am on March 30, 2021** indicating that they wish to offer comment. Be sure to specify if the comment is associated with the public hearing or the full board meeting. Comment may be offered by these individuals when their names are announced by the chairman.
- Public participation connections will be muted following the public comment periods.
- Should the Board enter into a closed session, public participants will be blocked from seeing and hearing the discussion. When the Board re-enters into open session, public participation connections to see and hear the discussions will be restored.
- Please call from a location without background noise.
- Dial (804) 367-4578 to report an interruption during the broadcast.
- FOIA Council *Electronic Meetings Public Comment* form for submitting feedback on this electronic meeting may be accessed at http://foiacouncil.dls.virginia.gov/sample%20letters/welcome.htm

**JOIN WEBEX MEETING**
https://virginia-dhp.my.webex.com/virginia-dhp.my/j.php?MTID=m0766054dba11040cae975dcd8ab4c661

**Meeting number (access code)**: 132 025 6966
**Meeting password:** Pharmacy21!

**JOIN BY PHONE**
**+1-408-418-9388 United States Toll**
**Dial-In Password:** 74276229

# Proposed Text – For a Public Hearing
## March 30, 2021
(No Board action on March 30, 2021)

**18VAC110-60-10 Definitions**

In addition to words and terms defined in §§ 54.1-3408.3 and 54.1-3442.5 of the Code of Virginia, the following words and terms when used in this chapter shall have the following meanings, unless the context clearly indicates otherwise:

"90-day supply" means the amount of cannabis oil reasonably necessary to ensure an uninterrupted availability of supply for a 90-day period for registered patients.

"Batch" means a quantity of cannabis oil from a production lot that is identified by a batch number or other unique identifier.

"Board" means the Board of Pharmacy.

"Certification" means a written statement, consistent with requirements of § 54.1-3408.3 of the Code of Virginia, issued by a practitioner for the use of cannabis oil for treatment of or to alleviate the symptoms of any diagnosed condition or disease determined by the practitioner to benefit from such use.

"Dispensing error" means one or more of the following was discovered after the final verification by the pharmacist, regardless of whether the patient received the oil:

1. Variation from the intended oil to be dispensed, including:

a. Incorrect oil;

b. Incorrect oil strength;

c. Incorrect dosage form;

d. Incorrect patient; or

e. Inadequate or incorrect packaging, labeling, or directions.

2. Failure to exercise professional judgment in identifying and managing:

a. Known therapeutic duplication;

b. Known drug-disease contraindications;

c. Known drug-drug interactions;

d. Incorrect drug dosage or duration of drug treatment;

e. Known drug-allergy interactions;

f. A clinically significant, avoidable delay in therapy; or

g. Any other significant, actual, or potential problem with a patient's drug therapy.

3. Delivery of an oil to the incorrect patient.

4. An act or omission relating to the dispensing of cannabis oil that results in, or may reasonably be expected to result in, injury to or death of a registered patient or results in any detrimental change to the medical treatment for the patient.

"Electronic tracking system" means an electronic radio-frequency identification (RFID) seed-to-sale tracking system that tracks the Cannabis from either the seed or immature plant stage until the cannabis oil is sold to a registered patient, parent, ~~or~~ legal guardian, or registered agent or until the Cannabis, including the seeds, parts of plants, and extracts, are destroyed. The electronic tracking system shall include, at a minimum, a

central inventory management system and standard and ad hoc reporting functions as required by the board and shall be capable of otherwise satisfying required recordkeeping.

"On duty" means that a pharmacist is on the premises at the address of the permitted pharmaceutical processor and is available as needed.

"PIC" means the pharmacist-in-charge.

"Production" or "produce" means the manufacture, planting, preparation, cultivation, growing, harvesting, propagation, conversion, or processing of marijuana, (i) directly or indirectly by extraction from substances of natural origin, (ii) independently by means of chemical synthesis, or (iii) by a combination of extraction and chemical synthesis. "Production" or "produce" includes any packaging or repackaging of the substance or labeling or relabeling of its container.

"Qualifying patient" means a Virginia resident who has received from a practitioner, as defined in § 54.1-3408.3 of the Code of Virginia, a written certification for the use of cannabis oil for treatment of or to alleviate the symptoms of any diagnosed condition or disease.

"Registered patient" means a qualifying patient who has been issued a registration by the board for the dispensing of cannabis oil to such patient.

"Registration" means an identification card or other document issued by the board that identifies a person as a practitioner or a qualifying patient, parent, ~~or~~ legal guardian, or registered agent.

"Resident" means a person whose principal place of residence is within the Commonwealth as evidenced by a federal or state income tax return or a current Virginia driver's license. If a person is a minor, residency may be established by evidence of Virginia residency by a parent or legal guardian.

"Temperature and humidity" means temperature and humidity maintained in the following ranges:

| Room or Phase | Temperature | Humidity |
|---|---|---|
| Mother room | 65 - 75° | 50% - 60% |
| Nursery phase | 71 - 85° F | 65% - 75% |
| Vegetation phase | 71 - 85° F | 55% - 65% |
| Flower/harvest phase | 71 - 85° F | 55% - 60% |
| Drying/extraction rooms | < 75° F | 55% - 60% |

**18VAC110-60-20 Fees**

A. Fees are required by the board as specified in this section. Unless otherwise provided, fees listed in this section shall not be refundable.

B. Registration of practitioner.

| | |
|---|---|
| 1. Initial registration. | $50 |
| 2. Annual renewal of registration. | $50 |
| 3. Replacement of registration for a qualifying practitioner whose information has changed or whose original registration certificate has been lost, stolen, or destroyed. | $50 |

C. Registration by a qualifying patient, parent, ~~or~~ legal guardian, or registered agent.

| | |
|---|---|
| 1. Initial registration of a patient. | $50 |
| 2. Annual renewal of registration of a patient. | $50 |
| 3. Initial registration of a parent or legal guardian. | $25 |
| 4. Annual renewal of registration of a parent or guardian. | $25 |
| 5. Initial registration or annual renewal of a registered agent. | $25 |
| 6. Replacement of registration for a qualifying patient, parent, ~~or~~ legal guardian, or registered agent whose original registration certificate has been lost, stolen, or destroyed. | $25 |

D. Pharmaceutical processor permit.

| | |
|---|---|
| 1. Application. | $10,000 |
| 2. Initial permit. | $60,000 |
| 3. Annual renewal of permit. | $10,000 |
| 4. Change of name of processor. | $100 |
| 5. Change of PIC or any other information provided on the permit application. | $100 |
| 6. Change of ownership not requiring a criminal background check. | $100 |
| 7. Change of ownership requiring a criminal background check. | $250 |
| 8. Any acquisition, expansion, remodel, or change of location requiring an inspection. | $1,000 |
| 9. Reinspection fee. | $1,000 |
| 10. Registration of each cannabis oil product. | $25 |

**18VAC110-60-40 Prohibited practices for practitioners**

A. A practitioner who issues certifications shall not:

1. Directly or indirectly accept, solicit, or receive anything of value from any person associated with a pharmaceutical processor or provider of paraphernalia, excluding information on products or educational materials on the benefits and risks of cannabis oil;

2. Offer a discount or any other thing of value to a qualifying patient, parent, ~~or~~ guardian, or registered agent based on the patient's agreement or decision to use a particular pharmaceutical processor or cannabis oil product;

3. Examine a qualifying patient for purposes of diagnosing the condition or disease at a location where cannabis oil is dispensed or produced; or

4. Directly or indirectly benefit from a patient obtaining a certification. Such prohibition shall not prohibit a practitioner from charging an appropriate fee for the patient visit.

B. A practitioner who issues certifications, and such practitioner's coworker, employee, spouse, parent, or child, shall not have a direct or indirect financial interest in a pharmaceutical processor or any other entity that may benefit from a qualifying patient's acquisition, purchase, or use of cannabis oil, including any formal or informal agreement whereby a pharmaceutical processor or other person provides compensation if the practitioner issues a certification for a qualifying patient or steers a qualifying patient to a specific pharmaceutical processor or cannabis oil product.

C. A practitioner shall not issue a certification for himself or for family members, employees, or coworkers.

D. A practitioner shall not provide product samples containing cannabis oil other than those approved by the U.S. Food and Drug Administration.

**18VAC110-60-50 Registration of a patient, parent, or legal guardian, or registered agent**

A. A qualifying patient for whom a practitioner has issued a certification shall register with the board in accordance with this section. If the qualifying patient is a minor or an incapacitated adult, the qualifying patient's parent or legal guardian shall register with the board in accordance with this section. For a registration application to be considered complete, the following items shall be submitted:

1. A copy of the certification issued by a registered practitioner;

2. Proof of residency of the qualifying patient and proof of residency of a parent or legal guardian, if applicable, such as a government-issued identification card or tax receipt;

3. Proof of identity of the qualifying patient and, if the patient is a minor, proof of identity of the parent or legal guardian in the form of a government-issued identification card;

4. Proof of the qualifying patient's age in the form of a birth certificate or other government-issued identification;

5. Payment of the appropriate fees; and

6. Such other information as the board may require to determine the applicant's suitability for registration or to protect public health and safety.

B. A patient, or the patient's parent or legal guardian, may choose a registered agent to receive cannabis oil on behalf of the patient. An individual may serve as a registered agent for no more than two registered patients. For a registration application to be approved, the following shall be submitted:

1. The name, address, birthdate, and registration number of each registered patient for whom the individual intends to act as a registered agent;

2. Proof of identity in the form of a copy of a government-issued identification card;

3. Payment of the applicable fee; and

4. Such other information as the board may require to determine the applicant's suitability for registration or to protect public health and safety.

C. A qualifying patient shall not be issued a written certification by more than one practitioner during a given time period.

~~C.~~ D. Patients, parents, ~~and~~ legal guardians, and registered agents issued a registration shall carry their registrations with them whenever they are in possession of cannabis oil.

**18VAC110-60-60 Denial of a qualifying patient, parent, or legal guardian, or registered agent registration application**

A. The board may deny an application or renewal of the registration of a qualifying patient, parent, ~~or~~ legal guardian, or registered agent if the applicant:

1. Does not meet the requirements set forth in law or regulation or fails to provide complete information on the application form;

2. Does not provide acceptable proof of identity, residency, or age of the patient to the board;

3. Provides false, misleading, or incorrect information to the board;

4. Has had a qualifying registration of a qualifying patient, parent, ~~or~~ legal guardian, or registered agent denied, suspended, or revoked by the board in the previous six months;

5. Has a certification issued by a practitioner who is not authorized to certify patients for cannabis oil; or

6. Has a prior conviction of a violation of any law pertaining to controlled substances.

B. If the board denies an application or renewal of a qualifying patient, parent, ~~or~~ legal guardian, or registered agent applicant, the board shall provide the applicant with notice of the grounds for the denial and shall inform the applicant of the right to request a hearing pursuant to § 2.2-4019 of the Code of Virginia.

**18VAC110-60-70 Reporting requirements for practitioners, patients, parents, ~~or~~ legal guardians, or registered agents**

A. A practitioner shall report to the board, on a form prescribed by the board, the death of a registered patient or a change in status involving a registered patient for whom the practitioner has issued a certification if such change affects the patient's continued eligibility to use cannabis oil or the practitioner's inability to continue treating the patient. A practitioner shall report such death, change of status, or inability to continue treatment not more than 15 days after the practitioner becomes aware of such fact.

B. A patient, parent, or legal guardian who has been issued a registration shall notify the board of any change in the information provided to the board not later than 15 days after such change. The patient, parent, or legal guardian shall report changes that include a change in name, address, contact information, medical status of the patient, or change of the certifying practitioner. The patient, parent, or legal guardian shall report such changes on a form prescribed by the board.

C. A registered agent who has been issued a registration shall notify the board of any change in the information provided to the board not later than 15 days after such change, to include a change in the identifying information of the patient for whom he is serving as a registered agent.

D. If a patient, parent, ~~or~~ legal guardian, or registered agent notifies the board of any change that results in information on the registration of the patient, parent, ~~or~~ legal ~~guardian's registration~~ guardian, or registered agent being inaccurate, the board shall issue a replacement registration. Upon receipt of a new registration, the qualifying patient, parent, ~~or~~ legal guardian, or registered agent shall destroy in a nonrecoverable manner the registration that was replaced.

~~D.~~ E. If a patient, parent, ~~or~~ legal guardian, or registered agent becomes aware of the loss, theft, or destruction of the registration of such patient, parent, ~~or~~ legal guardian, or registered agent, the ~~patient, parent, or legal guardian~~ registrant shall notify the board not later than five business days after becoming aware of the loss, theft, or destruction, and submit the fee for a replacement registration. The board shall inactivate the initial registration upon receiving such notice and issue a replacement registration upon receiving the applicable fee, provided the applicant continues to satisfy the requirements of law and regulation.

**18VAC110-60-80 Proper storage and disposal of cannabidiol oil or THC-A oil by patients, parents, ~~or~~ legal guardians, or registered agents**

A. A registered patient, parent, ~~or~~ legal guardian, or registered agent shall exercise reasonable caution to transport and store cannabis oil in a manner to prevent theft, loss, or access by unauthorized persons.

B. A registered patient, parent, ~~or~~ legal guardian, or registered agent shall dispose of all usable cannabis oil in possession of the registered patient, parent, ~~or~~ legal ~~guardian's possession~~ guardian, or registered agent no later than 10 calendar days after the expiration of the patient's registration if such registration is not renewed, or sooner should the patient no longer wish to possess cannabis oil. A registered patient, parent, ~~or~~ legal guardian, or registered agent shall complete such disposal by one of the following methods:

1. By removing the oil from the original container and mixing it with an undesirable substance such as used coffee grounds, dirt, or kitty litter. The mixture shall be placed in a sealable bag, empty can, or other container to prevent the drug from leaking or breaking out of a garbage bag.

2. By transferring it to law enforcement via a medication drop-box or drug take-back event if permissible under state and federal law.

**18VAC110-60-90 Revocation or suspension of a qualifying patient, parent, ~~or~~ legal guardian, or registered agent registration**

The board may revoke or suspend the registration of a registrant (i.e., a patient, parent, ~~or~~ legal guardian, or registered agent) under the following circumstances:

1. The patient's practitioner notifies the board that the practitioner is withdrawing the written certification submitted on behalf of the patient, and 30 days after the practitioner's withdrawal of the written certification, the patient has not obtained a valid written certification from a different practitioner;

2. The ~~patient, parent, or legal guardian~~ registrant provided false, misleading, or incorrect information to the board;

3. The ~~patient, parent, or legal guardian~~ registrant is no longer a resident of Virginia;

4. The ~~patient, parent~~, ~~or legal guardian~~ registrant obtained more than a 90-day supply of cannabis oil in a 90-day period;

5. The ~~patient, parent, or legal guardian~~ registrant provided or sold cannabis oil to any person, including another ~~registered patient, parent, or legal guardian~~ registrant;

6. The ~~patient, parent, or legal guardian~~ registrant permitted another person to use the registration of the ~~patient, parent, or legal guardian~~ registrant, except as required for a registered agent to act on behalf of a patient;

7. The ~~patient, parent, or legal guardian~~ registrant tampered, falsified, altered, modified, or allowed another person to tamper, falsify, alter, or modify the registration of the ~~patient, parent, or legal guardian~~ registrant;

8. The registration of the ~~patient, parent, or legal guardian~~ registrant was lost, stolen, or destroyed, and the ~~patient, parent, or legal guardian~~ registrant failed to notify the board or notified the board of such incident more than five business days after becoming aware that the registration was lost, stolen, or destroyed;

9. The ~~patient, parent, or legal guardian~~ registrant failed to notify the board of a change in registration information or notified the board of such change more than ~~14~~ 15 days after the change; or

10. The ~~patient, parent, or legal guardian~~ registrant violated any federal or state law or regulation.

**18VAC110-60-130 Granting of a pharmaceutical processor permit**

A. The board may issue a pharmaceutical processor permit when all requirements of the board have been met, to include:

1. Designation of a PIC;

2. Evidence of criminal background checks for all employees and delivery agents of the processor to ensure compliance with § 54.1-3442.6 of the Code of Virginia;

3. Evidence of utilization of an electronic tracking system; and

4. A satisfactory inspection of the facility conducted by the board or ~~its~~ the board's agents.

B. The permit shall not be awarded until any deficiency identified by inspectors has been corrected and the facility has been satisfactorily reinspected if warranted.

C. Before any permit is issued, the applicant shall attest to compliance with all state and local laws and ordinances. A pharmaceutical processor permit shall not be issued to any person to operate from a private dwelling or residence.

D. If an applicant has been awarded a pharmaceutical processor permit and has not commenced operation of such facility within 180 days of being notified of the issuance of a pharmaceutical processor permit, the board may rescind such permit, unless such delay was caused by circumstances beyond the control of the permit holder.

E. A pharmaceutical processor shall be deemed to have commenced operation if Cannabis plants are under cultivation by the processor in accordance with the approved application.

F. In the event a permit is rescinded pursuant to this section, the board may award a pharmaceutical processor permit by selecting among the qualified applicants who applied for the pharmaceutical processor permit subject to rescission. If no other qualified applicant who applied for such pharmaceutical processor permit satisfied the criteria for awarding a permit, the board shall publish in accordance with this section a notice of open applications for a pharmaceutical processor permit.

G. Once the permit is issued, ~~Cannabis may not be grown or held in the pharmaceutical processor earlier than two weeks prior to the opening date designated on the application~~ a processor may begin cultivation of Cannabis. Once Cannabis has been placed in the pharmaceutical processor, a pharmacist shall be present during hours of operation to ensure the safety, security, and integrity of the Cannabis. If there is a change in the designated opening date, the pharmaceutical processor shall notify the board office, and a pharmacist shall continue to be on site on a daily basis.

**18VAC110-60-160 Grounds for action against a pharmaceutical processor permit**

In addition to the bases enumerated in § 54.1-3316 of the Code of Virginia, the board may suspend, revoke, or refuse to grant or renew a permit issued; place such permit on probation; place conditions on such permit; or take other actions permitted by statute or regulation on the following grounds:

1. Any criminal conviction under federal or state statutes or regulations or local ordinances, unless the conviction was based on a federal statute or regulation related to the possession, purchase, or sale of cannabis oil that is authorized under state law and regulations;

2. Any civil action under any federal or state statute or regulation or local ordinance (i) relating to the applicant's, licensee's, permit holder's, or registrant's profession or (ii) involving drugs, medical devices, or fraudulent practices, including fraudulent billing practices;

3. Failure to maintain effective controls against diversion, theft, or loss of Cannabis, cannabis oil, or other controlled substances;

4. Intentionally or through negligence obscuring, damaging, or defacing a permit or registration card;

5. Permitting another person to use the permit of a permit holder or registration of a qualifying patient, parent, ~~or~~ legal guardian, or registered agent, except as required for a registered agent to act on behalf of a patient;

6. Failure to cooperate or give information to the board on any matter arising out of conduct at a pharmaceutical processor; or

7. Discontinuance of business for more than 60 days, unless the board approves an extension of such period for good cause shown upon a written request from a pharmaceutical processor. Good cause includes exigent circumstances that necessitate the closing of the facility. Good cause shall not include a voluntary closing of the pharmaceutical processor or production facility.

**18VAC110-60-170 Pharmaceutical processor employee licenses and registrations**

A. A pharmacist with a current, unrestricted license issued by the board practicing at the location of the address on the pharmaceutical processor application shall be in full and actual charge of a pharmaceutical processor and serve as the pharmacist-in-charge.

B. A pharmacist with a current, unrestricted license issued by the board shall provide personal supervision on the premises of the pharmaceutical processor at all times during hours of operation or whenever the processor is being accessed.

C. A person who holds a current, unrestricted registration as a pharmacy technician pursuant to § 54.1-3321 of the Code of Virginia and who has had at least two years of experience practicing as a pharmacy technician may perform the following duties under supervision of a pharmacist:

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

2. The preparation of labels for dispensing the oils or patient information;

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

4. The measuring of the oil to be dispensed;

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

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

7. The selling of the oil to the registered patient, parent, ~~or~~ legal guardian, or registered agent; and

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

D. A pharmacist with a current, unrestricted license; a registered pharmacy intern who has completed the first professional year of pharmacy school; or a pharmacy technician with a current, unrestricted registration issued by the board may perform duties associated with the cultivation, extraction, and dispensing of the oils as authorized by the PIC or as otherwise authorized in law.

E. A person who does not maintain licensure as a pharmacist or registration as a pharmacy technician but has received a degree in horticulture or has at least two years of experience cultivating plants may perform duties associated with the cultivation of Cannabis as authorized by the PIC.

F. A person who does not maintain licensure as a pharmacist or registration as a pharmacy technician but has received a degree in chemistry or pharmacology or has at least two years of experience extracting chemicals from plants may perform duties associated with the extraction of cannabis oil as authorized by the PIC.

G. A pharmaceutical processor may employ individuals who may have less than two years of experience to perform (i) cultivation-related duties under the supervision of an individual who has received a degree in horticulture or a certification recognized by the board or who has at least two years of experience cultivating plants and (ii) extraction-related duties under the supervision of an individual who has a degree in chemistry or pharmacology or at least two years of experience extracting chemicals from plants.

~~G.~~ H. A pharmacist on duty shall directly supervise the activities in all areas designated for cultivation, extraction, and dispensing or have a process in place, approved by the board, that provides adequate supervision to protect the security of the Cannabis, seeds, extracts, and cannabis oil and shall ensure quality of the dispensed oils. Pursuant to § 54.1-3442.6 of the Code of Virginia, the PIC may authorize certain employee access to secured areas designated for cultivation and other areas approved by the board. No pharmacist shall be required to be on the premises during such authorized access. The PIC shall ensure security measures are adequate to protect the cannabis from diversion at all times.

~~H.~~ I. Except for certain employee access to secured areas designated for cultivation and other areas approved by the board and authorized by the PIC pursuant § 54.1-3442.6, at no time shall a pharmaceutical processor operate or be accessed without a pharmacist on duty.

~~I.~~ J. No person shall be employed by or serve as an agent of a pharmaceutical processor without being at least 18 years of age.

~~J.~~ K. No person who has had a license or registration suspended or revoked or been denied issuance of such license or registration shall serve as an employee or agent of the pharmaceutical processor unless such license or registration has been reinstated and is current and unrestricted.

**18VAC110-60-190 Pharmacy technicians; ratio; supervision and responsibility**

A. The ratio of pharmacy technicians to pharmacists on duty in the areas of a pharmaceutical processor designated for production or dispensing shall not exceed four pharmacy technicians to one pharmacist.

B. The pharmacist providing direct supervision of pharmacy technicians may be held responsible for the pharmacy technicians' actions. Any violations relating to the dispensing of cannabis oil resulting from the actions of a pharmacy technician shall constitute grounds for action against the license of the pharmacist and the registration of the pharmacy technician. As used in this subsection, "direct supervision" means a supervising pharmacist who:

1. Is on duty where the pharmacy technician is performing routine cannabis oil production or dispensing functions; and

2. Conducts in-process and final checks on the pharmacy technician's performance.

C. Pharmacy technicians shall not:

1. Counsel a registered patient or the patient's parent ~~or~~, legal guardian, or registered agent regarding (i) cannabis oil, or other drugs either before or after cannabis oil has been dispensed or (ii) any medical information contained in a patient medication record;

2. Consult with the practitioner who certified the qualifying patient, or the practitioner's agent, regarding a patient or any medical information pertaining to the patient's cannabis oil or any other drug the patient may be taking;

3. Interpret the patient's clinical data or provide medical advice;

4. Determine whether a different formulation of cannabis oil should be substituted for the cannabis oil product or formulation recommended by the practitioner or requested by the registered patient or parent or legal guardian; or

5. Communicate with a practitioner who certified a registered patient, or the practitioner's agent, to obtain a clarification on a qualifying patient's written certification or instructions.

**18VAC110-60-200 Responsibilities of the PIC**

A. No person shall be PIC for more than one pharmaceutical processor or for one processor and a pharmacy at any one time. A processor shall employ the PIC at the pharmaceutical processor for at least 35 hours per week, except as otherwise authorized by the board.

B. The PIC or the pharmacist on duty shall control all aspects of the practice of the pharmaceutical processor. Any decision overriding such control of the PIC or other pharmacist on duty may be grounds for disciplinary action against the pharmaceutical processor permit.

C. The pharmaceutical processor PIC shall be responsible for ensuring that:

1. Pharmacy technicians are registered and all employees are properly trained;

2. All record retention requirements are met;

3. All requirements for the physical security of the Cannabis, to include the seeds, any parts or extracts of the Cannabis plants, and the cannabis oil are met;

4. The pharmaceutical processor has appropriate pharmaceutical reference materials to ensure that cannabis oil can be properly dispensed;

5. The following items are conspicuously posted in the pharmaceutical processor in a location and in a manner so as to be clearly and readily identifiable to registered patients, parents, ~~or~~ legal guardians, or registered agents:

a. Pharmaceutical processor permit;

b. Licenses for all pharmacists practicing at the pharmaceutical processor; and

c. The price of all cannabis oil products offered by the pharmaceutical processor; and

6. Any other required filings or notifications are made on behalf of the processor as set forth in regulation.

D. When the PIC ceases practice at a pharmaceutical processor or no longer wishes to be designated as PIC, he shall immediately return the pharmaceutical processor permit to the board indicating the effective date on which he ceased to be the PIC.

E. An outgoing PIC shall have the opportunity to take a complete and accurate inventory of all Cannabis, to include plants, extracts, or cannabis oil on hand on the date he ceases to be the PIC, unless the owner submits written notice to the board showing good cause as to why this opportunity should not be allowed.

F. A PIC who is absent from practice for more than 30 consecutive days shall be deemed to no longer be the PIC. If the PIC knows of an upcoming absence of longer than 30 days, he shall be responsible for notifying the board and returning the permit. For unanticipated absences by the PIC that exceed 15 days with no known return date within the next 15 days, the permit holder shall immediately notify the board and shall obtain a new PIC.

G. An application for a permit designating the new PIC shall be filed with the required fee within 14 days of the original date of resignation or termination of the PIC on a form provided by the board. It shall be unlawful for a pharmaceutical processor to operate without a new permit past the 14-day deadline unless the board receives a request for an extension prior to the deadline. The executive director for the board may grant an extension for up to an additional 14 days for good cause shown.

**18VAC110-60-210 General provisions**

A. A pharmaceutical processor shall only sell cannabis oil ~~only~~ in a child-resistant, secure, and light-resistant container. Upon a written request from the registered patient, parent, ~~or~~ legal guardian, or registered agent, the oil may be dispensed in a non-child-resistant container so long as all labeling is maintained with the product.

B. Only a pharmacist may dispense cannabis oil to registered patients or parents or legal guardians of patients who are minors or incapacitated adults and who are registered with the board, or to a patient's registered agent. A pharmacy technician who meets the requirements of 18VAC110-60-170 C may assist, under the direct supervision of a pharmacist, in the dispensing and selling of cannabis oil.

C. The PIC or pharmacist on duty shall restrict access to the pharmaceutical processor to:

1. A person whose responsibilities necessitate access to the pharmaceutical processor and then for only as long as necessary to perform the person's job duties; or

2. A person who is a registered patient, parent, ~~or~~ legal guardian, or registered agent, in which case such person shall not be permitted behind the service counter or in other areas where Cannabis plants, extracts, or cannabis oil ~~is~~ are stored.

D. All pharmacists and pharmacy technicians shall at all times while at the pharmaceutical processor have their current license or registration available for inspection by the board or the board's agent.

E. While inside the pharmaceutical processor, all pharmaceutical processor employees shall wear name tags or similar forms of identification that clearly identify them, including their position at the pharmaceutical processor.

F. A pharmaceutical processor shall be open for registered patients, parents, ~~or~~ legal guardians, or registered agents to purchase cannabis oil products for a minimum of 35 hours a week, except as otherwise authorized by the board.

G. A pharmaceutical processor that closes during its normal hours of operation shall implement procedures to notify registered patients, parents, ~~and~~ legal guardians, and registered agents of when the pharmaceutical processor will resume normal hours of operation. Such procedures may include telephone system messages and conspicuously posted signs. If the pharmaceutical processor is or will be closed during its normal hours of operation for longer than two business days, the pharmaceutical processor shall immediately notify the board.

H. A pharmacist shall counsel registered patients, parents, ~~and~~ legal guardians, and registered agents, if applicable, regarding the use of cannabis oil. Such counseling shall include information related to safe techniques for proper use and storage of cannabis oil and for disposal of the oils in a manner that renders them nonrecoverable.

I. The pharmaceutical processor shall establish, implement, and adhere to a written alcohol-free, drug-free, and smoke-free work place policy that shall be available to the board or the board's agent upon request.

**18VAC110-60-220 Pharmaceutical processor prohibitions**

A. No pharmaceutical processor shall:

1. Cultivate Cannabis plants or produce or dispense cannabis oil in any place except the approved facility at the address of record on the application for the pharmaceutical processor permit;

2. Sell, deliver, transport, or distribute Cannabis, including cannabis oil, to any other facility, except for the wholesale distribution of cannabis oil products between pharmaceutical processors;

3. Produce or manufacture cannabis oil for use outside of Virginia; or

4. Provide cannabis oil samples.

B. Except for certain employee access to secured areas designated for cultivation and other areas approved by the board and authorized by the PIC pursuant to § 54.1-3442.6 of the Code of Virginia, no pharmaceutical processor shall be open or in operation, and no person shall be in the pharmaceutical processor, unless a pharmacist is on the premises and directly supervising the activity within the pharmaceutical processor. At all other times, the pharmaceutical processor shall be closed and properly secured.

C. No pharmaceutical processor shall sell anything other than cannabis oil products from the pharmaceutical processor.

D. A pharmaceutical processor shall not advertise cannabis oil products, except it may post the following information on websites:

1. Name and location of the processor;

2. Contact information for the processor;

3. Hours and days the pharmaceutical processor is open for dispensing cannabis oil products;

4. Laboratory results;

5. Product information and pricing; and

6. Directions to the processor facility.

E. No cannabis oil shall be consumed on the premises of a pharmaceutical processor, except for emergency administration to a registered patient.

F. No person except a pharmaceutical processor employee ~~or~~, a registered patient, parent, or legal guardian, or a registered agent shall be allowed on the premises of a processor with the following exceptions: laboratory staff may enter a processor for the sole purpose of identifying and collecting Cannabis, or cannabis oil samples for purposes of conducting laboratory tests; the board or the board's authorized representative may waive the prohibition upon prior written request.

G. All persons who have been authorized in writing to enter the facility by the board or the board's authorized representative shall obtain a visitor identification badge from a pharmaceutical processor employee prior to entering the pharmaceutical processor.

1. An employee shall escort and monitor an authorized visitor at all times the visitor is in the pharmaceutical processor.

2. A visitor shall visibly display the visitor identification badge at all times the visitor is in the pharmaceutical processor and shall return the visitor identification badge to a pharmaceutical processor employee upon exiting the pharmaceutical processor.

3. All visitors shall log in and out. The pharmaceutical processor shall maintain the visitor log that shall include the date, time, and purpose of the visit and that shall be available to the board.

4. If an emergency requires the presence of a visitor and makes it impractical for the pharmaceutical processor to obtain a waiver from the board, the processor shall provide written notice to the board as soon as practicable after the onset of the emergency. Such notice shall include the name and company affiliation of the visitor, the purpose of the visit, and the date and time of the visit. A pharmaceutical processor shall monitor the visitor and maintain a log of such visit as required by this subsection.

H. No cannabis oil shall be sold, dispensed, or distributed via a delivery service or any other manner outside of a pharmaceutical processor, except that a registered parent, ~~or~~ legal guardian, or registered agent or an agent of the processor may deliver cannabis oil to the registered patient or in accordance with 18VAC110-60-310 A. Products may also be wholesale distributed between pharmaceutical processors.

I. Notwithstanding the requirements of subsection F of this section, an agent of the board or local law enforcement or other federal, state, or local government officials may enter any area of a pharmaceutical processor if necessary to perform their governmental duties.

**18VAC110-60-230 Inventory requirements**

A. Each pharmaceutical processor prior to commencing business shall:

1. Conduct an initial comprehensive inventory of all Cannabis plants, including the seeds, parts of plants, extracts, and cannabis oil, at the facility. The inventory shall include, at a minimum, the date of the inventory, a summary of the inventory findings, and the name, signature, and title of the pharmacist or pharmacy technician who conducted the inventory. If a facility commences business with no Cannabis on hand, the pharmacist shall record this fact as the initial inventory; and

2. Establish ongoing inventory controls and procedures for the conduct of inventory reviews and comprehensive inventories of all Cannabis plants, including the seeds, parts of plants, extracts, and cannabis oil, that shall enable the facility to detect any diversion, theft, or loss in a timely manner.

B. Upon commencing business, each pharmaceutical processor and production facility shall conduct a weekly inventory of all Cannabis plants, including the seeds, parts of plants, and cannabis oil in stock, that shall include, at a minimum, the date of the inventory, a summary of the inventory findings, and the name, signature, and title of the pharmacist or pharmacy technician who conducted the inventory. ~~The record of all cannabis oil sold, dispensed, or otherwise disposed of shall show the date of sale; the name of the pharmaceutical processor; the registered patient, parent, or legal guardian to whom the cannabis oil was sold; the address of such person; and the kind and quantity of cannabis oil sold.~~

C. The record of all cannabis oil sold, dispensed, or otherwise disposed of shall show the date of sale or disposition; the name of the pharmaceutical processor; the name and address of the registered patient, parent, ~~or~~ legal guardian, or registered agent to whom the cannabis oil was sold; the kind and quantity of cannabis oil sold or disposed of; and the method of disposal.

D. A complete and accurate record of all Cannabis plants, including the seeds, parts of plants, and cannabis oil on hand shall be prepared annually on the anniversary of the initial inventory or such other date that the PIC may choose, so long as it is not more than one year following the prior year's inventory.

E. All inventories, procedures, and other documents required by this section shall be maintained on the premises and made available to the board or its agent.

F. Inventory records shall be maintained for three years from the date the inventory was taken.

G. Whenever any sample or record is removed by a person authorized to enforce state or federal law for the purpose of investigation or as evidence, such person shall tender a receipt in lieu thereof and the receipt shall be kept for a period of at least three years.

**18VAC110-60-251 Wholesale distribution of cannabis oil products**

A. Cannabis oil products from a batch that passed the microbiological, mycotoxin, heavy metal, residual solvent, and pesticide chemical residue tests and are packaged and labeled for sale with an appropriate expiration date in accordance with 18VAC110-60-300 may be wholesale distributed between pharmaceutical processors and between a pharmaceutical processor and a cannabis dispensing facility.

B. A pharmaceutical processor wholesale distributing the oil products shall create a record of the transaction that shows (i) the date of distribution, (ii) the names and addresses of the processor distributing the product and the processor or cannabis dispensing facility receiving the product, and (iii) the kind and quantity of product being distributed. The record of the transaction shall be maintained by the distributing pharmaceutical processor with its records of distribution, and a copy of the record shall be provided to and maintained by the processor or facility receiving the product in its records of receipt. Such records shall be maintained by each process or facility for three years in compliance with 18VAC110-60-260.

C. A pharmaceutical processor wholesale distributing the oil products shall provide the receiving processor or cannabis dispensing facility with a copy of the lab results for the distributed product or electronic access to the information that can be shared upon request to registered patients, parents, legal guardians, registered agents, registered practitioners who have certified qualifying patients, or an agent of the board.

D. A pharmaceutical processor wholesale distributing cannabis oil products shall store and handle products and maintain policies and procedures, to include a process for executing or responding to mandatory and voluntary recalls, in a manner that complies with 18VAC110-60-250.

E. If a pharmaceutical processor wholesale distributing cannabis oil products uses an electronic system for the storage and retrieval of records related to distributing cannabis oil, the pharmaceutical processor shall use a system that is compliant with 18VAC110-60-260.

**18VAC110-60-300 Laboratory requirements; testing**

A. No pharmaceutical processor shall utilize a laboratory to handle, test, or analyze cannabis oil unless such laboratory:

1. Is independent from all other persons involved in the cannabis oil industry in Virginia, which shall mean that no person with a direct or indirect interest in the laboratory shall have a direct or indirect financial interest in a pharmacist, pharmaceutical processor, certifying practitioner, or any other entity that may benefit from the production, manufacture, dispensing, sale, purchase, or use of cannabis oil; and

2. Has employed at least one person to oversee and be responsible for the laboratory testing who has earned from a college or university accredited by a national or regional certifying authority at least (i) a master's level degree in chemical or biological sciences and a minimum of two years of post-degree laboratory experience or (ii) a bachelor's degree in chemical or biological sciences and a minimum of four years of post-degree laboratory experience.

B. After processing and before dispensing the cannabis oil product, a pharmaceutical processor shall make a sample available from each batch of product for a laboratory to (i) test for microbiological contaminants, mycotoxins, heavy metals, residual solvents, and pesticide chemical residue and (ii) conduct an active ingredient analysis and terpenes profile. The sample size shall be a statistically valid sample as determined by the board.

C. From the time that a batch of cannabis oil product has been homogenized for sample testing until the laboratory provides the results from its tests and analysis, the pharmaceutical processor shall segregate and withhold from use the entire batch, except the samples that have been removed by the laboratory for testing. During this period of segregation, the pharmaceutical processor shall maintain the batch in a secure, cool, and dry location so as to prevent the batch from becoming contaminated or losing its efficacy.

D. Under no circumstances shall a pharmaceutical processor sell a cannabis oil product prior to the time that the laboratory has completed its testing and analysis and provided a certificate of analysis to the pharmaceutical processor or other designated facility employee.

E. The processor shall require the laboratory to immediately return or properly dispose of any cannabis oil products and materials upon the completion of any testing, use, or research.

F. If a sample of cannabis oil product does not pass the microbiological, mycotoxin, heavy metal, or pesticide chemical residue test based on the standards set forth in this subsection, the pharmaceutical processor shall dispose of the entire batch from which the sample was taken.

1. For purposes of the microbiological test, a cannabis oil sample shall be deemed to have passed if it satisfies the standards set forth in Section 1111 of the United States Pharmacopeia.

2. For purposes of the mycotoxin test, a sample of cannabis oil product shall be deemed to have passed if it meets the following standards:

| Test Specification | |
|---|---|
| Aflatoxin B1 | <20 ug/kg of Substance |
| Aflatoxin B2 | <20 ug/kg of Substance |
| Aflatoxin G1 | <20 ug/kg of Substance |
| Aflatoxin G2 | <20 ug/kg of Substance |

| | |
|---|---|
| Ochratoxin A | <20 ug/kg of Substance |

3. For purposes of the heavy metal test, a sample of cannabis oil product shall be deemed to have passed if it meets the following standards:

| Metal | Limits - parts per million (ppm) |
|---|---|
| Arsenic | <10 ppm |
| Cadmium | <4.1 ppm |
| Lead | <10 ppm |
| Mercury | <2 ppm |

4. For purposes of the pesticide chemical residue test, a sample of cannabis oil product shall be deemed to have passed if it satisfies the most stringent acceptable standard for a pesticide chemical residue in any food item as set forth in Subpart C of the federal Environmental Protection Agency's regulations for Tolerances and Exemptions for Pesticide Chemical Residues in Food, 40 CFR Part 180.

5. For purposes of the active ingredient analysis, a sample of the cannabis oil product shall be tested for:

a. Tetrahydrocannabinol (THC);

b. Tetrahydrocannabinol acid (THC-A);

c. Cannabidiols (CBD); and

d. Cannabidiolic acid (CBDA).

6. For the purposes of the residual solvent test, a sample of the cannabis oil product shall be deemed to have passed if it meets the standards and limits recommended by the American Herbal Pharmacopia for Cannabis Inflorescence. If a sample does not pass the residual solvents test, the batch can be remediated with further processing. After further processing, the batch must be retested for microbiological, mycotoxin, heavy metal, residual solvents, and pesticide chemical residue, and an active ingredient analysis and terpenes profile must be conducted.

G. If a sample of cannabis oil product passes the microbiological, mycotoxin, heavy metal, residual solvent, and pesticide chemical residue test, the entire batch may be utilized by the processor for immediate packaging and labeling for sale. An expiration date shall be assigned to the product that is based upon validated stability testing that addresses product stability when opened and the shelf-life for unopened products.

H. The processor shall require the laboratory to file with the board an electronic copy of each laboratory test result for any batch that does not pass the microbiological, mycotoxin, heavy metal, residual solvents, or pesticide chemical residue test at the same time that it transmits those results to the pharmaceutical processor. In addition, the laboratory shall maintain the laboratory test results and make them available to the board or an agent of the board.

I. Each pharmaceutical processor shall have such laboratory results available upon request to registered patients, parents, ~~or~~ legal guardians, or registered agents and registered practitioners who have certified qualifying patients.

**18VAC110-60-310 Dispensing of cannabis oil**

A. A pharmacist in good faith may dispense cannabis oil to any registered patient, parent, or legal guardian as indicated on the written certification or to a registered agent for a specific patient.

1. Prior to the initial dispensing of oil pursuant to each written certification, the pharmacist or pharmacy technician at the location of the pharmaceutical processor shall view a current photo identification of the patient, parent, ~~or~~ legal guardian, or registered agent. The pharmacist or pharmacy technician shall verify in the

Virginia Prescription Monitoring Program of the Department of Health Professions or other program recognized by the board that the registrations are current, the written certification has not expired, and the date and quantity of the last dispensing of cannabis oil to the registered patient.

2. The pharmacist or pharmacy technician shall make and maintain for three years a paper or electronic copy of the current written certification that provides an exact image of the document that is clearly legible.

3. Prior to any subsequent dispensing, the pharmacist, pharmacy technician, or delivery agent shall view the current written certification and a current photo identification and current registration of the patient, parent, ~~or~~ legal guardian, or registered agent and shall maintain record of such viewing in accordance with policies and procedures of the processor.

B. A pharmacist may dispense a portion of a registered patient's 90-day supply of cannabis oil. The pharmacist may dispense the remaining portion of the 90-day supply of cannabis oil at any time except that no registered patient, parent, ~~or~~ legal guardian, or registered agent shall receive more than a 90-day supply of cannabis oil for a patient in a 90-day period from any pharmaceutical processor.

C. A dispensing record shall be maintained for three years from the date of dispensing, and the pharmacist or pharmacy technician under the direct supervision of the pharmacist shall affix a label to the container of oil that contains:

1. A serial number assigned to the dispensing of the oil;

2. The brand name of cannabis oil that was registered with the board pursuant to 18VAC110-60-285 and its strength;

3. The serial number assigned to the oil during production;

4. The date of dispensing the cannabis oil;

5. The quantity of cannabis oil dispensed:

6. A terpenes profile and a list of all active ingredients, including:

a. Tetrahydrocannabinol (THC);

b. Tetrahydrocannabinol acid (THC-A);

c. Cannabidiol (CBD); and

d. Cannabidiolic acid (CBDA);

7. A pass rating based on the laboratory's microbiological, mycotoxins, heavy metals, residual solvents, and pesticide chemical residue analysis;

8. The name and registration number of the registered patient;

9. The name and registration number of the certifying practitioner;

10. Directions for use as may be included in the practitioner's written certification or otherwise provided by the practitioner;

11. The name or initials of the dispensing pharmacist;

12. Name, address, and telephone number of the pharmaceutical processor;

13. Any necessary cautionary statement; and

14. A prominently printed expiration date based on stability testing and the pharmaceutical processor's recommended conditions of use and storage that can be read and understood by the ordinary individual.

D. A pharmaceutical processor shall not label cannabis oil products as "organic" unless the Cannabis plants have been organically grown and the cannabis oil products have been produced, processed, manufactured, and certified to be consistent with organic standards in compliance with 7 CFR Part 205.

E. The cannabis oil shall be dispensed in child-resistant packaging, except as provided in 18VAC110-60-210 A. A package shall be deemed child-resistant if it satisfies the standard for "special packaging" as set forth in the Poison Prevention Packaging Act of 1970 Regulations, 16 CFR 1700.1(b)(4).

F. No person except a pharmacist or a pharmacy technician operating under the direct supervision of a pharmacist shall alter, deface, or remove any label so affixed.

G. A pharmacist shall be responsible for verifying the accuracy of the dispensed oil in all respects prior to dispensing and shall document that each verification has been performed.

H. A pharmacist shall document a registered patient's self-assessment of the effects of cannabis oil in treating the registered patient's diagnosed condition or disease or the symptoms thereof. A pharmaceutical processor shall maintain such documentation in writing or electronically for three years from the date of dispensing and such documentation shall be made available in accordance with regulation.

I. A pharmacist shall exercise professional judgment to determine whether to dispense cannabis oil to a registered patient, parent, ~~or~~ legal guardian, or registered agent if the pharmacist suspects that dispensing cannabis oil to the registered patient, parent, ~~or~~ legal guardian, or registered agent may have negative health or safety consequences for the registered patient or the public.

**18VAC110-60-320 Dispensing error review and reporting; quality assurance program**

A. A pharmaceutical processor shall implement and comply with a quality assurance program that describes, in writing, policies and procedures to detect, identify, and prevent dispensing errors. A pharmaceutical processor shall distribute the written policies and procedures to all pharmaceutical processor employees and shall make the written policies and procedures readily available on the premises of the pharmaceutical processor. The policies and procedures shall include:

1. Directions for communicating the details of a dispensing error to the practitioner who certified a qualifying patient and to the qualifying patient, the patient's parent or legal guardian, the patient's registered agent, or appropriate family member if the patient is deceased or is unable to fully comprehend the communication. The communication shall describe methods of correcting the dispensing error or reducing the negative impact of the error on the qualifying patient; and

2. A process to document and assess dispensing errors to determine the cause of the error and an appropriate response.

B. A pharmaceutical processor shall use the findings of its quality assurance program to develop systems and workflow processes designed to prevent dispensing errors. A pharmaceutical processor PIC shall:

1. Inform pharmaceutical processor employees of changes to policy, procedure, systems, or processes made as a result of recommendations generated by the quality assurance program;

2. Notify all processor employees that the discovery or reporting of a dispensing error shall be relayed immediately to a pharmacist on duty;

3. Ensure that a pharmacist performs a quality assurance review for each dispensing error. A pharmacist shall commence such review as soon as is reasonably possible, but no later than two business days from the date the dispensing error is discovered; and

4. Create a record of every quality assurance review. This record shall contain at least the following:

a. The date of the quality assurance review and the names and titles of the persons performing the review;

b. The pertinent data and other information relating to the dispensing error reviewed;

c. Documentation of contact with the registered patient, parent, ~~or~~ legal guardian, or registered agent, where applicable, and the practitioner who certified the patient;

d. The findings and determinations generated by the quality assurance review; and

e. Recommended changes to pharmaceutical processor policy, procedure, systems, or processes if any.

C. A pharmaceutical processor shall maintain for three years a copy of the pharmaceutical processor's quality assurance program and records of all reported dispensing errors and quality assurance reviews in an orderly manner and filed by date.

# Notice of Public Hearing

Pursuant to subsection D of § 54.1-3443, the Board of Pharmacy is giving notice of a public hearing to consider placement of chemical substances in Schedule I of the Drug Control Act. The virtual public hearing will be conducted at **9:15 a.m. on March 30, 2021.** Instructions will be included in the agenda for the board meeting, also on March 30th. Public comment may also be submitted electronically or in writing prior to March 30th to Caroline Juran, Executive Director of the Board of Pharmacy to caroline.juran@dhp.virginia.gov.

**The following compounds are classified as synthetic opioids. Compounds of this type have been placed in Schedule I (§ 54.1-3446(1)) in previous legislative sessions.**

1. **1-{1-[1-(4-bromophenyl)ethyl]-4-piperidinyl}-1,3-dihydro-2H-benzimidazol-2-one (other name: Brorphine),** its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers and salts is possible within the specific chemical designation.

2. **N-(4-chlorophenyl)-N-[1-(2-phenylethyl)-4-piperidinyl]-propanamide (other names: para-chlorofentanyl, 4-chlorofentanyl),** its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers and salts is possible within the specific chemical designation.

3. **2-[(4-methoxyphenyl)methyl]-N,N-diethyl-5-nitro-1H-benzimidazole-1-ethanamine (other name: Metonitazene),** its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers and salts is possible within the specific chemical designation.

4. **N,N-diethyl-2-{[(4-ethoxyphenyl) methyl]-1H-benzimidazol-1-yl}-ethan-1-amine (other name: Etazene, Desnitroetonitazene),** its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers and salts is possible within the specific chemical designation.

**Based on its chemical structure, the following compound is expected to have depressant properties. Compounds of this type have been placed in Schedule I (§ 54.1-3446(4)) in previous legislative sessions.**

5. **5-(2-chlorophenyl)-1,3-dihydro-3-methyl-7-nitro-2H-1,4-benzodiazepin-2-one (other name: Meclonazepam)**, its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

**The following compound is classified as a cannabimimetic agent. Compounds of this type have been placed in Schedule I (§ 54.1-3446(6)) in previous legislative sessions.**

6. **ethyl-2-[1-(5-fluoropentyl)-1H-indole-3-carboxamido]-3,3-dimethylbutanoate (other name: 5-fluoro EDMB-PICA)**, its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

# VIRGINIA BOARD OF PHARMACY
# SPECIAL CONFERENCE COMMITTEE MINUTES

Wednesday, December 9, 2020
Commonwealth Conference Center
Second Floor
Board Room 3

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

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|---|---|
| CALL TO ORDER: | A meeting of a Special Conference Committee of the Board of Pharmacy was called to order at 9:07 am. |
| PRESIDING: | Glenn Bolyard, Committee Chair |
| MEMBERS PRESENT: | Ryan Logan, Committee Member |
| STAFF PRESENT: | Mykl Egan, Discipline Case Manager<br>Ileita Redd, Discipline Program Specialist<br>Jessica Kelley, DHP Adjudication Specialist<br>Claire Foley, DHP Adjudication Specialist |
| NDIEC Medical Supplies & Innovation Pharmacy<br>Permit No. 0201-004884 | Solange Sirri, Pharmacist-in-Charge of NDIEC Medical Supplies and Innovation Pharmacy ("NDIEC") appeared as a representative of NDIEC to discuss allegations that the pharmacy may have violated certain laws and regulations governing the conduct of a pharmacy as stated in the October 29, 2020 Notice. |
| Closed Meeting: | Upon a motion by Mr. Logan, and duly seconded by Mr. Bolyard, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of NDIEC. Additionally, he moved that Mykl Egan and Ileita Redd attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations. |
| Reconvene: | Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision. |

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|---|---|
| Decision: | Upon a motion by Mr. Logan and duly seconded by Mr. Bolyard, the Committee voted unanimously to assess a monetary penalty against NDIEC, place a condition in the current PIC and to order an unannounced inspection of the pharmacy within six months. |
| BAILEYS PHARMACY<br>Permit No. 0201-004427 | Ibrahim Mohamed, Pharmacist-in-Charge of Baileys Pharmacy appeared as a representative of Baileys Pharmacy to discuss allegations that the pharmacy may have violated certain laws and regulations governing the conduct of a pharmacy as stated in the September 29, 2020 Notice. Baileys Pharmacy was represented by Hunter Jamerson, Esq. |
| Closed Meeting: | Upon a motion by Mr. Logan, and duly seconded by Mr. Bolyard, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of Baileys Pharmacy. Additionally, he moved that Mykl Egan and Ileita Redd attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations. |
| Reconvene: | Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision. |
| Decision: | Upon a motion by Mr. Logan and duly seconded by Mr. Bolyard, the Committee voted unanimously to refer the matter to a formal administrative hearing. |
| LINCARE, INC.<br>Permit No. 0206-008395 | No one appeared as a representative of Lincare, Inc. to discuss allegations that the facility may have violated certain laws and regulations governing the conduct of a medical equipment supplier as stated in the October 29, 2020 Notice. |

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| Closed Meeting: | Upon a motion by Mr. Logan, and duly seconded by Mr. Bolyard, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of Lincare, Inc.. Additionally, he moved that Mykl Egan and Ileita Redd attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations. |
| Reconvene: | Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision. |
| Decision: | Upon a motion by Mr. Logan and duly seconded by Mr. Bolyard, the Committee voted unanimously to assess a monetary penalty against Lincare, Inc. |
| ADJOURNED: | 1:18 pm |

_____
Glen Bolyard, Chair

_____
Date

_____
Ellen B. Shinaberry
Deputy Executive Director

_____
Date

(DRAFT/UNAPPROVED)

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

December 10, 2020
Virtual Meeting

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

CALL TO ORDER: A virtual Webex meeting of the Board of Pharmacy was called to order at 9:20 AM. Due to the COVID-19 declared state of emergency and consistent with Amendment 28 to HB29 (Budget Bill for 2018-2020) and the applicable provisions of § 2.2-3708.2 in the Freedom of Information Act, the Board convened a virtual meeting to consider such regulatory and business matters as was presented on the agenda necessary for the board to discharge its lawful purposes, duties, and responsibilities.

PRESIDING: Kristopher Ratliff, Chairman

MEMBERS PRESENT:
Cheryl H. Nelson, Vice Chairman
James L. Jenkins, Jr.
Glen Bolyard
Ryan Logan
Patricia Richards-Spruill
Sarah Melton
Dale St.Clair
William Lee
Bernard Henderson, Jr.

STAFF PRESENT:
Caroline D. Juran, Executive Director (On-Site)
Ellen B. Shinaberry, Deputy Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director
Annette Kelley, Deputy Executive Director
Beth O'Halloran, Deputy Executive Director
Elaine Yeatts, Senior Policy Analyst, DHP (On-Site)
David E. Brown, D.C., Director, DHP
Barbara Allison-Bryan, M.D., Chief Deputy, DHP
James Rutkowski, Assistant Attorney General
Melody Morton, Inspection Manager, DHP
Kiara Christian, Executive Assistant

PHARMACISTS AWARDED 1-HOUR OF LIVE OR REAL-TIME INTERACTIVE
Cheryl Nelson
David Ombengi
Katrina C Trelease

| | |
|---|---|
| CONTINUING EDUCATION FOR ATTENDING MEETING: | Caroline Juran |
| QUORUM | With ten members participating, a quorum was established. |
| APPROVAL OF AGENDA: | Mr. Ratliff reported that staff recommended additions to the tentative agenda previously provided. |
| **MOTION:** | **The agenda was unanimously approved as amended as described below:**<br>• **Insert topic Authorization for the Ad-hoc committee to direct staff to collect additional information necessary before the review of pharmaceutical processor applications. (motion by Nelson, seconded by Jenkins)** |
| APPROVAL OF PREVIOUS BOARD MEETING MINUTES | Ms. Nelson offered that the September 8 Informal Conference minutes should be amended to correctly identify Aviance S. Lewis as a Pharmacist. |
| **MOTION:** | **The Board voted unanimously to adopt the minutes for the September 8, 2020 Informal Conference as amended by removing pharmacy technician and replacing with Pharmacist, and adopted the minutes for the other meetings held between September 9, 2020 and November 16, 2020 as presented. ( motion by Nelson, seconded by Richards-Spruill)** |
| PUBLIC COMMENTS: | Mr. Ratliff offered a reminder that the public comment period related to Regulatory action on medication carousel or RFID was closed. Mr. Ratliff stated, as indicated in the meeting notice on Regulatory Townhall and in the agenda package that comments would be received during this public comment period via WebEx from those persons who submitted an email to Caroline Juran no later than 8am on December 10, 2020 indicating that they wish to offer comment.<br><br>Christina Barrille, Executive Director of the Virginia Pharmacists Association (VPhA), thanked the board for their work thorough the pandemic and for the board prioritizing the state protocol workgroup meetings. She said that VPhA is planning a conference to help educate pharmacist interested in implementing the new services into their practice. VPhA anticipates that HHS will implement authority for Pharmacist to prescribe therapies to patients with a positive COVID test. She encouraged the board to take a proactive position for the board to keep medical cannabis oversite under control of medical providers. Ms. Barrille asked the board to take due diligence when reviewing pharmaceutical processor applications. She asked that the guidance for |

collaborative practice agreement found on page 79 of the agenda packet be amended to remove number 2 to conform to the code. She offered support of the recommendation for a periodic review of the collaborative practice agreements. She thanked the committee for accepting VPhA's bullet point 2 located on page 96 of the agenda packet. Ms. Barille shared an invitation to a VPhA workshop to be held with The Medical Society of Virginia regarding the storage and administration of Pfizer's vaccine.

DHP DIRECTOR'S REPORT:

Dr. Brown welcomed Bernard Henderson to the board. Dr. Brown stated the Legislative Session would be held virtually this year in response to the COVID pandemic. He said there are no bills from the Department of Health Professions being presented. Dr. Brown offered that he anticipated bills being introduced to allow pharmaceutical processors to distribute marijuana flower.

Dr. Allison Bryan thanked pharmacist for their services provided for administration of the COVID vaccine. She offered her anticipation of the medical use authorization from the FDA for the Pfizer COVID vaccine.

LEGISLATIVE/ REGULATORY/ GUIDANCE

REPORT ON REGULATORY ACTION:

Ms. Yeatts provided an overview of regulatory actions on pages 51 and 52 of the agenda packet. Many of the actions are in the Governor's office.

Mr. Ratliff asked about the prohibition against incentives to transfer prescriptions. Ms. Yeatts stated she would follow up with the Governor's office for an update.

ADOPTION OF PROPOSED REGULATION TO PROHIBIT OIL PRODUCTS INTENDED TO BE VAPED THAT CONTAIN VITAMIN E ACETATE

Ms. Yeatts provided the board with a review of the emergency action leading up to the proposed regulation language as presented on page 56 of the agenda packet.

**MOTION:**

**The board voted unanimously to adopt the language in 18VAC110-60-280 as presented. (motion by Nelson, seconded by St. Clair)**

ADOPTION OF EXEMPT REGULATION TO PLACE CHEMICALS INTO SCHEDULE I

Ms. Yeatts provided an overview of the exempt regulations to place chemicals into schedule one. She reviewed page 57-62 of the agenda packet.

**MOTION:**

**The board voted unanimously to adopt the final regulation amending 18VAC110-20-322 as presented which places the following chemicals into Schedule I:**

- **N,N-diethyl-2-[(4-methoxyphenyl)methyl]-1H-benzimidazole-1-ethanamine (other name: Metodesnitazene)**
- **4-fluoro-3-methyl-alpha-pyrrolidinovalerophenone (other name: 4-fluoro-3-methyl-alphaPVP)**
- **4-fluoro-alpha-methylamino-valerophenone (other name: 4-fluoropentedrone)**
- **N-(1,4-dimethylpentyl)-3,4-dimethoxyamphetamine (other name: N-(1,4-dimethylpentyl)-3,4- DMA)**
- **4,5-methylenedioxy-N,N-diisopropyltryptamine (other name: 4,5-MDO-DiPT)**
- **alpha-pyrrolidinocyclohexanophenone (other name: alpha-PCYP)**
- **3,4-methylenedioxy-alpha-pyrrolidinoheptiophenone (other name: MDPV8)**
- **Bromazolam**
- **Deschloroetizolam**
- **7-chloro-5-(2-fluorophenyl)-1,3-dihydro-1,4-benzodiazepin-2-one (other name: Norfludiazepam)**
- **Methyl-2-[1-(4-fluorobutyl)-1H-indole-3-carboxamido]-3,3-dimethylbutanoate (other name: 4-fluoro-MDMB-BUTICA)**
- **Ethyl-2-[1-(5-fluoropentyl)-1H-indole-3-carboxamido]-3-methylbutanoate (other name: 5- fluoro-EMB-PICA)**

ADOPTION OF EXEMPT REGULATIONS – SCHEDULING CHANGE FOR CONSISTENCY WITH DEA

Ms. Yeatts reviewed page 67 of the agenda. Ms. Juran clarified that the language mirrors the action that was taken by DEA, and offered that DEA only schedules products I-V, and does not govern schedule VI.

**MOTION:**

**The board voted unanimously to amend 18VAC110-20-323 as presented by deleting number 4 which removes cannabidiol from Schedule V to conform with DEA's action. (motion by Nelson, seconded by Lee)**

CONSIDERATION OF AMENDMENTS TO INCORPORATE CHANGES CURRENTLY IN APPROVED PILOTS- MEDICATION CAROUSELS AND RFID TECHNOLOGY

Ms. Yeatts provided a review on the background of the action. Ms. Yeatts pointed out the highlighted language that was not included in the notice of intent. Ms. Yeatts reminded the board that the action is now to propose language to go into the regulation, and that there would be a 60 day public comment period and public hearing

Ms. Juran provided an overview of the changes made. There was discussion by the board concerning the verification rate. Ms. Juran gave a review of the background of robotic technology and medication carousel and offered that no errors had been reported with use of the technology.

**MOTION:**

**The board voted unanimously to adopt amendments recommended by the Regulation Committee to 18VAC110-20-425 and new section 18VAC110-20-505, as posted with the Notice of Intended Regulatory Action (NOIRA), to incorporate allowances for medication carousels with robotic systems and for use of RFID technology in provision of floor stock. (motion by Lee, seconded by Nelson)**

AMENDMENTS TO GUIDANCE DOCUMENTS

Ms. Yeatts recommended that Guidance 110-13 be reviewed as a separate topic so that the board may consider public comment received.

Ms. Yeatts reviewed Guidance Documents on pages 75-98 of the agenda packet stating many changes were to conform to legislative changes made by the General Assembly and recommendations made by the regulation committee.

Guidance Document 110-39

The board discussed the Guidance Document 110-39 "Continuous Hours Worked by Pharmacist and Breaks",allowing a pharmacist to use professional judgement when closing the pharmacy, and whether public notice is required.

**MOTION:**

**The board voted 9-0 (Logan abstained), to amend the recommendation of the Regulation Committee and adopt Guidance Document 110-39 with the addition of "14 days" before "in advance of the closure". (motion by Richards-Spruill, seconded by St. Clair).**

Guidance Document 110-1, 110-29, 110, 44, 110-40, repeal Guidance Document 110-41

**MOTION:**

**The board voted unanimously to accept the recommendations from the Regulation Committee to adopt Guidance Document 110-1, 110-29, 110, 44, and 110-40 as presented, and to repeal Guidance Document 110-41.**

Guidance Document 110-13

Ms. Yeatts provided a review of Guidance Document 110-13 on page number 79 of the agenda packet.

Ms. Juran reminded the board that this chapter will be considered for periodic review later on the agenda. There was discussion about removing number 2 from the document. Ms. Juran stated that removing number 2 from the document does not remove the requirement of the regulation. In order to change the requirement, the regulation must be amended. Ms. Yeatts stated that removing number 2 is not going to change the requirement which is word for word in the regulation.

**A motion was made to strike number 2 from guidance document 110-13. (motion by Lee, seconded by Jenkins). Second retracted by Jenkins. There was no second and the motion died.**

**MOTION:**

**The board voted 7-3 (opposed Henderson, Lee, Ratliff) to adopt Guidance Document 110-13 as presented. (motion by St. Clair, seconded by Nelson)**

ADOPTION OF A NOTICE OF PERIODIC REVIEW

Ms. Yeatts reviewed the recommendation by the regulation committee to initiate a periodic review of the following chapters:

- 18 VAC 110-20 Regulations Governing the Practice of Pharmacy
- 18 VAC 110-21 Regulations Governing the Licensure of Pharmacist and Registration of Pharmacy Technicians
- 18 VAC 110-30 Regulations for the Practitioners of the Healing Arts to Sell Controlled Substances
- 18 VAC 110-40 Regulations Governing Collaborative Practice Agreements
- 18 VAC 110-50 Regulations Governing Wholesale Distributors, Manufacturers and Warehousers

**MOTION:**

**The board voted unanimously to accept the recommendation of the Regulation Committee to initiate a periodic review for the recommended chapters.**

AUTHORIZATION FOR THE AD-HOC COMMITTEE TO ASK STAFF TO COLLECT ADDITIONAL INFORMATION NECESSARY FOR REVIEW OF PHARMACEUTICAL PROCESSORS

Mr. Ratliff asked the board to consider authorization for the Ad-hoc committee to direct staff to collect additional information necessary for review of pharmaceutical processor applications.

**MOTION:**

**The board voted unanimously to delegate authority to the ad hoc committee to direct staff to collect additional information from the pharmaceutical processors applications if necessary. (motion by Nelson, seconded by Bolyard)**

**REPORTS:**

CHAIRMAN'S REPORT

Mr. Ratliff thanked pharmacist and technicians for their services during COVID. He offered that he looks forward to attending the NABP Interactive Forum. Mr. Ratliff thanked board staff, Cheryl Nelson, and Jim Jenkins, and welcomed Mr. Bernard Henderson to the board.

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| REPORT ON BOARD OF HEALTH PROFESSIONS | Mr. Logan offered that the Board of Health Professions meeting for November was rescheduled for January. |
| REPORT ON LICENSURE REPORT | Ms. O' Halloran reviewed page 100 of the agenda packet |
| REPORT ON INSPECTION PROGRAM | Mr. Johnson reviewed the report provided on pages 101-111 of the agenda packet. Melody Morton, Inspection Manager, was available for questions about current inspections. She provided an overview of the inspection process during the COVID-19 declared emergency. |
| REPORT ON PHARMACEUTICAL PROCESSORS | Ms. Kelley reviewed the report provided on page 112 of the agenda packet. |
| REPORT ON DISCIPLINARY PROGRAM | Ms. Shinaberry reviewed the disciplinary report provided on page 113 of the agenda packet. |
| EXECUTIVE DIRECTORS REPORT | Ms. Juran reviewed the report provided on page 114 of the agenda packet. She reviewed the legislation reports on paged that were recently required of the Board. |
| CLOSED SESSION: | Upon a motion by Ms. Nelson, and duly seconded by Mr. Richards-Spruill, the panel voted 10-0, to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia ("Code"), for the purpose of deliberation to reach a decision regarding a consent order involving Andrew E. Norris. Additionally, it was moved that Caroline Juran, Ellen Shinaberry, Kiara Christian and Jim Rutkowski attend the closed meeting. |
| RECONVENE: | Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the panel re-convened an open meeting and announced the decision. (motion by Nelson, seconded by Henderson) |
| DECISION:<br>*Andrew E. Norris* | Upon a motion by Nelson, and duly seconded by Mr. Richards-Spruill, the panel voted 10-0 to accept the consent order proposed by Ms. Shinaberry regarding Andrew E. Norris. |
| **MEETING ADJOURNED:** | 1:13 PM |

Kristopher Ratliff, Chairman

DATE:

Caroline D. Juran, Executive Director

DATE:

(DRAFT/UNAPPROVED)

# VIRGINIA BOARD OF PHARMACY

## PUBLIC HEARING TO SCHEDULE CERTAIN CHEMICALS IN SCHEDULE I

December 10, 2020
Virtual Meeting

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: The public hearing was called to order at 9:07a.m.

PRESIDING: Kristopher Ratliff, Chairman

MEMBERS PRESENT:
Cheryl Nelson, Vice Chairman
Glen Bolyard
James L. Jenkins, Jr.
Ryan Logan
Patricia Richards-Spruill
William Lee
Sarah Melton
Dale St. Clair
Bernard Henderson

STAFF PRESENT:
Caroline D. Juran, Executive Director (On-Site)
Ellen B. Shinaberry, Deputy Executive Director
James Johnson, Deputy Executive Director
Annette Kelley, Deputy Executive Director
Beth O' Halloran, Deputy Executive Director
Elaine Yeatts, Senior Policy Analyst, DHP (On-Site)
David E. Brown, D.C., Director, DHP
Barbara Allison-Bryan, M.D., Chief Deputy, DHP
James Rutkowski, Assistant Attorney General
Melody Morton, Inspection Manager, DHP
Kiara Christian, Executive Assistant

CALL FOR PUBLIC COMMENT:

**Mr. Ratliff called for comment to consider placement of the following chemicals into Schedule I:**

**Synthetic Opioid:**

- **N,N-diethyl-2-[(4-methoxyphenyl)methyl]-1H-benzimidazole-1-ethanamine (other name: Metodesnitazene)**

**Compounds expected to have hallucinogenic properties:**

- **4-fluoro-3-methyl-alpha-pyrrolidinovalerophenone (other name: 4-fluoro-3-methyl-alpha-PVP)**
- **4-fluoro-alpha-methylamino-valerophenone (other name: 4-fluoropentedrone)**
- **N-(1,4-dimethylpentyl)-3,4-dimethoxyamphetamine (other name: N-(1,4-dimethylpentyl)-3,4-DMA)**
- **4,5-methylenedioxy-N,N-diisopropyltryptamine (other name: 4,5-MDO-DiPT)**

- **alpha-pyrrolidinocyclohexanophenone (other name: alpha-PCYP)**
- **3,4-methylenedioxy-alpha-pyrrolidinoheptiophenone (other name: MDPV8)**

**Compounds expected to have depressant properties:**

- **Bromazolam**
- **Deschloroetizolam**
- **7-chloro-5-(2-fluorophenyl)-1,3-dihydro-1,4-benzodiazepin-2-one (other name: Norfludiazepam)**

**Cannabimimetric agents:**

- **methyl 2-[1-(4-fluorobutyl)-1H-indole-3-carboxamido]-3,3-dimethylbutanoate (other name:4-fluoro-MDMB-BUTICA)**
- **ethyl 2-[1-(5-fluoropentyl)-1H-indole-3-carboxamido]-3-methylbutanoate (other name: 5-fluoro-EMB-P1CA)**

If approved by the Board of Pharmacy, the placement of these substances in Schedule I shall go into effect 30 days following publication of the proposed regulation and remain in effect for a period of 18 months. The chemicals will then be de-scheduled unless a general law is passed by the General Assembly placing the chemicals into Schedule I

PULIC COMMENT: Robyn Weimer, Virginia Department of Forensic Science, briefly reviewed the recommendation submitted to the board for consideration of placing into Schedule I.

ADJOURN: The public hearing adjourned at 9:16am.

Kristopher Ratliff, Chairman

Caroline D. Juran, Executive Director

Date

Date

(DRAFT/UNAPPROVED)

# VIRGINIA BOARD OF PHARMACY

## PUBLIC HEARING FOR REVISION TO SCHEDULING TO CONFORM TO DEA DE-SCHEDULING FOR EPIDIOLEX

December 10, 2020
Virtual Meeting

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: The public hearing was called to order at 9:07a.m.

PRESIDING: Kristopher Ratliff, Chairman

MEMBERS PRESENT:
Cheryl Nelson, Vice Chairman
Glen Bolyard
James L. Jenkins, Jr.
Ryan Logan
Patricia Richards-Spruill
William Lee
Sarah Melton
Dale St. Clair
Bernard Henderson

STAFF PRESENT:
Caroline D. Juran, Executive Director (On-Site)
Ellen B. Shinaberry, Deputy Executive Director
James Johnson, Deputy Executive Director
Annette Kelley, Deputy Executive Director
Beth O' Halloran, Deputy Executive Director
Elaine Yeatts, Senior Policy Analyst, DHP (On-Site)
David E. Brown, D.C., Director, DHP
Barbara Allison-Bryan, M.D., Chief Deputy, DHP
James Rutkowski, Assistant Attorney General
Melody Morton, Inspection Manager, DHP
Kiara Christian, Executive Assistant

CALL FOR PUBLIC COMMENT: Mr. Ratliff noted that to conform the Drug Control Act to recent changes enacted by the Drug Enforcement Administration, the board will consider:

- Deleting #4 from 18VAC110-20-323 which will remove cannabidiol from Schedule V and by default, place it into Schedule VI.

The revision action would remain into effect permanently, unless otherwise amended.

PULIC COMMENT: Jan Burrows, State Government Affairs Director, Greenwich BioScience, offered support of removing Epidiolex from Schedule V in accordance with Federal Law.

Dillon Bishop, Cannabiz Business Association, offered support of de-scheduling Epidiolex.

ADJOURN: The public hearing adjourned at 9:16am.

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| Kristopher Ratliff, Chairman | Caroline D. Juran, Executive Director |
| Date | Date |

(DRAFT/UNAPPROVED)

# VIRGINIA BOARD OF PHARMACY
# SPECIAL CONFERENCE COMMITTEE MINUTES

Tuesday January 12, 2021
Commonwealth Conference Center
Second Floor
Board Room 2

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

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| CALL TO ORDER: | A meeting of a Special Conference Committee of the Board of Pharmacy was called to order at 9:04 am. |
| PRESIDING: | Cheryl Nelson, Committee Chair |
| MEMBERS PRESENT: | William Lee, Committee Member |
| STAFF PRESENT: | Mykl Egan, Discipline Case Manager<br>Ileita Redd, Discipline Program Specialist<br>Jessica Kelley, DHP Adjudication Specialist |
| SANDRA TRAINUM<br>Registration No. 0230-001534 | Sandra Trainum, pharmacy technician, did not appear to discuss allegations that she may have violated certain laws and regulations governing her practice as a pharmacy technician as stated in the October 29, 2020, Notice. |
| Closed Meeting: | Upon a motion by Mr. Lee, and duly seconded by Ms. Nelson, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of Sandra Trainum. Additionally, he moved that Mykl Egan and Ileita Redd attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations. |
| Reconvene: | Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision. |

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|---|---|
| Decision: | Upon a motion by Mr. Lee, and duly seconded by Ms. Nelson, the Committee unanimously voted to refer the matter to a Formal Hearing and to offer Ms. Trainum a Consent Order. |
| JONATHAN RIEDY<br>License No. 0202-214328 | Jonathan Riedy, pharmacist, did not appear to discuss allegations that he may have violated certain laws and regulations governing his practice as a pharmacist as stated in the August 13, 2020, Notice. |
| Closed Meeting: | Upon a motion by Ms. Nelson, and duly seconded by Mr. Lee, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of Jonathan Riedy. Additionally, she moved that Mykl Egan and Ileita Redd attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations. |
| Reconvene: | Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision. |
| Decision: | Upon a motion by Ms. Nelson, and duly seconded by Mr. Lee, the Committee unanimously voted to order Mr. Riedy to take four additional hours of continuing education. |
| WALGREENS #10416<br>Permit No. 0201-004180 | No one appeared as a representative of Walgreens #10416 to discuss allegations that it may have violated certain laws and regulations governing the conduct of a pharmacy as stated in the November 12, 2020 Notice. |
| Closed Meeting: | Upon a motion by Mr. Lee, and duly seconded by Ms. Nelson, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of |

Walgreens #10416. Additionally, he moved that Mykl Egan and Ileita Redd attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

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

Decision: Upon a motion by Mr. Lee and duly seconded by Ms. Nelson, the Committee voted unanimously to issue a monetary penalty against Walgreens #10416 and to order that an unannounced inspection of Walgreens take place within 6 months.

ADJOURNED: 3:00 pm

_____ _____

Cheryl Nelson, Chair

Ellen B. Shinaberry
Deputy Executive Director

_____ _____

Date

Date

(DRAFT/UNAPPROVED)

# VIRGINIA BOARD OF PHARMACY
# SPECIAL CONFERENCE COMMITTEE MINUTES

Tuesday, January 26, 2021
Commonwealth Conference Center
Second Floor
Board Room 3

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

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| CALL TO ORDER: | A meeting of a Special Conference Committee of the Board of Pharmacy was called to order at 9:15 am. |
| PRESIDING: | Glenn Bolyard, Committee Chair |
| MEMBERS PRESENT: | Ryan Logan, Committee Member |
| STAFF PRESENT: | Mykl Egan, Discipline Case Manager<br>Ileita Redd, Discipline Program Specialist<br>Jessica Kelley, DHP Adjudication Specialist |
| GREEN HEALTH INTEGRATIVE & WELLNESS PHARMACY<br>Permit No. 0201-004861 | Kwame Binfo Ennin, Pharmacist-in-Charge of Green Health Integrative & Wellness Pharmacy appeared as a representative of Green Health Integrative & Wellness Pharmacy to discuss allegations that the pharmacy may have violated certain laws and regulations governing the conduct of a pharmacy as stated in the November 12, 2020 Notice. |
| Closed Meeting: | Upon a motion by Mr. Logan, and duly seconded by Mr. Bolyard, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of Green Health Integrative & Wellness Pharmacy. Additionally, he moved that Mykl Egan and Ileita Redd attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations. |
| Reconvene: | Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee |

reconvened in open meeting and announced the decision.

Decision: Upon a motion by Mr. Logan and duly seconded by Mr. Bolyard, the Committee voted unanimously to assess a monetary penalty against Green Health Integrative & Wellness Pharmacy, order Mr. Ennin to take additional continuing education hours and place Green Health Integrative & Wellness Pharmacy on probation under certain terms and conditions.

ADJOURNED: 11:30 a.m.

_____
Glen Bolyard, Chair

_____
Ellen B. Shinaberry
Deputy Executive Director

_____
Date

_____
Date

# (DRAFT/UNAPPROVED)
## VIRGINIA BOARD OF PHARMACY
## MINUTES OF A PANEL OF THE BOARD

Tuesday, February 23, 2021
Commonwealth Conference Center
Second Floor
Board Room 2

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

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

CALL TO ORDER: A meeting of a panel of the Board of Pharmacy ("Board") was called to order at 11:12 AM.

PRESIDING: Kris Ratliff, Chairman

MEMBERS PRESENT:
Dale St. Clair
Bill Lee
Ryan Logan
Cheryl Nelson
Bernie Henderson
Jim Jenkins

STAFF PRESENT:
Caroline D. Juran, Executive Director
Ellen B. Shinaberry, Deputy Executive Director
James Rutkowski, Assistant Attorney General
Kiara Christian, Administrative Assistant

QUORUM: With six (7) members of the Board present, a panel of the board was established.

PATIENT'S CHOICE DISCOUNT PHARMACY
License No. 0201-004571

A formal hearing was held in the matter of Patient's Choice Discount Pharmacy to discuss allegations that Patient's Choice Discount Pharmacy may have violated certain laws and regulations governing the practice of pharmacy in Virginia.

Sean Murphy, Asst. Attorney General for the Commonwealth, presented the case with assistance from Jess Kelly, DHP Adjudication Specialist.

Preston Grobes, Owner and Pharmacist in Charge of Patient's Choice Discount Pharmacy was present and was represented by counsel Yohanna Manning, Esq and Damarius Ortez-Gonzalez, Esq.

Emily Buss, DHP Senior Pharmacy Inspector, testified by telephone on behalf of the Commonwealth.

Mr. Grobes and Timothy O'Connell, MD testified in person on behalf of Patient's Choice Discount Pharmacy.
Willis Triplett, Pharm.D, Pharmacy consultant, and Courtney Cousineau, patient of Patient's Choice Discount Pharmacy, testified by telephone on behalf of Patient's Choice Discount Pharmacy.

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| CLOSED MEETING: | Upon a motion by Ms. Nelson, and duly seconded by Mr. Logan, the panel voted 7-0, to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia ("Code"), for the purpose of deliberation to reach a decision regarding the matter of Patient's Choice Discount Pharmacy. Additionally, she moved that Caroline Juran, Ellen Shinaberry, Kiara Christian and Jim Rutkowski attend the closed meeting. |
| RECONVENE: | Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the panel re-convened an open meeting and announced the decision. |
| DECISION: | Upon a motion by Mr. Jenkins, and duly seconded by Mr. Henderson, the panel voted 7-0 to accept the Findings and Facts and Conclusion of Law proposed by the Commonwealth and revised by the Board. Upon a motion by Mr. Lee, and duly seconded by Mr. St. Clair, the panel voted 7-0 to issue a monetary penalty and require additional unannounced inspections. |
| ADJOURN: | With all business concluded, the meeting adjourned at 6:39 PM. |

Kris Ratliff, Chair

Caroline D. Juran
Executive Director

Date

## Legislative Report

## 2021 General Assembly

HB 1737 **Nurse practitioners; practice without a practice agreement.**

*Summary as passed House:*

**Nurse practitioners; practice without a practice agreement.** Reduces from five to two the number of years of full-time clinical experience a nurse practitioner must have to be eligible to practice without a written or electronic practice agreement. The bill has an expiration date of July 1, 2022.

HB 1747 **Clinical nurse specialist; licensure of nurse practitioners as specialists, etc.**

*Summary as passed House:*

**Clinical nurse specialist; licensure; practice.** Changes for clinical nurse specialists the requirement to register with the Board of Nursing as a clinical nurse specialist to licensure by the Boards of Medicine and Nursing to practice as a nurse practitioner in the category of clinical nurse specialist and provides that a nurse practitioner licensed as a clinical nurse specialist shall practice pursuant to a practice agreement between the clinical nurse specialist and a licensed physician and in a manner consistent with the standards of care for the profession and applicable law and regulations. For the transition of registration to licensure, the bill requires the Boards of Medicine and Nursing to jointly issue a license to practice as a nurse practitioner in the category of a clinical nurse specialist to an applicant who is an advance practice registered nurse who has completed an advanced graduate-level education program in the specialty category of clinical nurse specialist and who is registered by the Board of Nursing as a clinical nurse specialist on July 1, 2021.

HB 1817 **Certified nurse midwives; practice.**

*Summary as passed:*

**Practice of certified nurse midwives.** Expands the categories of practitioners with whom a certified nurse midwife may enter into a practice agreement to include other certified nurse midwives who have practiced for at least two years, and allows a certified nurse midwife who has practiced at least 1,000 hours may practice without a practice agreement. The bill also provides that certified nurse midwives shall practice in accordance with regulations of the Boards of Medicine and Nursing and consistent with the Standards for the Practice of Midwifery set by the American College of Nurse-Midwives and shall consult and collaborate with and refer patients to such other health care providers as may be appropriate for the care of the patient.

HB 1862 **Employee protections; medicinal use of cannabis oil.**

*Summary as passed House:*

**Employee protections; medicinal use of cannabis oil.** Prohibits an employer from discharging, disciplining, or discriminating against an employee for such employee's lawful use of cannabis oil pursuant to a valid written certification issued by a practitioner for the treatment or to eliminate the symptoms of the employee's diagnosed condition or disease. The bill provides that such prohibition does not (i) restrict an employer's ability to take any adverse employment action for any work impairment caused by the use of cannabis oil or to prohibit possession during work hours or (ii) require an employer to commit any act that would cause the employer to be in violation of federal law or that would result in the loss of a federal contract or federal funding.

HB 1913 **Career fatigue and wellness in certain health care providers; programs to address, civil immunity.**

*Summary as introduced:*

**Programs to address career fatigue and wellness in certain health care providers; civil immunity; emergency.** Expands civil immunity for health care professionals serving as members of or consultants to entities that function primarily to review, evaluate, or make recommendations related to health care services to include health care professionals serving as members of or consultants to entities that function primarily to address issues related to career fatigue and wellness in health care professionals licensed, registered, or certified by the Boards of Medicine, Nursing, or Pharmacy, or in students enrolled in a school of medicine, osteopathic medicine, nursing, or pharmacy located in the Commonwealth. The bill contains an emergency clause and is identical to SB 1205.

EMERGENCY

HB 1953 **Licensed certified midwives; clarifies definition, licensure, etc.**

*Summary as passed:*

**Licensed certified midwives; licensure; practice.** Defines "practice of licensed certified midwifery," directs the Boards of Medicine and Nursing to establish criteria for the licensure and renewal of a license as a certified midwife, and requires licensed certified midwives to practice in consultation with a licensed physician in accordance with a practice agreement. The bill also directs the Department of Health Professions to convene a work group to study the licensure and regulation of certified nurse midwives, certified midwives, and certified professional midwives to determine the appropriate licensing entity for such professionals. The bill requires the Department to report its findings and conclusions to the Governor and the General Assembly by November 1, 2021. This bill is identical to SB 1320.

HB 1987 **Telemedicine; coverage of telehealth services by an insurer, etc.**

*Summary as passed:*

**Telemedicine.** Requires the Board of Medical Assistance Services to amend the state plan for medical assistance to provide for payment of medical assistance for remote patient monitoring services provided via telemedicine for certain high-risk patients, makes clear that nothing shall preclude health insurance carriers from providing coverage for services delivered through real-time audio-only telephone that are not telemedicine, and clarifies rules around prescribing of Schedule II through VI drugs via telemedicine, including establishing a practitioner-patient relationship via telemedicine.

HB 1988 **Cannabis oil; processing and dispensing by pharmaceutical processors.**

*Summary as passed:*

**Board of Pharmacy; pharmaceutical processors; processing and dispensing cannabis oil.** Effects numerous changes to the processing and dispensing of cannabis oil by pharmaceutical processors in the Commonwealth. The bill defines the term "designated caregiver facility" and allows any staff member or employee of a designated caregiver facility to assist with the possession, acquisition, delivery, transfer, transportation, and administration of cannabis oil for any patients residing in the designated caregiver facility. The bill allows written certifications for use of cannabis oil to include an authentic electronic practitioner signature. The bill also eliminates the requirement that a pharmacist have oversight of the cultivation and processing areas of a pharmaceutical processor, instead requiring pharmaceutical processors to designate a person to oversee cultivation and production areas; removes the requirement that a cannabis dispensing facility undergo quarterly inspections, instead requiring that inspections occur no more than once annually; and allows pharmaceutical processors to remediate cannabis oil that fails any quality testing standard. The bill requires pharmaceutical processors to maintain evidence of criminal background checks for all employees and delivery agents of the pharmaceutical processor. The bill directs the Board of Pharmacy to promulgate regulations implementing the provisions of the bill and regulations creating reasonable restrictions on advertising and promotion by pharmaceutical processors by September 1, 2021.

HB 2061 **VIIS; any health care provider in the Commonwealth that administers immunizations to participate.**

*Summary as introduced:*
**Virginia Immunization Information System; health care entities; required participation.** Requires any health care provider in the Commonwealth that administers immunizations to participate in the Virginia Immunization Information System (VIIS) and report patient immunization history and information to VIIS. Under current law, participation in VIIS is optional for authorized health care entities. The bill has a delayed effective date of January 1, 2022.

HB 2079 **Pharmacists; initiation of treatment with and dispensing and administering of drugs and devices.**

*Summary as passed House:*

**Pharmacists; initiation of treatment; certain drugs and devices.** Expands provisions governing the initiation of treatment with and dispensing and administering of drugs and devices by pharmacists to allow the initiation of treatment with and dispensing and administering of drugs, devices, and controlled paraphernalia to persons 18 years of age or older, in accordance with protocols developed by the Board of Pharmacy in collaboration with the Board of Medicine and the Department of Health, and of (i) vaccines included on the Immunization Schedule published by the Centers for Disease Control and Prevention; (ii) tuberculin purified protein derivative for tuberculosis testing; (iii) controlled substances for the prevention of human immunodeficiency virus, including controlled substances prescribed for pre-exposure and post-exposure prophylaxis pursuant to guidelines and recommendations of the Centers for Disease Control and Prevention; and (iv) drugs, devices, controlled paraphernalia, and other supplies and equipment available over-the-counter, covered by the patient's health carrier when the patient's out-of-pocket cost is lower than the out-of-pocket cost to purchase an over-the-counter equivalent of the same drug, device, controlled paraphernalia, or other supplies or equipment. The bill requires any pharmacist who administers a vaccination pursuant to clause (i) to report such administration to the Virginia Immunization Information System. The bill also (a) requires the Board of Pharmacy, in collaboration with the Board of Medicine and the Department of Health, to establish protocols for the initiation of treatment with and dispensing and administering of drugs, devices, and controlled paraphernalia by pharmacists in accordance with the provisions of the bill by November 1, 2021; (b) requires the Board of Pharmacy, in collaboration with the Board of Medicine, to adopt regulations within 280 days of the bill's enactment to implement the provisions of the bill; and (c) requires the Board of Pharmacy to convene a work group composed of an equal number of representatives of the Boards of Pharmacy and Medicine and other stakeholders to provide recommendations regarding the developing of protocols for the initiation of treatment with and dispensing and administering of certain drugs and devices by pharmacists to persons 18 years of age or older.

HB 2218 **Pharmaceutical processors; permits processors to produce & distribute cannabis products.**

*Summary as passed:*

**Pharmaceutical processors; cannabis products.** Permits pharmaceutical processors to produce and distribute cannabis products other than cannabis oil and for that purpose defines the terms "botanical cannabis," "cannabis product," and "usable cannabis." The bill requires the Board of Pharmacy to establish testing standards for botanical cannabis and botanical cannabis products, establish a registration process for botanical cannabis products, and promulgate emergency regulations to implement the provisions of the bill. The bill provides that if a practitioner determines it is consistent with the standard of care to dispense botanical cannabis to a minor,

the written certification shall specifically authorize such dispensing. The bill allows the Board of Pharmacy to assess and collect botanical cannabis regulatory fees to cover costs associated with the implementation of the provisions of the bill, including costs for new personnel, training, promulgation of regulations and guidance documents, and information technology. The bill exempts the Board of Pharmacy's acquisition of a commercially available cannabis-specific software product to implement the provisions of the bill from the Virginia Public Procurement Act. This bill is identical to SB 1333.

SB 1115 **Industrial hemp; increases maximum THC concentration.**

*Summary as passed Senate:*

**Industrial hemp; federal hemp producer license; emergency.** Updates Virginia's industrial hemp laws to address the new hemp producer license issued by the U.S. Department of Agriculture. The bill changes drug laws to exclude the industrial hemp possessed by a federally licensed hemp producer from the definition of "marijuana" and to exclude certain amounts of tetrahydrocannabinol (THC) in such industrial hemp from the prohibition on THC. The bill exempts federally licensed hemp producers from state industrial hemp registration requirements and adds such producers to the list of those eligible to receive funds from the Tobacco Indemnification and Community Revitalization Fund.

The bill makes other changes to industrial hemp laws, including (i) excluding from the definition of "dealer" any retail establishment that sells a completed product containing industrial hemp; (ii) making optional the monitoring and random testing of industrial hemp by the Commissioner of Agriculture and Consumer Services and authorizing the random sampling of such hemp; (iii) removing the requirement that the Attorney General of the United States be notified when a Virginia grower, dealer, or processor exceeds the federal THC limit; and (iv) directing the Commissioner to adopt regulations establishing a fee structure for registration.

Finally, the bill exempts employees of the Virginia Department of Agriculture and Consumer Services from prosecution for possession or distribution of industrial hemp when possession is necessary in the performance of their duties. The bill contains an emergency clause.

EMERGENCY

SB 1464 **Drug Control Act; adds certain chemicals to Schedule I of Act.**

*Summary as introduced:*
**Drug Control Act; Schedule I.** Adds certain chemicals to Schedule I of the Drug Control Act. The Board of Pharmacy has added these substances to Schedule I in an expedited regulatory process. A substance added via this process is removed from the schedule after 18 months unless a general law is enacted adding the substance to the schedule.

## CHAPTER 1

*An Act to facilitate the administration of the COVID-19 vaccine: emergency.*

[H 2333]

Approved February 15, 2021

Be it enacted by the General Assembly of Virginia:

**1.** *§ 1. As used in this act, "eligible health care provider" means any of the following who, due to their education and training, are authorized to administer drugs: (i) any person licensed by a health regulatory board within the Department of Health Professions whose license is in good standing, or was in good standing within the 20 years immediately prior to lapsing; (ii) any emergency medical services provider licensed or certified by the Department of Health (the Department) whose license or certification is in good standing, or was in good standing within the 20 years immediately prior to lapsing; and (iii) any health professions student enrolled in an accredited program in the Commonwealth who is in good academic standing with such student's school and provided that the school certifies that the student has been properly trained in the administration of vaccines. Eligible health care providers may also be employees of localities, pharmacies, or hospitals. Localities, pharmacies, or hospitals that offer their employees to support vaccination clinics shall (i) verify employee certification or licensure, (ii) document completion of the required training, and (iii) provide a list of qualified and available vaccinators to the Department.*

*§ 2. During a state of emergency related to the COVID-19 pandemic declared by the Governor pursuant to § 44-146.17 of the Code of Virginia, an eligible health care provider participating in the program established pursuant to § 3 of this act may administer the COVID-19 vaccine to citizens of the Commonwealth, in accordance with this act.*

*§ 3. The Department shall establish a program to enable eligible health care providers to volunteer to administer the COVID-19 vaccine to residents of the Commonwealth during a state of emergency related to the COVID-19 pandemic declared by the Governor pursuant to § 44-146.17 of the Code of Virginia. Such program shall include (i) a process by which an eligible health care provider may register to participate in the program and (ii) the training requirements for participating eligible health care providers related to the administration of the COVID-19 vaccine, including training on the intramuscular injection of the COVID-19 vaccine and contraindications and side effects of the COVID-19 vaccine. For the purposes of such program, requirements related to background investigation, training, and orientation for Medical Reserve Corps volunteers shall be waived. To facilitate volunteering, the Department shall place a volunteer link*

*on its website's home page in the same visible location as the other links, such as "GET COVIDWISE." to make the process to volunteer as a health care provider easily accessible.*

*The Department shall make a list of eligible health care providers who have registered pursuant to this section of the act and complied with requirements for training established by the Department available to each local health department and to hospitals operating community vaccination clinics, and the Department, a local health department, or a hospital operating a community vaccination clinic may request that an eligible health care provider included on such list administer the COVID-19 vaccine at a vaccination clinic operated by or in partnership with the Department, local health department, or hospital. Information included on the list shall not be used for any other purpose and shall not be used after the expiration or revocation of all states of emergency declared by the Governor related to the COVID-19 pandemic.*

*§ 4. The Department shall ensure that each site at which COVID-19 vaccinations are provided by eligible health care providers who provide such vaccination in accordance with this act meet the following requirements:*

*1. A sufficient number of eligible health care providers whose scope of practice includes administration of vaccines shall be available at each site at which COVID-19 vaccines are administered by eligible health care providers pursuant to this act to ensure appropriate oversight of administration of vaccines by eligible health care providers whose scope of practice does not include administration of vaccines.*

*2. A sufficient number of eligible health care providers or other persons who are certified to administer cardiopulmonary resuscitation (CPR) are available at each site at which COVID-19 vaccines are administered by eligible health care providers pursuant to this act; however, a valid certification to perform CPR shall not be required to administer COVID-19 in accordance with this act.*

*3. Any person who administers a COVID-19 vaccination in accordance with this act shall collect data, including data related to the race and ethnicity of the person to whom the vaccine is administered, and the person who administers a COVID-19 vaccination or the entity that operates a community vaccination site in accordance with this act shall report such data to the Virginia Immunization Information System established pursuant to § 32.1-46.01 of the Code of Virginia.*

*§ 5. A person who is licensed as a nurse practitioner by the Boards of Medicine and Nursing or licensed as a physician assistant by the Board of Medicine who administers the COVID-19*

*vaccine pursuant to this act may administer such vaccine without a written or electronic practice agreement.*

*A health professions student who administers the COVID-19 vaccine pursuant to this act shall be supervised by any eligible health care provider who holds a license issued by a health regulatory board within the Department of Health Professions, and the supervising health care provider shall not be required to be licensed in the same health profession for which the student is studying.*

*§ 6. An eligible health care provider who is a health professions student shall, as part of the registration process established by the Department, provide such information necessary to demonstrate that he is in good academic standing with the accredited program in which he is enrolled and that he has been properly trained in the administration of vaccines as may be required by the Department. Information about a health professions student shall not be disclosed by the institution of higher education at which the health professions student is studying unless the health professions student has consented to such disclosure in accordance with the provisions of the federal Family Educational Rights and Privacy Act of 1974, 20 U.S.C. § 1232g and § 23.1-405 of the Code of Virginia, as applicable.*

*Clinical vaccination experience undertaken by a health professions student pursuant to this act may count toward meeting clinical hour requirements of the educational program in which the student is enrolled, subject to a requirement for written verification of such clinical vaccine experience.*

*§ 7. In the absence of gross negligence or willful misconduct, any eligible health care provider or entity overseeing any eligible health care provider who administers the COVID-19 vaccine pursuant to this act shall not be liable for (i) any actual or alleged injury or wrongful death or (ii) any civil cause of action arising from any act or omission arising out of, related to, or alleged to have resulted in the contraction of or exposure to the COVID-19 virus or to have resulted from the administration of the COVID-19 vaccine.*

**2.** *§ 1. That the Department of Health (the Department) shall establish a process by which entities, including medical care facilities, hospitals, hospital systems, corporations, businesses, pharmacies, public and private institutions of higher education, localities, and any other professional or community entity operating in the Commonwealth, may volunteer their facilities as sites at which the COVID-19 vaccine may be administered to citizens of the Commonwealth. The Department shall include on its website a link to information regarding such process and an online form that may be used by such entities to register their facilities to serve as sites at which the COVID-19 vaccine may be administered. The Commissioner of Health shall approve such sites*

*in collaboration with local departments of health. In the absence of gross negligence or willful misconduct, any entity that volunteers its facility as a site at which the COVID-19 vaccine may be administered pursuant to this act and at which the COVID-19 vaccine is lawfully administered shall not be liable for (i) any actual or alleged injury or wrongful death or (ii) any civil cause of action arising from any act or omission arising out of, related to, or alleged to have resulted in the contraction of or exposure to the COVID-19 virus or to have resulted from the administration of the COVID-19 vaccine.*

**3.** *§ 1. That a public institution of higher education or a private institution of higher education in the Commonwealth may volunteer to provide assistance to the Department of Health and local health departments for data processing, analytics, and program development related to the COVID-19 vaccine through the use of its employees, students, technology, and facilities. Such assistance may include collecting and organizing data on the administration of the COVID-19 vaccine and locations where the vaccine is being administered and performing other nonclinical staffing responsibilities. In the absence of gross negligence or willful misconduct, any institution or individual affiliated with an institution acting pursuant to this act shall not be liable for any civil or criminal penalties.*

**4.** *§ 1. That localities with fire departments, emergency medical services departments, and volunteer rescue squads may establish and staff vaccine administration clinics for the purpose of administering COVID-19 vaccines. Vaccines shall be administered at such clinics only by EMTs, paramedics, licensed practical nurses, or registered nurses trained in the administration of vaccines and may be provided under the existing operating medical director (OMD) license for such local fire department or emergency medical services department. The Department of Health or hospitals serving the locality are authorized to provide vaccines to locality-created vaccine administration clinics upon the request of the locality, provided that such clinics meet the requirements under this act. In the absence of gross negligence or willful misconduct, any locality and OMD overseeing the administration of or EMT, paramedic, licensed practical nurse, or registered nurse who administers the COVID-19 vaccine pursuant to this act shall not be liable for (i) any actual or alleged injury or wrongful death or (ii) any civil cause of action arising from any act or omission arising out of, related to, or alleged to have resulted in the contraction of or exposure to the COVID-19 virus or to have resulted from the administration of the COVID-19 vaccine.*

5. That an emergency exists and this act is in force from its passage.

# Chart of current regulatory actions
# As of March 10, 2021

| Chapter | | Action / Stage Information |
|---|---|---|
| [18 VAC 110 - 20] | Regulations Governing the Practice of Pharmacy | Reporting of immunizations to VIIS [Action 5598]<br>Emergency - *Register Date: 10/12/20*<br>*Effective: 9/22/20 to 3/21/22* |
| [18 VAC 110 - 20] | Regulations Governing the Practice of Pharmacy | Implementation of legislation for pharmacists initiating treatment [Action 5604]<br>Emergency/NOIRA<br>*Effective: 1/3/21 to 7/2/22*<br>*Comment on NOIRA closed: 3/3/21* |
| [18 VAC 110 - 20] | Regulations Governing the Practice of Pharmacy | Use of medication carousels and RFID technology [Action 5480]<br>*Proposed at DPB* |
| [18 VAC 110 - 20] | Regulations Governing the Practice of Pharmacy | Handling fee [Action 5519]<br>Fast-Track - *Register Date: 2/1/21*<br>*Effective:3/18/21* |
| [18 VAC 110 - 20] | Regulations Governing the Practice of Pharmacy | Prohibition against incentives to transfer prescriptions [Action 4186]<br>Final - *At Governor's Office for 1022 days* |
| [18 VAC 110 - 20] | Regulations Governing the Practice of Pharmacy | Brown bagging and white bagging [Action 4968]<br>Final - *At Governor's Office for 133 days* |
| [18 VAC 110 - 20] | Regulations Governing the Practice of Pharmacy | (E) Scheduling of chemicals in Schedule I [Action 5666]<br>Final - *Register Date: 2/1/21*<br>*Effective: 3/3/21* |
| [18 VAC 110 - 20] | Regulations Governing the Practice of Pharmacy | (E) De-scheduling of drug to conform to DEA [Action 5667]<br>Final - *Register Date: 1/18/21* [Stage 9168] |
| [18 VAC 110 - 21] | Regulations Governing the Licensure of Pharmacists and Registration of Pharmacy Technicians | Implementation of legislation for registration of pharmacy technicians [Action 5603]<br>Emergency/NOIRA<br>*Effective: 1/3/21 to 7/2/22*<br>*Comment on NOIRA closed: 3/3/21* |

| | | |
|---|---|---|
| [18 VAC 110 - 21] | Regulations Governing the Licensure of Pharmacists and Registration of Pharmacy Technicians | CE credit for volunteer hours [Action 5546]<br>Fast-Track - *Register Date: 2/1/21*<br>*Effective: 3/18/21* |
| [18 VAC 110 - 30] | Regulations for Practitioners of the Healing Arts to Sell Controlled Substances | Limited license for prescribing Schedule VI drugs in non-profit clinics [Action 5605]<br>Emergency/NOIRA<br>*Effective: 1/4/21 to 7/3/22*<br>*Comment on NOIRA closed: 3/3/21* |
| [18 VAC 110 - 50] | Regulations Governing Wholesale Distributors, Manufacturers and Warehousers | Delivery of Schedule VI prescription devices [Action 5084]<br>Final - *Register Date: 2/1/21*<br>*Effective: 3/3/21* |
| [18 VAC 110 - 60] | Regulations Governing Pharmaceutical Processors | Amendments resulting from SB976 of the 2020 General Assembly [Action 5629]<br>Emergency/NOIRA<br>*Effective: 2/8/21 to 8/7/22*<br>*Comment on NOIRA closes: 3/31/21* |
| [18 VAC 110 - 60] | Regulations Governing Pharmaceutical Processors | Response to petition for rulemaking [Action 5611]<br>NOIRA - *Register Date: 3/1/21*<br>*Comment closes: 3/31/21* |
| [18 VAC 110 - 60] | Regulations Governing Pharmaceutical Processors | Registered agents and wholesale distribution [Action 5398]<br>Proposed - *Register Date: 3/1/21*<br>*Comment period: 3/1/21 to 4/30/21*<br>*Public hearing: 3/30/21* |
| [18 VAC 110 - 60] | Regulations Governing Pharmaceutical Processors | Prohibition of products for vaping or inhalation with vitamin E acetate [Action 5452]<br>Proposed - *At Secretary's Office for 19 days* |
| [18 VAC 110 - 60] | Regulations Governing Pharmaceutical Processors | Acquisition of industrial hemp [Action 5602]<br>Fast-Track - *Register Date: 2/1/21*<br>*Effective: 3/18/21* |

**Agenda Item:** **Regulatory Action – Adoption of Final Regulations**

**Scheduling Chemicals in Schedule I - Exempt action**

**Included in agenda package:**

Copy of Notice of Public Hearing listing chemicals to be scheduled in Schedule I

Amendments to regulation: 18VAC110-20-322

**Staff Note:**

A public hearing was conducted before the meeting this morning.

Action is exempt from the provisions of the Administrative Process Act in accordance with § 2.2-4006.

**Board action:**

Adoption of final regulation in sections 322

# Notice of Public Hearing

Pursuant to subsection D of § 54.1-3443, the Board of Pharmacy is giving notice of a public hearing to consider placement of chemical substances in Schedule I of the Drug Control Act. The virtual public hearing will be conducted at **9:15 a.m. on March 30, 2021.** Instructions will be included in the agenda for the board meeting, also on March 30th. Public comment may also be submitted electronically or in writing prior to March 30th to Caroline Juran, Executive Director of the Board of Pharmacy to caroline.juran@dhp.virginia.gov.

**The following compounds are classified as synthetic opioids. Compounds of this type have been placed in Schedule I (§ 54.1-3446(1)) in previous legislative sessions.**

1. **1-{1-[1-(4-bromophenyl)ethyl]-4-piperidinyl}-1,3-dihydro-2H-benzimidazol-2-one (other name: Brorphine),** its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers and salts is possible within the specific chemical designation.

2. **N-(4-chlorophenyl)-N-[1-(2-phenylethyl)-4-piperidinyl]-propanamide (other names: para-chlorofentanyl, 4-chlorofentanyl),** its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers and salts is possible within the specific chemical designation.

3. **2-[(4-methoxyphenyl)methyl]-N,N-diethyl-5-nitro-1H-benzimidazole-1-ethanamine (other name: Metonitazene),** its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers and salts is possible within the specific chemical designation.

4. **N,N-diethyl-2-{[(4-ethoxyphenyl) methyl]-1H-benzimidazol-1-yl}-ethan-1-amine (other name: Etazene, Desnitroetonitazene),** its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers and salts is possible within the specific chemical designation.

**Based on its chemical structure, the following compound is expected to have depressant properties. Compounds of this type have been placed in Schedule I (§ 54.1-3446(4)) in previous legislative sessions.**

5. **5-(2-chlorophenyl)-1,3-dihydro-3-methyl-7-nitro-2H-1,4-benzodiazepin-2-one (other name: Meclonazepam)**, its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

**The following compound is classified as a cannabimimetic agent. Compounds of this type have been placed in Schedule I (§ 54.1-3446(6)) in previous legislative sessions.**

6. **ethyl-2-[1-(5-fluoropentyl)-1H-indole-3-carboxamido]-3,3-dimethylbutanoate (other name: 5-fluoro EDMB-PICA)**, its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

## Board Of Pharmacy

## Scheduling of chemicals in Schedule I

### 18VAC110-20-322. Placement of chemicals in Schedule I.

A. Pursuant to subsection D of § 54.1-3443 of the Code of Virginia, the Board of Pharmacy places the following in Schedule I of the Drug Control Act:

1. Synthetic opioids.

a. N-[2-(dimethylamino)cyclohexyl]-N-phenylfuran-2-carboxamide (other name: Furanyl UF-17), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation.

b. N-[2-(dimethylamino)cyclohexyl]-N-phenylpropionamide (other name: UF-17), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation.

2. Research chemicals.

a. 5-methoxy-N,N-dibutyltryptamine (other name: 5-methoxy-DBT), its optical, position, and geometric isomers, salts, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

b. 1-(1,3-benzodioxol-5-yl)-2-(ethylamino)-1-butanone (other name: Eutylone, bk-EBDB), its optical, position, and geometric isomers, salts, and salts of isomers

whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

c. 1-(1,3-benzodioxol-5-yl)-2-(butylamino)-1-pentanone (other name: N-butylpentylone), its optical, position, and geometric isomers, salts, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

d. N-benzyl-3,4-dimethoxyamphetamine (other name: N-benzyl-3,4-DMA), its optical, position, and geometric isomers, salts, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

e. 3,4-methylenedioxy-N-benzylcathinone (other name: BMDP), its optical, position, and geometric isomers, salts, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

3. Cannabimimetic agents.

a. Ethyl 2-({1-[(4-fluorophenyl)methyl]-1H-indazole-3-carbonyl}amino)-3-methylbutanoate (other name: EMB-FUBINACA), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

b. Methyl 2-[1-4-fluorobutyl)-1H-indazole-3-carboxamido]-3,3-dimethylbutanoate (other name: 4-fluoro-MDMB-BUTINACA), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

The placement of drugs listed in this subsection shall remain in effect until June 10, 2021, unless enacted into law in the Drug Control Act.

B. Pursuant to subsection D of § 54.1-3443 of the Code of Virginia, the Board of Pharmacy places the following in Schedule I of the Drug Control Act:

1. Synthetic opioids.

a. N-phenyl-N-[1-(2-phenylmethyl)-4-piperidinyl]-2-furancarboxamide (other name: N-benzyl Furanyl norfentanyl), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation.

b. 1-[2-methyl-4-(3-phenyl-2-propen-1-yl)-1-piperazinyl]-1-butanone (other name: 2-methyl AP-237), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation.

2. Research chemicals.

a. N-hexyl-3,4-dimethoxyamphetamine (other names: N-hexyl-3.4-DMA), its optical, position, and geometric isomers, salts, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

b. N-heptyl-3,4-dimethoxyamphetamine (other names: N-heptyl-3.4-DMA), its optical, position, and geometric isomers, salts, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

c. 2-(isobutylamino)-1-phenylhexan-1-one (other names: N-Isobutyl Hexedrone, α-isobutylaminohexanphenone), its optical, position, and geometric isomers, salts, and

salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

d. 1-(benzo[d][1,3]dioxol-5-yl)-2-(sec-butylamino)pentan-1-one (other name: N-sec-butyl Pentylone), its optical, position, and geometric isomers, salts, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

e. 2-fluoro-Deschloroketamine (other name: 2-(2-fluorophenyl)-2-(methylamino)-cyclohexanone), its optical, position, and geometric isomers, salts, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

3. Cannabimimetic agents.

a. Methyl 2-[1-(5-fluoropentyl)-1H-indole-3-carboxamido]-3-methylbutanoate (other name: MMB 2201), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

b. Methyl 2-[1-(4-penten-1-yl)-1H-indole-3-carboxamido]-3-methylbutanoate (other names: MMB022, MMB-4en-PICA), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

c. Methyl 2-[1-(5-fluoropentyl)-1H-indole-3-carboxamido]-3-phenylpropanoate (other name: 5-fluoro-MPP-PICA), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

d. 1-(5-fluoropentyl)-N-(1-methyl-1-phenylethyl)-1H-indole-3-carboxamide (other name: 5-fluoro CUMYL-PICA), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

The placement of drugs listed in this subsection shall remain in effect until February 4, 2022, unless enacted into law in the Drug Control Act.

C. Pursuant to subsection D of § 54.1-3443 of the Code of Virginia, the Board of Pharmacy places the following in Schedule I of the Drug Control Act:

1. Synthetic opioids.

a. N-phenyl-N-(4-piperidinyl)-propanamide (other name: Norfentanyl), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation.

b. N,N-diethyl-2-(2-(4-isopropoxybenzyl)-5-nitro-1H-benzimidazol-1-yl)ethan-1-amine (other name: Isotonitazene), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation.

2. Research chemicals.

a. (2-ethylaminopropyl)benzofuran (other name: EAPB), its optical, position, and geometric isomers, salts, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

b. 2-(ethylamino)-1-phenylheptan-1-one (other name: N-ethylheptedrone), its optical, position, and geometric isomers, salts, and salts of isomers whenever the existence

of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

c. 4-ethyl-2,5-dimethoxy-N-[(2-hydroxyphenyl)methyl]-benzeneethanamine (other name: 25E-NBOH), its optical, position, and geometric isomers, salts, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

d. 4-hydroxy-N-ethyl-N-propyltryptamine (other name: 4-hydroxy-EPT), its optical, position, and geometric isomers, salts, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

e. N-ethyl-1-(3-hydroxyphenyl)cyclohexylamine (other name: 3-hydroxy-PCE), its optical, position, and geometric isomers, salts, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

f. 1-cyclopropionyl lysergic acid diethylamide (other name: 1cP-LSD), its optical, position, and geometric isomers, salts, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

g. 1-(4-methoxyphenyl)-N-methylpropan-2-amine (other names: para-Methoxymethamphetamine, PMMA), its optical, position, and geometric isomers, salts, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

3. Cannabimimetic agents.

a. Methyl 2-[1-(pent-4-enyl)-1H-indazole-3-carboxamindo]-3,3-dimethylbutanoate (other name: MDMB-4en-PINACA), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

b. N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-butylindazole-3-carboxamide (other name: ADB-BUTINACA), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

c. N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(5-chloropentyl)indazole-3-carboxamide (other name: 5-chloro-AB-PINACA), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

d. Methyl 2-({1-[(4-fluorophenyl)methyl]-1H-indole-3-carbonyl}amino)-3-methylbutanoate (other names: MMB-FUBICA, AMB-FUBICA), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

The placement of drugs listed in this subsection shall remain in effect until May 24, 2022, unless enacted into law in the Drug Control Act.

D. Pursuant to subsection D of § 54.1-3443 of the Code of Virginia, the Board of Pharmacy places the following in Schedule I of the Drug Control Act:

1. Synthetic opioid. N,N-diethyl-2-[(4-methoxyphenyl)methyl]-1H-benzimidazole-1-ethanamine (other name: Metodesnitazene), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation.

2. Compounds expected to have hallucinogenic properties.

a. 4-fluoro-3-methyl-alpha-pyrrolidinovalerophenone (other name: 4-fluoro-3-methyl-alpha-PVP), its salts, isomers (optical, position, and geometric), and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

b. 4-fluoro-alpha-methylamino-valerophenone (other name: 4-fluoropentedrone), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers (optical, position, and geometric), and salts of isomers is possible within the specific chemical designation.

c. N-(1,4-dimethylpentyl)-3,4-dimethoxyamphetamine (other name: N-(1,4-dimethylpentyl)-3,4-DMA), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers (optical, position, and geometric), and salts of isomers is possible within the specific chemical designation.

d. 4,5-methylenedioxy-N,N-diisopropyltryptamine (other name: 4,5-MDO-DiPT), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers (optical, position, and geometric), and salts of isomers is possible within the specific chemical designation.

e. Alpha-pyrrolidinocyclohexanophenone (other name: alpha-PCYP), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers (optical, position, and geometric), and salts of isomers is possible within the specific chemical designation.

f. 3,4-methylenedioxy-alpha-pyrrolidinoheptiophenone (other name: MDPV8), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers (optical,

position, and geometric), and salts of isomers is possible within the specific chemical designation.

3. Compounds expected to have depressant properties.

a. Bromazolam, its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

b. Deschloroetizolam, its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

c. 7-chloro-5-(2-fluorophenyl)-1,3-dihydro-1,4-benzodiazepin-2-one (other name: Norfludiazepam), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

4. Cannabimimetic agents.

a. Methyl 2-[1-(4-fluorobutyl)-1H-indole-3-carboxamido]-3,3-dimethylbutanoate (other name: 4-fluoro-MDMB-BUTICA), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

b. Ethyl 2-[1-(5-fluoropentyl)-1H-indole-3-carboxamido]-3-methylbutanoate (other name: 5-fluoro-EMB-PICA), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

chemical designation.

The placement of drugs listed in this subsection shall remain in effect until September 2, 2022, unless enacted into law in the Drug Control Act.

E. Pursuant to subsection D of § 54.1-3443 of the Code of Virginia, the Board of Pharmacy places the following in Schedule I of the Drug Control Act:

1. Synthetic opioids.

a. 1-{1-[1-(4-bromophenyl)ethyl]-4-piperidinyl}-1,3-dihydro-2H-benzimidazol-2-one (other name: Brorphine), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers and salts is possible within the specific chemical designation.

b. N-(4-chlorophenyl)-N-[1-(2-phenylethyl)-4-piperidinyl]-propanamide (other names: para-chlorofentanyl, 4-chlorofentanyl), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers and salts is possible within the specific chemical designation.

c. 2-[(4-methoxyphenyl)methyl]-N,N-diethyl-5-nitro-1H-benzimidazole-1-ethanamine (other name: Metonitazene), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers and salts is possible within the specific chemical designation.

d. N,N-diethyl-2-{[(4-ethoxyphenyl) methyl]-1H-benzimidazol-1-yl}-ethan-1-amine (other name: Etazene, Desnitroetonitazene), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers and salts is possible within the specific chemical designation.

2. Chemical with depressant properties.

5-(2-chlorophenyl)-1,3-dihydro-3-methyl-7-nitro-2H-1,4-benzodiazepin-2-one (other name: Meclonazepam), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

3. Cannabimimetic agent.

ethyl-2-[1-(5-fluoropentyl)-1H-indole-3-carboxamido]-3,3-dimethylbutanoate (other name: 5-fluoro EDMB-PICA), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

The placement of drugs listed in this subsection shall remain in effect until (18 months from effective date), unless enacted into law in the Drug Control Act.

**Agenda Item:** **Regulatory Action – Adoption of Proposed Regulations – Pharmacists initiating treatment**

**Included in agenda package:**

Copy of Notice posted on Townhall

No comments on the NOIRA were received

Copy of Emergency regulations

**Staff note:**

Emergency regulations remain in effect for 18 months and must be replaced by permanent regulations.

**Board action:**

Adoption of proposed regulations identical to the emergency regulation or as amended by the Board.

**Board**

Board of Pharmacy

**Chapter**

Regulations Governing the Practice of Pharmacy [18 VAC 110 - 20]

Action:

## Implementation of legislation for pharmacists initiating treatment

Action 5604 / Stage 9074

### Emergency/NOIRA Stage

| Documents | | |
|---|---|---|
| Emergency Text | 1/29/2021 1:19 pm | Sync Text with I |
| Agency Background Document | 9/21/2020 | Upload / Replac |
| Attorney General Certification | 10/23/2020 | |
| Governor's Review Memo | 1/1/2021 | |
| Registrar Transmittal | 1/1/2021 | |

| Status | |
|---|---|
| **Public Hearing** | Will be held at the **proposed** stage |
| **Emergency Authority** | 2.2-4011(B) |
| **Exempt from APA** | No, this stage/action is subject to Article 2 of the *Administrative Process Act* |
| **Attorney General Review** | Submitted to OAG: 9/21/2020<br>Review Completed: 10/23/2020<br>Result: Certified |
| **DPB Review** | Submitted on 10/23/2020<br>Policy Analyst: Melanie West<br>Review Completed: 11/6/2020<br>*DPB's policy memo is "Governor's Confidential Working Papers"* |
| **Secretary Review** | Secretary of Health and Human Resources Review Completed: 11/24/2020 |
| **Governor's Review** | Review Completed: 1/1/2021<br>Result: Approved |
| **Virginia Registrar** | Submitted on 1/1/2021<br>The Virginia Register of Regulations<br>Publication Date: 2/1/2021 Volume: 37 Issue: 12 |
| **Comment Period** | Ended 3/3/2021<br>0 comments |
| **Effective Date** | 1/3/2021 |
| **Expiration Date** | 7/2/2022 |

**Emergency Regulation**

**Board Of Pharmacy**

**Implementation of legislation for pharmacists initiating treatment**

**18VAC110-20-150. Physical standards for all pharmacies.**

A. The prescription department shall not be less than 240 square feet. The patient waiting area or the area used for counseling, devices, cosmetics, and proprietary medicines shall not be considered a part of the minimum 240 square feet. The total area shall be consistent with the size and scope of the services provided.

B. Access to stock rooms, rest rooms, and other areas other than an office that is exclusively used by the pharmacist shall not be through the prescription department. A rest room in the prescription department, used exclusively by pharmacists and personnel assisting with dispensing functions, may be allowed provided there is another rest room outside the prescription department available to other employees and the public. This subsection shall not apply to prescription departments in existence prior to November 4, 1993.

C. The pharmacy shall be constructed of permanent and secure materials. Trailers or other moveable facilities or temporary construction shall not be permitted.

D. The entire area of the location of the pharmacy practice, including all areas where drugs are stored, shall be well lighted and well ventilated; the proper storage temperature shall be maintained to meet USP-NF specifications for drug storage.

E. The prescription department counter work space shall be used only for the compounding and dispensing of drugs and necessary recordkeeping.

F. A sink with hot and cold running water shall be within the prescription department. A pharmacy issued a limited-use permit that does not stock prescription drugs as part of its operation is exempt from this requirement.

G. Adequate refrigeration facilities equipped with a monitoring thermometer for the storage of drugs requiring cold storage temperature shall be maintained within the prescription department if the pharmacy stocks such drugs.

H. A pharmacy stocking drugs requiring cold storage temperature shall record the temperature daily and adjust the thermostat as necessary to ensure an appropriate temperature range. The record shall be maintained manually or electronically for a period of two years.

I. The physical settings of a pharmacy in which a pharmacist initiates treatment with, dispenses, or administers drugs and devices pursuant to § 54.1-3303.1 of the Code of Virginia and 18VAC110-21-46 shall protect patient confidentiality and comply with the Health Insurance Portability and Accountability Act, 42 USC § 1320d et seq.

**18VAC110-21-46. Initiation of treatment by a pharmacist.**

A. Pursuant to § 54.1-3303.1 of the Code of Virginia, a pharmacist may initiate treatment with, dispense, or administer the following drugs and devices to persons 18 years of age or older:

1. Naloxone or other opioid antagonist, including such controlled paraphernalia as defined in § 54.1-3466 of the Code of Virginia as may be necessary to administer such naloxone or other opioid antagonist;

2. Epinephrine;

3. Injectable or self-administered hormonal contraceptives, provided the patient completes an assessment consistent with the United States Medical Eligibility Criteria for Contraceptive Use;

4. Prenatal vitamins for which a prescription is required;

5. Dietary fluoride supplements, in accordance with recommendations of the American Dental Association for prescribing of such supplements for persons whose drinking water has a fluoride content below the concentration recommended by the U.S. Department of Health and Human Services; and

6. Medications covered by the patient's health carrier when the patient's out-of-pocket cost is lower than the out-of-pocket cost to purchase an over-the-counter equivalent of the same drug.

B. Pharmacists who initiate treatment with, dispense, or administer a drug or device pursuant to subsection A of this section shall:

1. Follow the statewide protocol adopted by the board for each drug or device.

2. Notify the patient's primary health care provider that treatment has been initiated with such drug or device or that such drug or device has been dispensed or administered to the patient, provided that the patient consents to such notification. If the patient does not have a primary health care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and, upon request, provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located. If the pharmacist is initiating treatment with, dispensing, or administering injectable or self-administered hormonal contraceptives, the pharmacist shall counsel the patient regarding seeking preventative care, including (i) routine well-woman visits, (ii) testing for sexually transmitted infections, and (iii) pap smears.

3. Maintain a patient record for a minimum of six years following the last patient encounter with the following exceptions:

a. Records that have previously been transferred to another practitioner or health care provider or provided to the patient or the patient's personal representative; or

b. Records that are required by contractual obligation or federal law to be maintained for a longer period of time.

4. Perform the activities in a manner that protects patient confidentiality and complies with the Health Insurance Portability and Accountability Act, 42 USC § 1320d et seq.

**Agenda Item: Regulatory Action – Adoption of Proposed Regulations – Pharmacy technician registration and training**

**Included in agenda package:**

Copy of Notice posted on Townhall

Copy of comment on Notice of Intended Regulatory Action (NOIRA)

Copy of Emergency regulations

**Staff note:**

Emergency regulations remain in effect for 18 months and must be replaced by permanent regulations.

**Board action:**

Adoption of proposed regulations identical to the emergency regulation or as amended by the Board

**Board**
Board of Pharmacy

**Chapter**
**Regulations Governing the Licensure of Pharmacists and Registration of Pharmacy Technicians [18 VAC 110 - 21]**

Action:
## Implementation of legislation for registration of pharmacy technicians
Action 5603 / Stage 9137

### Emergency/NOIRA Stage

| Documents | | |
|---|---|---|
| Emergency Text | 1/29/2021 1:19 pm | Sync Text with I |
| Agency Background Document | 11/4/2020 | Upload / Replac |
| Attorney General Certification | 11/9/2020 | |
| Governor's Review Memo | 1/2/2021 | |
| Registrar Transmittal | 1/2/2021 | |

| Status | |
|---|---|
| **Public Hearing** | Will be held at the **proposed** stage |
| **Emergency Authority** | 2.2-4011 |
| **Exempt from APA** | No, this stage/action is subject to Article 2 of the *Administrative Process Act* |
| **Attorney General Review** | Submitted to OAG: 11/4/2020<br>Review Completed: 11/18/2020<br>Result: Certified |
| **DPB Review** | Submitted on 11/18/2020<br>Policy Analyst: Jeannine Rose<br>Review Completed: 11/20/2020<br>*DPB's policy memo is "Governor's Confidential Working Papers"* |
| **Secretary Review** | Secretary of Health and Human Resources Review Completed: 11/23/2020 |
| **Governor's Review** | Review Completed: 1/2/2021<br>Result: Approved |
| **Virginia Registrar** | Submitted on 1/2/2021<br>The Virginia Register of Regulations<br>Publication Date: 2/1/2021 Volume: 37 Issue: 12 |
| **Comment Period** | Ended 3/3/2021<br>0 comments |
| **Effective Date** | 1/3/2021 |
| **Expiration Date** | 7/2/2022 |

**Public comment on proposed reg**

on Tue, Mar 2, 2021 at 9:37 AM Jill McCormack <JMcCormack@nacds.org> wrote:
March 2, 2021, 2021

Caroline Juran, R.Ph., Executive Director
Board of Pharmacy
Virginia Department of Health Professions
9960 Maryland Drive, Suite 300
Richmond, 23233

**RE:** 18 VAC 110-20 - requirements for registration of pharmacy technician trainees and for pharmacy technician training programs

Dear Ms. Juran:

On behalf of our members jointly operating more than 1,233 pharmacies in the Commonwealth of Virginia, the Virginia Association of Chain Drug Stores (VACDS) and the National Association of Chain Drug Stores (NACDS) appreciates the opportunity to comment on 18 VAC 110-20 that establishes requirements for registration of pharmacy technician trainees and for pharmacy technician training programs. Our members have two main concerns:

1.) Under 18VAC110-21-135, the rule does not specify how long the technician trainee registration process will take. The statute references "issuance of a registration." Thus, there is a concern about the length of time that would pass before the trainee can begin working in the pharmacy after they have applied for registration. Can you please provide clarity around the timeframe for registration process? If it is the case that it may delay the trainee's ability to begin working, we ask that the Board to amend the language to reflect the way this process is works in IL or IN:

IL: "*An applicant for licensure as a registered pharmacy technician may assist a pharmacist in the practice of pharmacy for a period of up to 60 days prior to the issuance of a license if the applicant has submitted the required fee and an application for licensure to the Department. The applicant shall keep a copy of the submitted application on the premises where the applicant is assisting in the practice of pharmacy.*"

IN:

*(1) may work as a pharmacy technician in training without a permit for not more than thirty (30) consecutive days after the applicant files an application under this section;*
*(2) shall provide the applicant's employer with a receipt issued by the board that:*
*(A) provides the date an application under this section was filed; and*

*(B) indicates that the fee has been paid; before the applicant may begin work as a pharmacy technician in training; and*

*(3) may request an additional thirty (30) day period to practice a pharmacy technician in training without a permit. The board may approve a request under this subdivision if the board determines that the extension is for good cause.*

2) In regard to 18VAC110-21-140 (C), we would ask the Board to make a technical amendment for consistency by adding "NHA certification": *In lieu of the requirements of subsection B of this section, an applicant may provide evidence of current PTCB certification or NHA certification.*

Thank you in advance for your consideration of our comments.

Jill McCormack
Jermaine Smith, President, VACDS

**Emergency Regulations**

**Board Of Pharmacy**

**Implementation of legislation for registration of pharmacy technicians**

**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~~ a 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~~ only if the person is currently registered as a pharmacy technician trainee.

**18VAC110-21-10. Definitions.**

Part I General

Provisions

In addition to words and terms defined in §§ 54.1-3300 and 54.1-3401 of the Code of Virginia, the following words and terms when used in this chapter shall have the following meanings, unless the context clearly indicates otherwise:

"ACPE" means the Accreditation Council for Pharmacy Education.

"ASHP" means the American Society of Health-System Pharmacists.

"Board" means the Virginia Board of Pharmacy.

"CE" means continuing education as required for renewal of licensure by the board.

"CEU" means a continuing education unit awarded for credit as the equivalent of 10 contact hours.

"Contact hour" means the amount of credit awarded for 60 minutes of participation in and successful completion of a continuing education program.

"Foreign school of pharmacy" means a school outside the United States and its territories offering a course of study in basic sciences, pharmacology, and pharmacy of at least four years in duration resulting in a degree that qualifies a person to practice pharmacy in that country.

"FPGEC certificate" means the certificate given by the Foreign Pharmacy Equivalency Committee of NABP that certifies that the holder of such certificate has passed the Foreign Pharmacy Equivalency Examination and a credential review of foreign training to establish educational equivalency to board approved schools of pharmacy and has passed approved examinations establishing proficiency in English.

"Inactive license" means a license that is registered with the Commonwealth but does not entitle the licensee to practice, and the holder of which is not required to submit documentation of CE necessary to hold an active license.

"NABP" means the National Association of Boards of Pharmacy.

"NHA" means National Healthcareer Association.

"Pharmacy technician trainee" means a person who is registered with the board and is currently enrolled in an approved pharmacy technician training program ~~and is performing~~ to perform duties restricted to pharmacy technicians for the purpose of obtaining practical experience in accordance with provisions of subsection G of § 54.1-3321 ~~D~~ of the Code of Virginia.

"PTCB" means the Pharmacy Technician Certification Board, co-founded by the American Pharmaceutical Association and the American Society of Health System Pharmacists, as the national organization for the voluntary examination and certification of pharmacy technicians.

**18VAC110-21-20. 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 | $235 |
| 2. Pharmacy intern registration | $20 |
| 3. Pharmacy technician trainee registration | $20 |
| ~~3.~~ 4. Pharmacy technician registration | $35 |
| ~~4.~~ 5. Approval of a pharmacy technician training program | $200 |
| ~~5.~~ 6. Approval of a continuing education program | $130 |

D. Annual renewal fees.

| | |
|---|---|
| 1. Pharmacist active license – due no later than December 31 | $120 |
| 2. Pharmacist inactive license – due no later than December 31 | $60 |
| 3. Pharmacy technician registration – due no later than December 31 | $35 |
| 4. Pharmacy technician training program | $100 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 or registration 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 or registration after the expiration date of such license or registration shall be grounds for disciplinary action by the board.

| | |
|---|---|
| 1. Pharmacist license | $40 |
| 2. Pharmacist inactive license | $20 |
| 3. Pharmacy technician registration | $15 |
| 4. Pharmacy technician training program | $20 |

F. Reinstatement fees. Any person or entity attempting to renew a license 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 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 | $275 |
| 2. Pharmacist license after revocation or suspension | $650 |
| 3. Pharmacy technician registration | $45 |
| 4. Pharmacy technician <u>or pharmacy technician trainee</u> registration after revocation or suspension | $165 |
| 5. A pharmacy technician training program 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 a reinstatement fee of $75. A pharmacy technician training program that ceases operation and wishes to resume shall not be eligible for reinstatement but shall apply for a new registration. | |

G. Miscellaneous fees.

| | |
|---|---|
| 1. Duplicate wall certificate | $50 |
| 2. Returned check | $35 |
| 3. Duplicate license or registration | $15 |
| 4. Verification of licensure or registration | $35 |

**18VAC110-21-40. Unprofessional conduct.**

The following practices shall constitute unprofessional conduct within the meaning of § 54.1-3316 of the Code of Virginia:

1. Failing to comply with provisions of § 32.1-127.1:03 of the Code of Virginia related to the confidentiality and disclosure of patient records or related to providing patient records to another practitioner or to the patient or the patient's personal representative;

2. Willfully or negligently breaching the confidentiality of a patient unless otherwise required or permitted by applicable law;

3. Failing to maintain the confidentiality of information received from the Prescription Monitoring Program, obtaining such information for reasons other than to assist in determining the validity of a prescription to be filled, or misusing information received from the program;

4. Engaging in disruptive or abusive behavior in a pharmacy or other health care setting that interferes with patient care or could reasonably be expected to adversely impact the quality of care rendered to a patient;

5. Engaging or attempting to engage in a relationship with a patient that constitutes a professional boundary violation in which the practitioner uses his professional position to take advantage of the vulnerability of a patient or the patient's family, including sexual misconduct with a patient or a member of the patient's family or other conduct that results or could result in personal gain at the expense of the patient;

6. Failing to maintain adequate safeguards against the diversion of controlled substances;

7. Failing to appropriately respond to a known dispensing error in a manner that protects the health and safety of the patient;

8. Delegating a task within the practice of pharmacy to a person who is not adequately trained to perform such a task;

9. Failing by the pharmacist in charge to ensure that pharmacy interns ~~and~~, pharmacy technicians, and pharmacy technician traineees working in the pharmacy are registered and that such registration is current;

10. Failing to exercise professional judgment in determining whether a prescription meets the requirements of law before dispensing;

11. Obtaining money or property of a patient or client by fraud or misrepresentation;

12. Providing false information or failing to cooperate with an employee of the Department of Health Professions in the conduct on an investigation or inspection;

13. Violating any provision of this chapter, 18VAC110-20, or Chapter 33 (§ 54.1-3300 et seq.) or 34 (§ 54.1-3400 et seq.) of Title 54.1 of the Code of Virginia;

14. Performing any act likely to deceive, defraud, or harm the public; or

15. Having a restriction of a license to practice pharmacy or a registration as a pharmacy technician in another jurisdiction in the United States.

**18VAC110-21-135. Registration as a pharmacy technician trainee.**

A. A person desiring to gain practical pharmacy experience toward completion of a pharmacy technician training program in Virginia shall first register with the board as a pharmacy technician trainee on a form provided by the board prior to engaging in the duties of a pharmacy technician pursuant to § 54.1-3321 of the Code of Virginia.

B. In order to be eligible to register as a pharmacy technician trainee, an applicant shall be enrolled in a pharmacy technician training program. An expiration date, not to exceed two years, shall be assigned to the registration to cover the estimated time period for the trainee to complete the practical pharmacy experience required for completion of the training program and pass the required examination. If the trainee is no longer enrolled in the training program, takes a voluntary break from the program, or is otherwise not actively progressing toward completion of such program, the registration is no longer valid and shall be returned to the board immediately.

C. A pharmacy technician trainee shall be directly monitored by a supervising pharmacist who holds a current active license and assumes full responsibility for the training and supervision of the trainee.

D. A pharmacy technician trainee shall notify the board in writing of any change in address of record within 14 days of such change.

**18VAC110-21-140. Application for registration as a pharmacy technician (Effective until July 1, 2022).**

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. To be registered as a pharmacy technician, an applicant shall provide evidence of the following:

1. Satisfactory completion of a board-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 enrolled in an approved pharmacy technician training program pursuant to § 54.1-3321 D of the Code of Virginia may perform tasks restricted to pharmacy technicians for no more than nine consecutive months from the date the trainee begins performing duties restricted to a pharmacy technician without becoming registered as a pharmacy technician.~~

**18VAC110-21-141. Requirements for pharmacy technician training (Effective July 1, 2022).**

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. To be registered as a pharmacy technician, an applicant shall provide evidence of the following:

1. Completion of a pharmacy technician training program that is:

a. Jointly accredited by the ASHP and ACPE;

b. An accredited training program operated through the Department of Education's Career and Technical Education Program;

c. Operated through a federal agency or branch of the military; or

d. Accredited by an accreditation body approved by the board.

2. Successfully having passed a national certification examination administered by PTCB or NHA.

C. A pharmacy technician who has previously practiced in another United States jurisdiction may be eligible to obtain registration as a pharmacy technician upon documentation of previous practice and having passed a national certification examination administered by PTCB or NHA.

D. A person who successfully completed or was enrolled in a board-approved pharmacy technician training program but did not successfully pass a national examination prior to July 1,

2022, may be eligible to obtain registration as a pharmacy technician after successfully passing a national certification examination administered by PTCB or NHA and submitting to the board documentation of such completion or enrollment in a board-approved pharmacy technician training program and passing examination score.

E. A person who passed a national certification examination administered by PTCB or NHA but did not complete a board-approved pharmacy technician training program prior to July 1, 2022, may be eligible to obtain registration as a pharmacy technician upon documentation of having passed such examination.

**18VAC110-21-150. Criteria for approval for training programs (Effective until July 1, 2022).**

A. Any person wishing to apply for approval of a pharmacy technician training program shall submit the application fee, a sample certificate, 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 the prescriber's 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, including the program approval number, 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 certificate, 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.

**18VAC110-21-160. ~~Examination.~~ (Repealed.).**

~~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 18VAC110-21-80 F.~~

**18VAC110-21-170. Renewal and reinstatement of registration.**

A. Pharmacy technician registrations expire on December 31 and shall be renewed annually prior to that date by the submission of a renewal fee, renewal form, and an e-profile number issued by NABP. A pharmacy technician newly registered on or after July 1 shall not be required to renew that registration until December 31 of the following year. Failure to receive the application for renewal shall not relieve the pharmacy technician of the responsibility for renewing the registration by the expiration date.

B. A pharmacy technician who fails to renew his registration by the expiration date may renew his registration at any time within one year of its expiration by submission of the renewal fee and late fee, renewal form, and attestation of having met the continuing education requirements.

C. A pharmacy technician who fails to renew his registration for more than one year following expiration and who wishes to reinstate such registration shall submit an application for reinstatement, pay the current renewal fee and a reinstatement fee, and submit documentation showing compliance with continuing education requirements. Reinstatement is at the discretion of the board and may be granted by the executive director of the board provided no grounds exist to deny said reinstatement. Practicing as a pharmacy technician with a lapsed registration shall be illegal and may subject the registrant to disciplinary action by the board.

D. A person who fails to reinstate a pharmacy technician registration within five years of expiration shall ~~not be eligible for reinstatement and shall repeat an approved training program and repeat and pass the examination or hold current PTCB certification before applying to be reregistered~~:

1. Take and pass a national certification examination administered by PTCB or NHA;

2. Document completion of 20 hours of continuing education; and

3. Pay the current renewal fee and a reinstatement fee.

**18VAC110-21-180. Requirements for continued competency.**

A. A pharmacy technician shall be required to have completed a minimum of 0.5 CEUs or five contact hours of approved continuing education for each annual renewal of registration. Hours in excess of the number required for renewal may not be transferred or credited to another year.

B. An approved continuing education program shall meet the requirements as set forth in 18VAC110-21-120 B or 18VAC110-21-130 B.

C. Upon written request of a pharmacy technician, the board may grant an extension of up to one year in order for the pharmacy technician to fulfill the continuing education requirements for the period of time in question. The granting of an extension shall not relieve the pharmacy technician from complying with current year requirements. Any subsequent extension shall be granted for good cause shown.

D. Up to one hour of the five hours required for annual renewal may be satisfied through delivery of pharmacy services as a pharmacy technician, without compensation, to low-income individuals receiving health services through a local health department or a free clinic organized in whole or primarily for the delivery of those services. One hour of continuing education may be credited for three hours of providing such volunteer services, as documented by the health department or free clinic.

E. ~~Original documentation~~ Documentation showing successful completion of continuing education programs shall be maintained by the pharmacy technician for a period of two years following the renewal of his registration. The pharmacy technician shall provide such documentation to the board upon request in a manner to be determined by the board.

**Agenda Item: Regulatory Action – Adoption of Proposed Regulations – Limited licenses for non-profits**

**Included in agenda package:**

Copy of Notice posted on Townhall

No comments on the NOIRA were received

Copy of Emergency regulations

**Staff note:**

Emergency regulations remain in effect for 18 months and must be replaced by permanent regulations.

**Board action:**

Adoption of proposed regulations identical to the emergency regulation or as amended by the Board.

**Board**
Board of Pharmacy

**Chapter**
**Regulations for Practitioners of the Healing Arts to Sell Controlled Substances [18 VAC 110 - 30]**

Action:
## Limited license for prescribing Schedule VI drugs in non-profit clinics
Action 5605 / Stage 9075
### Emergency/NOIRA Stage

| Documents | | |
|---|---|---|
| Emergency Text | 1/29/2021 1:21 pm | Sync Text with I |
| Agency Background Document | 9/21/2020 (modified 10/8/2020) | Upload / Replac |
| Attorney General Certification | 10/5/2020 | |
| Governor's Review Memo | 1/4/2021 | |
| Registrar Transmittal | 1/4/2021 | |

| Status | |
|---|---|
| **Public Hearing** | Will be held at the **proposed** stage |
| **Emergency Authority** | 2.2-4011(B) |
| **Exempt from APA** | No, this stage/action is subject to Article 2 of the *Administrative Process Act* |
| **Attorney General Review** | Submitted to OAG: 9/21/2020<br>Review Completed: 10/5/2020<br>Result: Certified |
| **DPB Review** | Submitted on 10/5/2020<br>Policy Analyst: Cari Corr<br>Review Completed: 10/14/2020<br>*DPB's policy memo is "Governor's Confidential Working Papers"* |
| **Secretary Review** | Secretary of Health and Human Resources Review Completed: 11/24/2020 |
| **Governor's Review** | Review Completed: 1/4/2021<br>Result: Approved |
| **Virginia Registrar** | Submitted on 1/4/2021<br>The Virginia Register of Regulations<br>Publication Date: 2/1/2021 Volume: 37 Issue: 12 |
| **Comment Period** | Ended 3/3/2021<br>0 comments |
| **Effective Date** | 1/4/2021 |
| **Expiration Date** | 7/3/2022 |

**Emergency Regulation**

**Board Of Pharmacy**

**LImited license for prescribing Schedule VI drugs in non-profit clinics**

**18VAC110-30-10. Definitions.**

The following words and terms when used in this chapter shall have the following meanings unless the context clearly indicates otherwise.

"Board" means the Virginia Board of Pharmacy.

"Controlled substance" means a drug, substance or immediate precursor in Schedules I through VI of the Drug Control Act.

"Licensee" means a practitioner who is licensed by the Board of Pharmacy to sell controlled substances.

"Personal supervision" means the licensee must be physically present and render direct, personal control over the entire service being rendered or acts being performed. Neither prior nor future instructions shall be sufficient nor shall supervision be rendered by telephone, written instructions, or by any mechanical or electronic methods.

"Practitioner" or "practitioner of the healing arts" means a doctor of medicine, osteopathic medicine or podiatry who possesses a current active license issued by the Board of Medicine. For the purpose of a limited-use permit for a nonprofit facility, a "practitioner" or "practitioner of the healing arts" may also mean a physician assistant with a current active license issued by the Board of Medicine or a nurse practitioner with a current active license issued by the Joint Boards of Nursing and Medicine.

"Sale" means barter, exchange, or gift, or offer thereof, and each such transaction made by any person, whether as an individual, proprietor, agent, servant or employee. It does not include the gift of manufacturer's samples to a patient.

"Special packaging" means packaging that is designed or constructed to be significantly difficult for children under five years of age to open or obtain a toxic or harmful amount of the controlled substance contained therein within a reasonable time and not difficult for normal adults to use properly, but does not mean packaging which all such children cannot open or obtain a toxic or harmful amount within a reasonable time.

"U.S.P.-N.F." means the United States Pharmacopeia-National Formulary.

**18VAC110-30-20. Application for 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. After June 7, 2016, 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.~~ Prior to engaging in the sale of Schedule VI controlled substances, excluding the combination of misoprostol and methotrexate, and hypodermic syringes and needles for the administration of prescribed controlled substances from a nonprofit facility, a doctor of medicine, osteopathic medicine, or podiatry; a nurse practitioner; or a physician assistant shall make application on a form provided by the board and be issued a limited-use license.

C. Any disciplinary action taken by the Board of Medicine, or in the case of a nurse practitioner, by the Joint Boards of Nursing and 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. After June 7, 2016, 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 of the Code of Virginia. A licensed practitioner of the healing arts shall apply for the facility permit on a form provided by the board.

B. For good cause shown, the board may issue a limited-use facility permit when the scope, degree, or type of services provided to the patient is of a limited nature. The 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 this chapter may be waived.

1. The limited-use facility permit application shall list the regulatory requirements for which a waiver is requested, if any, and a brief explanation as to why each requirement should not apply to that practice.

2. A policy and procedure manual detailing the type and volume of controlled substances to be sold and safeguards against diversion shall accompany the application.

3. The issuance and continuation of a limited-use facility permit shall be subject to continuing compliance with the conditions set forth by the board.

4. A limited-use facility permit may be issued to a nonprofit facility for the purpose of dispensing Schedule VI controlled substances, excluding the combination of misoprostol and methotrexate, and hypodermic syringes and needles for the administration of prescribed controlled substances.

C. 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.

**18VAC110-30-40. Acts to be performed by the licensee.**

A. The selection of the controlled substance from the stock, any preparation or packaging of a controlled substance or the preparation of a label for a controlled substance to be transferred to a patient shall be the personal responsibility of the licensee.

1. Any compounding of a controlled substance shall be personally performed by the licensee or a registered pharmacy technician under the supervision of the licensee.

2. A licensee may supervise one person who may be present in the storage and selling area to assist in performance of pharmacy technician tasks, as set forth in § 54.1-3321 of the Code of Virginia, provided such person is not licensed to sell controlled substances and is either:

a. A pharmacy technician registered with the board; or

b. A licensed nurse or physician assistant who has received training in technician tasks consistent with training required for pharmacy technicians.

3. Unless using one of the board-approved training courses for pharmacy technicians, a licensee who uses a nurse or physician assistant to perform pharmacy technician tasks shall develop and maintain a training manual and shall document that such licensee has successfully completed general training in the following areas:

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

b. The preparation of prescription labels or patient information;

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

d. The counting or measuring of the drug to be dispensed to include pharmacy calculations;

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

f. The stocking or loading of automated dispensing devices or other devices used in the dispensing process, if applicable; and

g. Applicable laws and regulations related to dispensing.

4. A licensee who employs or uses pharmacy technicians, licensed nurses or physician assistants to assist in the storage and selling area shall develop and maintain a site-specific training program and manual for training to work in that practice. The program shall include training consistent with that specific 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 in the practice in performing technician duties, and pharmacy calculations consistent with the duties in that practice.

5. A licensee shall maintain documentation of successful completion of the site-specific training program for each pharmacy technician, nurse or physician assistant for the duration of the employment and for a period of two years from date of termination of employment. Documentation for currently employed persons 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.

B. Prior to the dispensing, the licensee shall:

1. Conduct a prospective drug review and offer to counsel a patient in accordance with provisions of § 54.1-3319 of the Code of Virginia; and

2. Inspect the prescription product to verify its accuracy in all respects, and place his initials on the record of sale as certification of the accuracy of, and the responsibility for, the entire transaction.

C. If the record of sale is maintained in an automated data processing system as provided in 18VAC110-30-200, the licensee shall personally place his initials with each entry of a sale as a certification of the accuracy of, and the responsibility for, the entire transaction.

**18VAC110-30-270. Grounds for disciplinary action.**

In addition to those grounds listed in § 54.1-3316 of the Code of Virginia, the board may revoke, suspend, refuse to issue or renew a license to sell controlled substances or may deny any application if it finds that the licensee or applicant has had his license to practice medicine, osteopathic medicine, or podiatry or license as a physician assistant or nurse practitioner suspended or revoked in Virginia or in any other state or no longer holds a current active license to practice in the Commonwealth of Virginia.

**Agenda Item: Amendments to Guidance documents**

***Staff Note:***

1) The following guidance documents need to be revised:

110-27 – Responsibilities of a PIC
110-33 – Pharmacy interns working as pharmacy technicians
110-31 – Approved Capture Drugs and Drug Administering Equipment
2) Provisions in guidance document 110-20 refer to practice by pharmacy technicians in training. It is replaced by changes in Code and regulation, so it can now be repealed.

3) Guidance document 110-38, Requirements for non-resident pharmacies, was last revised in Dec. 2016. Guidance documents must be reviewed every 4 years; this document does not need to be revised but the Board must reaffirm the guidance.

***Board action:***

The Board can consider the staff recommendations in a block. If a member would like to take one of the actions out of the block, he/she can request to do so (does not require a separate motion). Motion: To amend guidance documents 110-27, ~~and~~ 110-31, and 110-33, to repeal 110-20, and to reaffirm 110-38.

# Virginia Board of Pharmacy

## PIC Responsibilities

This document is intended to assist a new pharmacist-in-charge (PIC) as a reminder of some of the responsibilities, and some "do's" and "don'ts". It is not intended to be a comprehensive list of all responsibilities and is not intended to negate individual responsibility of any other pharmacist practicing at the location. **Pharmacists should not be fearful that, by merely being the PIC of a pharmacy, they will be the subject of Board action for circumstances which are beyond their control.**

**New Pharmacies:**

- It is your responsibility to ensure that your pharmacy is ready to be inspected on the date assigned. At least 24 hours prior to a scheduled opening make sure that the pharmacy is ready, i.e. all enclosures to the prescription department are in place with appropriate locks on entrances, all counters and shelving are in place, hot and cold running water, refrigerator/freezer is working and at proper temperature with monitoring thermometer if drugs requiring storage at these temperatures plan to be stored, all minimum equipment is in place, and the alarm system is functional and fully protects the prescription department. Please note that Regulation 18 VAC 110-20-180 requires that the alarm device must be capable of detecting breaking by any means when activated, monitored in accordance with accepted industry standards, maintained in operating order, have an auxiliary source of power, and be capable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational. Additionally, the alarm must have at least one hard-wired communication method and a notification of any breach of the alarm must be communicated to the pharmacist-in-charge or a pharmacist working at the pharmacy. The system must be approved prior to stocking drugs. On the opening inspection, the inspector will "walk test" the system to ensure that there are no areas within the prescription department uncovered by the alarm. For example, if an inspector can stand in a corner of a bay and move his arms without setting off the alarm, the alarm will not pass. In most cases, more than one sensor is necessary to provide complete coverage. The inspector will also want assurances of monitoring and the ability to alert the monitoring company if the alarm system is breached even when the communication line is cut. Although not required, some PICs find it very helpful to have an alarm technician present at the time of the inspection to answer any questions the inspector may have or to make any adjustments or additions necessary to bring the system into compliance which may negate the need for a reinspection.

- If the new pharmacy will not be ready, you or the owner should notify the inspector as soon as it is known to prevent the inspector from making an unnecessary trip. If the inspector is not notified and the pharmacy cannot reasonably be inspected, a ~~$150~~ $300 reinspection fee will be assessed in order to schedule and conduct the reinspection.

- As PIC of a new pharmacy, you should be present at the opening inspection of the pharmacy. If you are not able to be present at the opening, you need to notify the Board prior to the date of the inspection with the reason why you are not able to be present. Additionally, you must ensure that another Virginia licensed pharmacist is present if you are absent. If deficiencies

are noted on the opening inspection, drugs may not be stocked and the permit will not be issued until you assure the Board in writing that the deficiencies have been corrected and the Board gives approval.

- If any deficiencies are noted on the opening inspection, as the PIC, you must personally notify the Board of corrections made prior to a permit being issued. Therefore, you should personally inspect any corrections to be sure they have been made properly before contacting the Board.

- Once the permit is issued, prescription drugs may not be stocked earlier than two weeks prior to the designated opening date. Once prescription drugs have been placed in the pharmacy, a pharmacist shall be present on a daily basis to ensure the safety and integrity of the drugs. If there is a change in the designated opening date, you must notify the board office, and a pharmacist shall continue to be on site on a daily basis.

- Once a permit has been issued, the pharmacy shall be fully operational within 90 days of issuance. For good cause shown, such as circumstances beyond the control of the permit holder, the board may grant an extension.

**Upon taking over responsibility as PIC:**

- A pharmacy permit application must be submitted to the Board indicating the effective date you intend to assume the role as PIC. Make sure when you sign an application to be a PIC that you are not still on record with the Board as being a PIC for more than one other pharmacy. Assuming you are eligible to assume the role of PIC, the Board will issue a pharmacy permit in your name. This is your permit. It must be displayed where the public can read it. If you do not receive the permit within two weeks of sending in the application call the Board and check on the status (804)-367-4456. All pharmacy permits expire on April 30th annually. Be sure that the permit is renewed each year. *Note: A pharmacist shall not be eligible to serve as PIC until after having obtained a minimum of two years of experience practicing as a pharmacist in Virginia or another jurisdiction in the United States. The board may grant an exception to the minimum number of years of experience for good cause shown.*

- A PIC is required to be in "full and actual charge of the pharmacy" and "fully engaged in the practice of pharmacy at the location designated on the application". Never agree to sign a pharmacy permit application as PIC unless you intend to meet the requirement of being fully engaged in practice at that pharmacy. There is no minimum number of hours established to define "fully engaged etc."

- Take an incoming change of PIC inventory of all Schedule II, III, IV, and V controlled substances, to include all expired drugs in Schedules II through V, prior to opening for business on the date you first assume the role as PIC, i.e., the effective date for the change of PIC indicated on the application. Sign and date the inventory and indicate whether the inventory was taken prior to the opening of business or after close of business, if you performed the inventory the night before the effective date for the change of PIC. For a 24-hour pharmacy with no opening or closing of business, you must clearly document whether the receipt or distribution of drugs on the inventory date occurred before or after the inventory was taken. If the pharmacy is a new pharmacy and you have no drugs on hand on opening date, you still

"take" an inventory, and record a zero balance. Additional guidance on how to perform an inventory, e.g., which drugs must be physically counted, is found in Guidance Document 110-16 at http://www.dhp.virginia.gov/pharmacy/pharmacy_guidelines.htm.

- Verify that every pharmacist working at your pharmacy holds a current license to practice pharmacy. Licensure can be verified by using the "license lookup" function on the Board's website at www.dhp.virginia.gov/pharmacy.

- Verify via the methods listed in the previous item that every person performing the duties of a pharmacy technician working at your pharmacy holds either a current pharmacy technician registration or pharmacy technician trainee registration. Persons enrolled in an approved pharmacy technician training program must apply for and be issued a pharmacy technician trainee registration prior to performing the duties of a pharmacy technician. The pharmacy technician trainee registration is valid for the estimated time period for the trainee to complete the practical pharmacy experience required for completion of the training program and pass the required examination, not to exceed two years. ~~or that there is documentation on site showing enrollment in a Board-approved training program for not more than nine months from the date the trainee began performing duties restricted to a pharmacy technician~~. When considering a person for employment as a pharmacy technician, verify through "License Lookup" at www.dhp.virginia.gov/pharmacy that the person has not been a registered pharmacy technician within the past 5 years. If the person has a pharmacy technician registration that expired less than 5 years ago, he or she must first renew or reinstate this registration before being authorized to perform the duties of a pharmacy technician in the pharmacy.

- You are responsible for ensuring that the practice of pharmacy is in overall compliance with laws and regulations. You are not responsible for individual actions of practicing pharmacists. It is **strongly** recommended that you perform a routine self-inspection of the pharmacy using the most current pharmacy inspection report which may be downloaded from http://www.dhp.virginia.gov . You should review pharmacy security equipment and procedures to ensure that they meet requirements, such as functional locks on enclosures, functional alarm systems, and access to keys and alarm restricted to pharmacists practicing at the location, including any emergency key kept in compliance with current regulations. Routinely check the refrigerator and freezer to ensure that there is a working thermometer placed within and that they are maintained at the required temperatures- between 36° and 46°F for refrigerators and between -13°F and 14°F for freezers. Also review record keeping systems to make sure they meet current requirements and that staff pharmacists are aware of their responsibilities. Additionally, you should review the list of deficiencies that may result in a monetary penalty identified in guidance document 110-9 found at http://www.dhp.virginia.gov/Pharmacy/pharmacy_guidelines.htm. You may choose to create a folder or notebook containing all required inventories, along with information indicating the location of all required documents for an inspector to review. This will ensure that all staff, even floater staff who may be on duty at the time of an unannounced inspection, know where to locate the required documents. Performing a self-inspection and staying organized will assist in identifying areas of non-compliance for which you should correct and will prevent the unnecessary citing of deficiencies.

- Notify the Board of any known violation of law or regulation on the part of another individual in your pharmacy or of any inability to have known deficiencies corrected.

**Safeguards against Diversion of All Controlled Substances:**

- The PIC "shall provide safeguards against diversion of all controlled substances". This responsibility should be taken very seriously. When an investigation involving the theft or loss of controlled substances is performed by the Board, the role of the PIC in providing safeguards against diversion is evaluated.

- It is the policy of the Board to include the name of the PIC (s) in the findings of fact in any disciplinary proceeding involving diversion of drugs.

- The PIC shall:

  - Ensure all security measures are in compliance and operational, e.g., locks to enclosures are functional, access to key and alarm code is restricted to pharmacists that practice at the location, emergency key and alarm code is securely stored;

  - Ensure the biennial inventory of **all** drugs in Schedules II, III, IV, and V, to include any expired drugs in Schedules II-V, is performed on any date which is within two years of the previous biennial inventory. Additional guidance on how to perform an inventory, e.g., which drugs must be physically counted, is found in Guidance Document 110-16 at http://www.dhp.virginia.gov/pharmacy/pharmacy_guidelines.htm

  - Ensure the pharmacy is in compliance each month with the perpetual inventory requirement of Schedule II drugs found in Regulation 18VAC110-20-240. Be sure to include **all** Schedule II drugs in the monthly perpetual inventory requirement, to include any drugs on-hand that were not dispensed during that month and any expired drugs. Additional guidance on performing the monthly perpetual inventory of Schedule II drugs may be found in Guidance Document 110-16 at http://www.dhp.virginia.gov/pharmacy/pharmacy_guidelines.htm

  - Notify the Board of any theft or unusual losses of drugs as soon as discovered. Within 30 days after the discovery of such theft or loss, furnish the Board with a listing of the kind, quantity and strength of such drugs lost. Maintain this listing for two years from the date of the transaction recorded.

  - Not permit access to the prescription department or controlled substances by a pharmacist, pharmacy intern, or pharmacy technician whose license or registration is currently suspended or revoked.

- The Board also offers the following *suggested* best practices to safeguard against diversion of controlled substances:

- Perform state and federal criminal background checks on all personnel with access to controlled substances;
- Require periodic urine drug screening of all personnel with access to controlled substances;
- Prohibit personnel from bringing smocks or bags into the prescription department;
- Prior to leaving the pharmacy, perform routine bag checks of all personnel with access to controlled substances;
- Ensure all personnel with access to controlled substances are routinely made aware of policies and procedures to prevent, identify, and address internal and external theft, to include armed robberies, and loss of controlled substances;
- In addition to the biennial inventory and perpetual inventory of Schedule II drugs, perform inventories, at least quarterly, of drugs at-risk for diversion and appropriately reconcile all discrepancies;
- Do not delegate the management of drug inventory to solely one individual;
- Review the amount of drugs received and drugs dispensed to ensure no suspicious activity exists, and monitor any adjustments made to the ongoing inventory and any excessive ordering;
- Install surveillance cameras to prevent and/or identify theft or loss of controlled substances; and
- Have full and timely access to all reports relating to inventories, invoices, and audits
- In addition to the reporting requirements in §54.1-2400.6, notify the Board of any separation of employee for known or suspected drug diversion.

**Upon leaving as PIC:**

- Although not required by law or regulation, you have the right to take an outgoing change of pharmacist-in-charge inventory of all Schedule II-V controlled substances unless the owner submits written notice to the board showing good cause as to why this opportunity should not be allowed. If you so take one, you should take a **copy** with you. Once you leave, you cannot ensure that the pharmacy will maintain it, and this inventory is your documentation of what drugs were on hand when you left if there is a subsequent diversion. If you request but are denied an opportunity to take this inventory, you should immediately report this to the Board.
- As you terminate your position as PIC, remove the pharmacy permit and return it directly to the Board office indicating the effective date of the termination of the PIC position. Do

not leave it on the wall. Do not return it to a corporate or district office or a district manager. It is your permit and your responsibility to return it to the Board immediately. For your protection, we would suggest that you return it by certified mail, return receipt requested.

# Virginia Board of Pharmacy

## Pharmacy Interns as Pharmacy Technicians
## Pharmacy Technician Ratio

For the purpose of gaining practical experience to meet requirements for becoming a pharmacist, a registered pharmacy intern is by law allowed to perform tasks restricted to pharmacists provided they are directly monitored by a pharmacist. When a pharmacy intern is engaged in obtaining required practical experience hours, to be used either by the college of pharmacy or submitted to the Board on an affidavit, the pharmacy intern is not counted in the pharmacist to pharmacy technician ratio. For example, one pharmacist could be supervising a pharmacy intern for experience and up to four pharmacy technicians at the same time.

The Board has determined that properly registered pharmacy interns may also act as pharmacy technicians without being registered as such during times when they are not gaining practical experience. Pharmacy interns when acting as pharmacy technicians, shall be considered part of the 1:4 pharmacist to technician ratio.

Pharmacy technician trainees ~~who are not yet registered but~~ performing technician tasks in a pharmacy ~~within the allotted nine months time in an approved training program~~, are considered to be acting as pharmacy technicians and as such, are included in the 1:4 pharmacist to technician ratio.

# Virginia Board of Pharmacy

## Guidance on

## APPROVED CAPTURE DRUGS AND DRUG ADMINISTERING EQUIPMENT

Animal control officers and other officials as defined in §3.1-796.66 of the Comprehensive Animal laws may possess drugs and drug administering equipment which are approved by the State Veterinarian for use in the capture of companion animals. Click below to access the most recent State Veterinarian's directive for Approved Capture Drugs and Drug Administering Equipment.

~~http://www.vdacs.virginia.gov/animals-animal-care-and-emergency.shtml~~

http://www.vdacs.virginia.gov/animals-animal-care.shtml

# Virginia Board of Pharmacy

## Practice by a Pharmacy Technician Trainee

Regulations of the Board of Pharmacy allow a person enrolled in a Board-approved pharmacy technician training program to perform duties restricted to pharmacy technicians, for the purpose of obtaining practical experience in accordance with § 54.1-3321 D of the Code of Virginia, for no more than nine months without that person becoming registered as a pharmacy technician. (*See Regulations 18VAC110-21-140, 18VAC110-20-111, and definition of "pharmacy technician trainee" in 18VAC110-20-10*)

The Board interprets the restriction of nine months of practice for a pharmacy technician trainee to mean **nine consecutive months** from the date the pharmacy technician trainee begins performing duties restricted to a pharmacy technician as part of a Board-approved pharmacy technician training program. For example, a pharmacy technician trainee completes the didactic or classroom portion of a training program and begins performing tasks restricted to a pharmacy technician on January 1st. The technician may conduct tasks restricted to a pharmacy technician until October 1st of that year. If she/he ceases enrollment in the pharmacy technician training program in March and enrolls in a second pharmacy technician training program in July, she/he may still only perform tasks restricted to a pharmacy technician until October 1st of that year. By that date, the trainee must either be registered with the Board as a pharmacy technician or cease performing any tasks restricted to pharmacy technicians.

***18VAC110-20-140. Application for registration as a pharmacy technician.***

*D. A pharmacy technician trainee enrolled in an approved pharmacy technician training program pursuant to § 54.1-3321 D of the Code of Virginia may perform tasks restricted to pharmacy technicians* ***for no more than nine months*** *from the date the trainee begins performing duties restricted to a pharmacy technician without becoming registered as a pharmacy technician.*

***18VAC110-20-111. Pharmacy technicians.***

*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.*

***18VAC110-21-10 Definitions.***

*"Pharmacy technician trainee" means a person who is currently enrolled in an approved pharmacy technician training program and is performing duties restricted to pharmacy*

*technicians for the purpose of obtaining practical experience in accordance with § 54.1-3321 D of the Code of Virginia.*

***§ 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.*

# Virginia Board of Pharmacy

## Requirement for Non-resident Pharmacies to Submit Current Inspection Report

The Board of Pharmacy may issue a permit to a non-resident pharmacy that meets requirements of law and regulation, including the submission of an inspection report satisfactory to the Board. The law (Code of Virginia) provides:

**§ 54.1-3434.1. Nonresident pharmacies to register with Board.**

...

*As a prerequisite to registering or renewing a registration with the Board, the nonresident pharmacy shall submit a copy of a current inspection report resulting from an inspection conducted by the regulatory or licensing agency of the jurisdiction in which it is located that indicates compliance with the requirements of this chapter, including compliance with USP-NF standards for pharmacies performing sterile and non-sterile compounding. The inspection report shall be deemed current for the purpose of this subdivision if the inspection was conducted (i) no more than six months prior to the date of submission of an application for registration with the Board or (ii) 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 nonresident pharmacy has not been inspected by the regulatory or licensing agency of the jurisdiction in which it is licensed 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.*

...

For the purpose of compliance with the requirement for such a report, the Board offers the following guidance:

An application for registration or renewal without an inspection report that indicates compliance with the requirements of this chapter, including compliance with USP-NF standards for pharmacies performing sterile and non-sterile compounding, will be deemed incomplete and a registration will not be issued or renewed until such time as a report or other acceptable documentation is produced. Inspection reports from the National Association of Boards of Pharmacy (NABP) that satisfy the inspection report requirements of §54.1-3434.1 will be deemed acceptable alternatives to an inspection by the licensing or regulatory agency of jurisdiction or an inspection by the Board of Pharmacy's own agent.

Notwithstanding submission of an inspection report from a source acceptable to the Board, the Board may deny an application on the grounds that the applicant failed to comply with applicable laws or regulations. The applicant would have an opportunity for a hearing before a committee of the Board.

An "opening" inspection report for a newly opened pharmacy or a new location for an existing pharmacy indicating compliance with the requirements of statute, including compliance with USP-NF standards for pharmacies performing non-sterile compounding, may satisfy the requirements for obtaining initial registration as a nonresident pharmacy. However, an "operational" inspection report shall be provided during the subsequent renewal of the registration. An "opening" inspection report for

a newly opened pharmacy or a new location for an existing pharmacy performing sterile compounding shall not satisfy the requirements for obtaining initial registration or renewal as a nonresident pharmacy. Submission of an "operational" inspection report indicating compliance with USP-NF standards for sterile compounding shall be required for consideration for obtaining initial registration or renewal as a nonresident pharmacy.

# FDA in Brief: FDA Announces Significant Milestone in Compounding Program to Protect Public Health Through Collaboration with States

October 26, 2020

**Media Inquiries**

Jeremy Kahn (mailto:Jeremy.Kahn@fda.hhs.gov)
301-796-8671 (http://wcms-internet.fda.gov/news-events/fda-brief/fda-brief-fda-advises-restaurants-not-sell-or-serve-recall

The following quote is attributed to FDA Commissioner Stephen M. Hahn, M.D.:

> **"We are pleased to have reached this important milestone and continue our collaborative efforts with states and other stakeholders to protect patients from the potential risks associated with poor quality compounded drugs, while ensuring appropriate access to compounded drugs for patients that have a medical need for them. The availability of our standard memorandum of understanding (MOU) for signature by the states will help enhance communication and maximize our federal and state resources for oversight of compounded drugs produced by traditional compounding pharmacies.**
>
> **These partnerships between states that enter into the MOU and the FDA will further our combined efforts to protect the public health by, among other things, state regulators' commitment to investigate complaints about adverse drug experiences and product quality issues involving drugs compounded at pharmacies within their state and distributed outside their state. State regulators will also have an efficient information sharing channel to advise the FDA when they receive reports of serious adverse drug experiences or serious product quality issues related to compounded drugs, such as contamination. This is expected to facilitate early collaboration on issues that have the potential to affect patients in multiple states.**
>
> **As states prepare to sign the MOU, we'll continue to work closely with them and other stakeholders to promote further improvement in the oversight of compounded drugs."**

**Additional Information**

Today, the U.S. Food and Drug Administration is announcing (https://www.federalregister.gov/public-inspection/2020-23687/memorandum-of-understanding-certain-distributions-of-compounded-human-drug-products-between-the) the availability for signature of the standard Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products (/media/143283/download) between state boards of pharmacy or other state agencies and FDA. As outlined in the agency's May FDA Voices (/news-events/fda-voices/fda-announces-latest-step-toward-finalizing-memorandum-understanding-states-addressing-compounded), once signed by states, the MOU will serve as an important information-sharing mechanism about compounders, primarily pharmacies, that distribute compounded drugs interstate.

Additionally, as part of the MOU, the agency has worked to refine the definition of "inordinate amount," a threshold for certain information identification and sharing which does not place a limit on the distribution of compounded human drug products interstate by a pharmacy located in a state that has entered into the MOU. The Federal Food, Drug, and Cosmetic Act (FD&C Act) sets a five percent limit on compounded drugs distributed outside the state by a pharmacist, pharmacy or physician located in a state that has not entered into the MOU.

To provide ample time for state review, the agency has increased the amount of time for signature, from 180 days to 365 days, before it intends to enforce the five percent limit in section 503A of the FD&C Act in states that have not signed the final MOU. This extension should correspond to a full legislative cycle for most states and allows more time for states to modify their laws and regulations, if necessary.

### Related Information

- Human Drug Compounding (/drugs/guidance-compliance-regulatory-information/human-drug-compounding)
- FDA Announces Latest Step Toward Finalizing Memorandum of Understanding with States Addressing Compounded Drug Distribution, While Preserving Access (/news-events/fda-voices/fda-announces-latest-step-toward-finalizing-memorandum-understanding-states-addressing-compounded)

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

Security controls are reviewed on an ongoing basis.

- Knowledge of individual tape passwords is required to access backups, and access to the system is limited to users obtaining prior supervisory approval. To avoid inadvertent data disclosure, a special additional procedure is performed to ensure that all Privacy Act data are removed from computer hard drives. Additional safeguards may also be built into the program by the system analyst as warranted by the sensitivity of the data set.
- FTEs and contractor employees who maintain records are instructed in specific procedures to protect the security of records and are to check with the system manager prior to making disclosure of data. When individually identifiable data are used in a room, admittance at either federal or contractor sites is restricted to specifically authorized personnel.
- Appropriate Privacy Act provisions and breach notification provisions are included in applicable contracts, and the CDC Project Director, contract officers, and project officers oversee compliance with these requirements. Upon completion of the contract, all data will be either returned to federal government or destroyed, as specified by the contract that includes breach notifications.
- Records that are eligible for destruction are disposed of using destruction methods prescribed by NIST SP 800–88. Hard copy records are placed in a locked container or designated secure storage area while awaiting destruction. Records are destroyed in a manner that precludes its reconstruction, such as secured cross shredding. Utilizing the HHS Security Rule Guidance Material found at *https://www.hhs.gov/hipaa/for-professionals/security/guidance/index.html*, electronic information will be deleted or overwritten using Department of Defense National Institute of Standards and Technology/General Services Administration (NIST/GSA) approved overwriting software that wipes the entire physical disk and not just the virtual disk. In addition, the physical destruction is obtained by using a National Security Agency/Central Security Service (NSA/CSS) approved degaussing device.

**PHYSICAL SAFEGUARDS:**

- Paper records are maintained in locked cabinets in restricted areas to which access is controlled by an electronic cardkey system and is limited to staff who have responsibility for conducting regulatory oversight.
- Electronic data files are stored in a restricted access location. The computer room is protected by an automatic sprinkler system and numerous automatic sensors (*e.g.*, water, heat, smoke, etc.) which are monitored, and a proper mix of portable fire extinguishers is located throughout the computer room. Computer workstations, lockable personal computers, and automated records are located in secured areas.

**RECORD ACCESS PROCEDURES:**

An individual seeking access to records about that individual in this system of records must submit a written access request to the System Manager, identified in the "System Manager" section of this SORN. The request must contain the requester's full name, address, and signature, and DOJ identification number if known. To verify the requester's identity, the signature must be notarized or the request must include the requester's written certification that the requester is the individual who the requester claims to be and that the requester understands that the knowing and willful request for or acquisition of a record pertaining to an individual under false pretenses is a criminal offense subject to a fine of up to $5,000. An accounting of disclosures that have been made of the records, if any, may also be requested.

**CONTESTING RECORD PROCEDURES:**

An individual seeking to amend a record about that individual in this system of records must submit an amendment request to the System Manager identified in the "System Manager" section of this SORN, containing the same information required for an access request. The request must include verification of the requester's identity in the same manner required for an access request; must reasonably identify the record and specify the information contested, the corrective action sought, and the reasons for requesting the correction; and should include supporting information to show how the record is inaccurate, incomplete, untimely, or irrelevant.

**NOTIFICATION PROCEDURES:**

An individual who wishes to know if this system of records contains records about that individual should submit a notification request to the System Manager identified in the "System Manager" section of this SORN. The request must contain the same information required for an access request and must include verification of the requester's identity in the same manner required for an access request.

**EXEMPTIONS PROMULGATED FOR THE SYSTEM:**

None.

**HISTORY:**

72 FR 35993 (July 2, 2007); 76 FR 4483 (Jan. 25, 2011), 83 FR 6591 (Feb. 14, 2018).

[FR Doc. 2020–23770 Filed 10–26–20; 8:45 am]

BILLING CODE 4163–18–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2015–N–0030]**

## Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products Between the State Board of Pharmacy or Other Appropriate State Agency and the Food and Drug Administration; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability; withdrawal.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) is announcing the availability of a final standard memorandum of understanding (MOU) entitled "Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products Between the [insert State Board of Pharmacy or Other Appropriate State Agency] and the U.S. Food and Drug Administration" (final standard MOU). The final standard MOU describes the responsibilities of a State Board of Pharmacy or other appropriate State agency that chooses to sign the MOU in investigating and responding to complaints related to drug products compounded in such State and distributed outside such State and in addressing the interstate distribution of inordinate amounts of compounded human drug products.

**DATES:** The announcement of the MOU is published in the **Federal Register** on October 27, 2020. FDA is withdrawing its revised draft standard MOU that published on September 10, 2018 (83 FR 45631), as of October 27, 2020.

**ADDRESSES:** Submit electronic comments on the final standard MOU to Docket No. FDA–2015–N–0030. Submit written comments on the final standard MOU to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm.

1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document. Submit written requests for single copies of the final standard MOU to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft document.

**FOR FURTHER INFORMATION CONTACT:** Alexandria Fujisaki, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5169, Silver Spring, MD 20993–0002, 240–402–4078.

**SUPPLEMENTARY INFORMATION:**

## I. Background

Section 503A of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 353a) describes the conditions that must be satisfied for drug products compounded by a licensed pharmacist or licensed physician to be exempt from the following sections of the FD&C Act: (1) Section 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B)) (concerning current good manufacturing practice (CGMP) requirements), (2) section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning the labeling of drugs with adequate directions for use), and (3) section 505 (21 U.S.C. 355) (concerning the approval of drugs under new drug applications or abbreviated new drug applications).

One of the conditions to qualify for the exemptions listed in section 503A of the FD&C Act is that (1) the drug product is compounded iu a State that has entered into an MOU with FDA that addresses the distribution of inordinate amounts of compounded drug products interstate and provides for appropriate investigation by a State agency of complaints relating to drug products distributed outside such State; or (2) if the drug product is compounded in a State that has not entered into such an MOU, the licensed pharmacist, pharmacy, or physician does not distribute, or cause to be distributed, compounded drug products out of the State in which they are compounded in quantities that exceed 5 percent of the total prescription orders dispensed or distributed by such pharmacy or physician (5 percent limit) (see section 503A(b)(3)(B)(i) and (ii) of the FD&C Act). Another condition to qualify for the exemptions listed in section 503A of the FD&C Act is that the drug is compounded for an identified individual patient based on the receipt of a valid prescription order or a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient (section 503A(a) of the FD&C Act). This MOU does not alter this condition.

Section 503A(b)(3)(B) of the FD&C Act directs FDA to develop, in consultation with the National Association of Boards of Pharmacy (NABP), a standard MOU for use by the States in complying with section 503A(b)(3)(B)(i).

FDA is withdrawing the revised draft standard MOU entitled "Memorandum of Understanding Addressing Certain Distributions of Compounded Drug Products Between the State of [insert State] and the U.S. Food and Drug Administration," which was issued in September 2018 (2018 revised draft standard MOU). The 2018 revised draft standard MOU is superseded by the final standard MOU.

## II. Previous Efforts To Develop a Standard MOU

In the **Federal Register** of January 21, 1999 (64 FR 3301), FDA announced the availability for public comment of a draft standard MOU, developed in consultation with NABP (1999 draft standard MOU). Over 6,000 commenters submitted comments on the 1999 draft standard MOU. Because of litigation over the constitutionality of the advertising, promotion, and solicitation provision in section 503A of the FD&C Act,[1] the draft standard MOU was not completed. In 2013, section 503A of the FD&C Act was amended by the Drug Quality and Security Act (DQSA) (Pub. L. 113–54) to remove the advertising, promotion, and solicitation provisions that were held unconstitutional, and FDA took steps to implement section 503A, including to continue to develop the standard MOU. In the **Federal Register** of February 19, 2015 (80 FR 8874), FDA withdrew the 1999 draft standard MOU and issued the 2015 draft standard MOU for public comment. FDA received more than 3,000 comments on the 2015 draft standard MOU. In the **Federal Register** of September 10, 2018 (83 FR 45631), FDA withdrew the 2015 draft standard MOU and issued the 2018 revised draft standard MOU for public comment. FDA received 38 comments during the comment period on the 2018 revised draft standard MOU. By this notice, FDA is withdrawing the 2018 revised draft standard MOU and issuing a final standard MOU, which the Agency developed in consultation with NABP for use by the States in complying with section 503A(b)(3)(B).

[1] The conditions of section 503A of the FD&C Act originally included restrictions on the advertising or promotion of the compounding of any particular drug, class of drug, or type of drug and the solicitation of prescriptions for compounded drugs. These provisions were challenged in court and held unconstitutional by the U.S. Supreme Court in 2002. See *Thompson* v. *Western States Med. Ctr.*, 535 U.S. 357 (2002).

## III. Final Standard MOU

In consultation with NABP, FDA has developed a final standard MOU. FDA considered the comments submitted on the 2015 draft standard MOU and 2018 revised draft standard MOU, as well as comments on the MOU provisions it received in connection with a draft guidance on section 503A of the FD&C Act entitled "Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act" (2013 draft 503A guidance) (see 78 FR 72901, December 4, 2013). Below, FDA has summarized and discussed key provisions of the final standard MOU and, where appropriate, summarized changes that the Agency made in the final standard MOU. Drug products intended for veterinary use, repackaged drug products, biological products subject to licensure through a biologics license application under section 351 of the Public Health Service Act (42 U.S.C. 262), and drug products compounded by outsourcing facilities under section 503B of the FD&C Act are not the subject of the final standard MOU.

### *A. Investigation of Complaints Relating to Compounded Human Drug Products Distributed Outside the State*

The final standard MOU provides that a State Board of Pharmacy or other appropriate State agency that enters into the MOU agrees to:

- Investigate complaints of adverse drug experiences and product quality issues relating to human drug products compounded at a pharmacy in the State and distributed outside the State. Investigations performed by the State Board of Pharmacy or other appropriate State agency under this MOU will include taking steps to assess whether there is a public health risk associated with the compounded drug product and whether such risk is adequately contained. Investigations will be performed pursuant to the State Board of Pharmacy's or other appropriate State ageucy's established investigatory policies and procedures, including those related to prioritizing complaints, provided they are not in conflict with the terms of the MOU;

- If the complaint is substantiated, take action that the State Board of Pharmacy or other appropriate State agency considers to be appropriate and warranted, in accordance with and as permitted by State law, to ensure that the relevant pharmacy investigates the root cause of the problem that is the subject of the complaint and undertakes sufficient corrective action to address any identified public health risk relating to the problem, including the risk that future similar problems may occur;
- Maintain records of the complaints it receives regarding adverse drug experiences or product quality issues relating to human drug products compounded at a pharmacy, the investigation of each complaint, and any response to or action taken as a result of a complaint, beginning when the State Board of Pharmacy or other appropriate State agency receives notice of the complaint. The State Board of Pharmacy or other appropriate State agency will maintain these records for at least 3 years. The 3-year period begins on the date of final action on a complaint, or the date of a decision that the complaint requires no action.
- Notify FDA by submission to an Information Sharing Network or by email to *StateMOU@fda.hhs.gov* as soon as possible, but no later than 5 business days, after receiving a complaint involving a serious adverse drug experience or serious product quality issue relating to a human drug product compounded at a pharmacy and distributed outside the State, and provide FDA with certain information about the complaint, including the following: name and contact information of the complainant, if available; name and address of the pharmacy that is the subject of the complaint; and a description of the complaint, including a description of any compounded human drug product that is the subject of the complaint;
- Share with FDA, as permitted by State law, the results of the investigation of a complaint after the State Board of Pharmacy or other appropriate State agency concludes its investigation of a complaint assessed to involve a serious adverse drug experience or serious product quality issue. This information iucludes the following: The State Board of Pharmacy's or other appropriate State agency's assessment of whether the complaint was substantiated, if available; and a description and the date of any actions the State Board of Pharmacy or other appropriate State agency has taken to address the complaint;
- Notify the appropriate regulator of physicians within the State of complaints of which the State Board of Pharmacy or other appropriate State agency receives that involve an adverse drug experience or product quality issue relating to human drug products compounded by a physician and distributed outside the State. The State Board of Pharmacy or other appropriate State agency will also notify FDA hy submission to an Information Sharing Network or by email to *StateMOU@fda.hhs.gov* as soon as possible, but no later than 5 business days, after receiving the complaint of the following information, if available: Name and contact information of the complainant; name and address of the physician that is the subject of the complaint; and description of the complaint, including a description of any compounded human drug product that is the subject of the complaint.

The types of complaints of compounded drug products that should be investigated include any adverse drug experience and product quality issnes. Even non-serious adverse drug experiences and product quality issues can be indicative of problems at a compounding facility that could result in product quality defects leading to serious adverse drug experiences if not corrected. For example, inflammation aronnd the site of an injection can indicate drug product contamination from inadequate sterile practicos at the compounding pharmacy. If the pharmacy or physician has inadequate sterile practices, other more serious contamination could result in serious adverse drug experiences.

The final standard MOU does not include specific directions to the State Boards of Pharmacy or other appropriate State agencies relating to how to conduct their investigation of complaints. Rather, as recommended by comments submitted to FDA previously, the details of such investigations are left to the State Board of Pharmacy's or other appropriate State agency's discretion. For example, a State Board of Pharmacy or other appropriate State agency may review an incoming complaint describing an adverse drug experience and determine that such a complaint does not warrant further investigation. In other cases, a State Board of Pharmacy or other appropriate State agency may determine that an incoming complaint contains insufficient information and investigate further to determine appropriate action.

The State Board of Pharmacy or other appropriate State agency signing the final standard MOU would agree to notify FDA about certain complaints and provide FDA with certain information about the complaints so FDA could investigate the complaints itself, or take other appropriate action. The 2018 revised draft standard MOU provided that notification would occur as soon as possible, but no later than 3 business days of receipt of the complaint. The final standard MOU provides that notification will occur as soon as possible, but no later than 5 business days after the State Board of Pharmacy or other appropriate State agency receives the complaint. This period will continue to facilitate early Federal/State collaboration on serious adverse drug experiences and serious product quality issues that have the potential to affect patients in multiple States, while providing for notification in a timeframe that is more feasible for the State Boards of Pharmacy or other appropriate State agencies. FDA increased the time for notifying FDA in the final standard MOU in response to comments expressing concern about having sufficient time to process complaints and notify FDA. We note that FDA has staff on call 24 hours a day to receive information in emergency situations.

Comments on the 2015 draft MOU expressed concern with certain provisions regarding States entering into the MOU and agreeing to take action not permitted by State law or implying that, after taking action, the State made a legal determination that a complaint had been resolved. The revised draft standard MOU clarified that the State should investigate and take action that the State considers to be appropriate with respect to the complaint in accordance with and as permitted by State law. FDA also clarified that, by signing the MOU, the State agrees to take steps to assess whether there is a public health risk associated with the compounded drug product and whether such risk is adequately contained rather than make definitive determinations of risk or confirm containment. The final staudard MOU retains these revisions that addressed the concerns from comments on the 2015 draft.

*B. Distribution of Inordinate Amounts of Compounded Human Drug Products Interstate*

For purposes of the final standard MOU, a pbarmacy has distributed an inordinate amount of compounded human drug products interstate if the number of prescription orders for compounded human drug products that the pharmacy distributed interstate during any calendar year is greater than 50 percent of the sum of the number of prescription orders for compounded human drug products that the pharmacy sent out of (or caused to be sent out of)

the facility in which the drug products were compounded during that same calendar year and the number of prescription orders for compounded human drug products that were dispensed (*e.g.*, picked up hy a patient) at the facility in which they are compounded during that same calendar year (Fig. 1). This concept is called the 50 percent threshold.

**Figure 1. Calculating an Inordinate Amount**

$$\frac{A}{B} = X, \text{ where:}$$

A = Number of prescription orders for compounded human drug products that the pharmacy distributed interstate during any calendar year

B = The sum of the number of prescription orders for compounded human drug products (i) that the pharmacy sent out of (or caused to be sent out of) the facility in which the drug products were compounded during that same calendar year; plus (ii) the number of prescription orders for compounded human drug products that were dispensed (e.g., picked up by a patient) at the facility in which they were compounded during that same calendar year

**If *X* is greater than 0.5, it is an inordinate amount and is a threshold for certain information identification and reporting under the MOU.**

The final standard MOU provides that State Boards of Pharmacy or other appropriate State agencies that enter into the MOU will agree to:

- On an annual basis, identify, using surveys, reviews of records during inspections, data submitted to an Information Sharing Network, or other mechanisms available to the State Board of Pharmacy or other appropriate State agency, pharmacies that distribute inordinate amounts of compounded human drug products interstate.
- For pharmacies that have been identified as distributing inordinate amounts of compounded human drug products interstate during any calendar year, the State Board of Pharmacy or other appropriate State agency will identify, using data submitted to the Information Sharing Network or other available mechanisms, during that same calendar year:
  - The total number of prescription orders for sterile compounded human drug products distributed interstate;
  - The names of States in which the pharmacy is licensed;
  - The names of States into which the pharmacy distributed compounded human drug products; and,
  - Whether the State inspected for and found during its most recent inspection that the pharmacy distributed compounded human drug products without valid prescription orders for individually identified patients.
- Within 30 business days of identifying a pharmacy that has distributed inordinate amounts of compounded human drug products interstate, the State Board of Pharmacy or other appropriate State agency will notify FDA, by submission to an Information Sharing Network or by email to *StateMOU@fda.hhs.gov*, and will include the following information:
  - Name and address of the pharmacy that distributed inordinate amounts of compounded human drug products interstate;
  - The number of prescription orders for compounded human drug products that the pharmacy sent out of (or caused to be sent out of) the facility in which the drug products were componnded during that same calendar year;
  - The number of prescription orders for compounded human drug products that were dispensed (*e.g.*, picked up by a patient) at the facility in which they are compounded during that same calendar year;
  - Total number of prescription orders for compounded human drug products distributed interstate during that same calendar year;
  - Total number of prescription orders for sterile compounded human drug products distrihuted interstate during that same calendar year;
  - The names of States in which the pharmacy is licensed as well as the names of States into which the pharmacy distributed compounded human drug products during that same calendar year; and
  - Whether the State Board of Pharmacy or other appropriate State agency inspected for and found during its most recent inspection that the pharmacy distrihuted compounded human drug products without valid prescriptions for individually identified patients during that same calendar year.
- If the State Board of Pharmacy or other appropriate State agency becomes aware of a physician who is distributing any amount of compounded human drug products interstate, it will notify the appropriate regulator of physicians within the State. The State Board of Pharmacy or other appropriate State agency will, within 30 days of identifying a physician who is distributing any amount of compounded human drug products interstate, also notify FDA by suhmission to an Information Sharing Network or by email to *StateMOU@fda.hhs.gov*.

Section 503A of the FD&C Act reflects Congress' recognition that compounding may be appropriate when it is based on receiving a valid prescription order or notation approved by the prescribing practitioner for an identified individual patient. However, drug products compounded under section 503A are not required to demonstrate that they are safe or effective, have labeling that bears adequate directions for use, or

conform to CGMP. Congress, therefore, imposed strict limitations on the distribution of drug products compounded under section 503A to protect the public health and the integrity of the drug approval process.

In particular, Congress did not intend for compounders operating under these statutory provisions to grow into conventional manufacturing operations making unapproved drugs, operating a substantial proportion of their business interstate, without adequate oversight. Although other provisions of the FD&C Act (*e.g.*, the adulteration provisions regarding drugs prepared, packed, or held under insanitary conditions) apply to drugs compounded by State-licensed pharmacies and physicians that may qualify for the exemptions under section 503A of the FD&C Act, and although FDA may take action in appropriate cases against compounders whose drugs violate these provisions or that operate outside of the conditions in section 503A, Congress recognized that these compounders are primarily overseen by the States. However, if a substantial proportion of a compounder's drug products are distributed outside a State's borders, adequate regulation of those drug products poses significant challenges to State regulators. States face logistical, regulatory, and financial challenges inspecting compounders located outside of their jnrisdiction. In addition, if a compounder distributes drug products to multiple States, it can be very difficult to gather the scattered information about possible adverse drug experiences or product quality issues associated with those drug products, connect them to the compounder, and undertake coordinated action to address a potentially serious public health problem.

Therefore, as a baseline measure, section 503A(b)(3)(B)(ii) of the FD&C Act limits the distribution of compounded drug products outside of the State in which they are compounded to 5 percent of the total prescription orders dispensed or distributed by a licensed pharmacist, pharmacy, or physician. It then directs FDA, in consultation with NABP, to develop a standard MOU that addresses the distribution of inordinate amounts of compounded drug products interstate and provides for appropriate investigation by a State agency of complaints relating to drug products compounded in and distrihuted outside such State. Development of the standard MOU involves FDA describing what inordinate amounts means and providing a mechanism for addressing distribution of inordinate amounts of compounded human drug products interstate, as long as the State agrees to appropriately investigate complaints relating to drug products compounded in and distributed out of the State. The 5 percent limitation in section 503A(b)(3)(B)(ii) does not apply to drug products compounded in a State that has entered into the standard MOU under section 503A(b)(3)(B)(i).

In the 2015 draft standard MOU, FDA proposed that distribution interstate up to a 30 percent limit would not be inordinate, and that States entering into the MOU would agree to take action regarding pharmacists, pharmacies, or physicians that distribute inordinate amounts of compounded drug products interstate. FDA received a number of comments indicating that certain pharmacies, such as pharmacies located near State borders and home infusion pharmacies, distribute more than 30 percent of their compounded human drug products to patients interstate because, for example, the patients are located in another nearby State, or because few pharmacies compound a particular drug product to treat an uncommon condition for patients dispersed throughout the country. The comments noted that the proposed definition of inordinate amounts and the proposed provision in which States agree to take action could prevent such pharmacies from fulfilling patients' medical needs for the drug products that they supply. Other comments expressed concern about instances in which pharmacies are located near a State border and distribute compounded drug products to the other side of that border. FDA also received general comments questioning the Agency's basis for the 30 percent limit and indicating that it was too low. Some comments snggested that FDA increase the limit, including a suggestion to increase it to 50 percent.

The 2018 revised draft standard MOU addressed these comments in two respects. First, it removed the provision in the 2015 draft standard MOU that States agree to take action with respect to the distribution of inordinate amounts of compounded human drug products interstate. Second, it changed what is considered "inordinate amounts" from a 30 percent limit to a 50 percent threshold. In the final standard MOU, the States are not agreeing to take action with respect to distribution of inordinate amounts of compounded human drug products interstate, but, instead, to notify FDA of pharmacies that have distributed an inordinate amount of compounded human drug products interstate. The Agency does not intend to take action against a pharmacy located in a State that has entered into the MOU solely because the pharmacy has exceeded the threshold for inordinate amounts. Rather, the State Board of Pharmacy or other appropriate State agency entering into the final standard MOU agrees to collect further information on pharmacies that have distributed inordinate amounts interstate and provide this information to FDA to help inform Agency inspectional priorities. The State Board of Pharmacy or other appropriate State agency also agrees to notify FDA and the appropriate state regulator of physicians if it becomes aware of physicians distributing any amount of compounded human drug products interstate.

We note that States generally have day-to-day oversight responsibilities over State-licensed pharmacies, pharmacists, and physicians. In general, FDA considers a State-licensed pharmacy or physician to be primarily overseen by the State, which is responsible both for regulation of the compounder and protection of its citizens who receive the compounded drug products. However, as discussed above, if a suhstantial proportion of a compounder's drug products is distributed outside a State's borders, adequate regulation of those drugs poses significant challenges to State regulators. In such cases, although State oversight continues to be critical, additional oversight by FDA may afford an important public health benefit.

As stated above, the final standard MOU uses 50 percent as the threshold beyond which the amount of compounded human drug products distributed interstate by a pharmacy would be considered inordinate. The 50 percent threshold is the threshold that, with regard to pharmacies, triggers an information identification and reporting obligation once it is reached. The Agency believes that more than 50 percent is an appropriate measure of "inordinate amounts" because it marks the point at which pharmacies are distributing the majority of their compounded human drug products interstate, and the regulatory challenges associated with interstate distributors discussed above become more pronounced. At this point, the risk posed by the distribution practices of the compounder may weigh in favor of additional Federal oversight in addition to State oversight.

FDA recognizes that, in some cases, pharmacies may distribute more than 50 percent of a small quantity of compounded human drug products to contiguous States. Although such pharmacies have exceeded the inordinate amounts threshold in the final standard MOU, FDA would

consider other information, such as the number of patients that will receive the compounded human drug products, if available, when assessing the pharmacy's priority for risk-based inspection. Accordingly, when a State Board of Pharmacy or other appropriate State agency identifies a pharmacy that distributes an inordinate amount of compounded human drug products interstate, the final standard MOU provides that the State entity will supply the Agency with certain information as described above. In addition, if the State Board of Pharmacy or other appropriate State agency becomes aware of a physician who is distributing any amount of compounded human drug products interstate, the State entity will notify both the appropriate regulator of physicians within the State and FDA. FDA intends to use this information to prioritize its oversight of compounders based on risk, focusing on those that appear likely to distribute large volumes of compounded human drug products, particularly when the distribution is to multiple States, the drug products are intended to be sterile, and there is information about a lack of valid prescriptions for individually identified patients.

The calculation of inordinate amounts in the final standard MOU, with clarifying changes to the language, is the same as the calculation proposed in the 2018 revised draft standard MOU, with the exception of a change in the timeframe used in the calculation from 1 month to 1 year and removing drugs compounded by physicians from the calculation made by the State Board of Pharmacy or other appropriate State agency. The 2015 draft standard MOU provided that a compounder is considered to have distributed an inordinate amount of compounded drug products interstate if the number of units of compounded drug products distributed interstate during any calendar month is equal to or greater than 30 percent of the number of units of compounded and non-compounded drug products distributed or dispensed both intrastate and interstate by such compounder during that calendar month. FDA received comments noting that because the calculation includes both compounded and non-compounded drug products, in many cases, a substantial factor in whether a compounder has distributed an inordinate amount of compounded drug products interstate is whether the compounder offers non-compounded drug products. For example, under that policy, many specialty compounding pharmacies that engage in distribution of compounded human drug products interstate and only distribute compounded drug products would be able to distribute fewer compounded drug products interstate before reaching an inordinate amount than a pharmacy that also fills prescriptions for non-compounded drug products, even if both pharmacies produced the same amount of compounded drug products. After considering the public comments, FDA does not believe that including non-compounded drug products within the calculation of inordinate amounts would help address the public health concerns associated with sending compounded human drug products interstate that Congress sought to address in section 503A(b)(3)(B) of the FD&C Act. Non-compounded drug products were excluded from the calculation of inordinate amounts in the 2018 revised draft MOU. This final standard MOU maintains this exclusion.[2] FDA removed drug products compounded by physicians from the inordinate amount calculation to clarify that the State Board of Pharmacy or other appropriate State agency signing the MOU does not agree to gather information about the distribution of compounded drug products interstate by physicians or to calculate inordinate amounts of drug products compounded by a physician and distributed interstate. Instead, the State Board of Pharmacy or other appropriate State agency signing the MOU agrees that if it becomes aware that a physician is distributing any amount of compounded human drug products interstate it will notify the State authority that regulates physicians and FDA. This focus on States calculating inordinate amounts of pharmacy compounding reflects FDA's understanding and feedback from State regulators that the distribution interstate of compounded drug products mainly involves pharmacy compounders.

FDA received comments on the 2018 revised draft MOU expressing concern about calculating inordinate amounts by calendar month. After considering these comments and recognizing the possibility for significant monthly fluctuations, we have provided for annual calculation of inordinate amounts in the final standard MOU.

This 50 percent threshold does not function as a limit on the distribution of compounded human drug products interstate, but, instead, is a threshold for triggering information gathering about pharmacy distribution of compounded drugs by the State Board of Pharmacy or other appropriate State agency and provision to FDA. The information gathered will be considered by the Agency for the purpose of helping to inform its risk-based inspection priorities.

*C. Definitions*

Appendix A retains the definitions of "adverse drug experience," "serious adverse drug experience," "product quality issue," and "serious product quality issue" from the 2018 revised draft standard MOU.

To clarify the meaning of "distribution of inordinate amounts of compounded drug products interstate," the proposed definition of "distribution" in the 2018 revised draft standard MOU has been omitted and "distribution of compounded human drug products interstate" and "inordinate amounts" are defined. "Distribution of compounded human drug products interstate" means that a pharmacy or physician has sent (or caused to be sent) a compounded drug product out of the state in which the drug was compounded. A pharmacy has distributed an "inordinate amount" of compounded human drug products interstate if the number of prescription orders for compounded human drug products that the pharmacy distributed interstate during any calendar year is greater than 50 percent of the sum of: (1) The number of prescription orders for compounded human drug products that the pharmacy sent out of (or caused to be sent out of) the facility in which the drug products were compounded during that same calendar year; plus (2) the number of prescription orders for compounded human drug products that were dispensed (*e.g.*, picked up by a patient) at the facility in which they were compounded during that same calendar year.

We received a number of comments on the 2015 draft standard MOU and the 2018 revised draft standard MOU stating that distributing and dispensing are mutually exclusive activities, such that if a drug product is distributed, it is not also dispensed, and vice versa. Some comments asserted, in particular, that a compounded drug product should not be considered to be "distributed" when it is provided pursuant to a prescription. Other stakeholders, however, agreed with the inclusion of drug products provided pursuant to a prescription within the definition of "distribution" and maintained that this interpretation was important to protect the public health.

After considering these comments and the public health objectives of section 503A(b)(3)(B) of the FD&C Act, FDA

[2] FDA also intends to exclude non-compounded drugs from the calculation of the 5 percent limit in section 503A(b)(3)(B)(ii).

considers that when a drug is picked up at the facility in which it was componnded, dispensing, but not distribution, occurs for purposes of 503A(b)(3)(B).

FDA helieves that in-person dispensing, where the transaction between the compounder and the patient is completed at the facility in which the drug product was compounded, is appropriately overseen, primarily, by the State outside the context of the MOU, regardless of whether the compounded drug product subsequently leaves the State. Such an intrastate, local transaction generally indicates a close connection among the patient, compounder, and prescriber. By contrast, transactions by mail often have a less direct nexus among the patient, compounder, and prescriber than in-person pick-ups and would be considered "distribution."

Drugs dispensed in-person that are later taken out of State will not contribute to reaching the threshold for inordinate amounts under the final MOU. Nor will complaints associated with compounded drug products dispensed this way and subsequently taken out of State be subject to the complaint investigation provisions of the final MOU. FDA expects that, in practice, the State in which the initial transaction occurred would handle such complaints. The State may, in its discretion, notify FDA of the complaint.

FDA is not persuaded hy comments urging the Agency to interpret "distribution" and "dispensing" to be entirely separate activities for purposes of section 503A(b)(3)(B) of the FD&C Act. These comments recommend using definitions for these terms used elsewhere in the FD&C Act and FDA regulations, and generally conclude that distribution does not include the transfer of a drug pursuant to a prescription.

The conditions in section 503A, including section 503A(b)(3)(B), must be interpreted consistent with the prescription requirement in section 503A(a) of the FD&C Act. If we were to interpret the word "distribution" to apply only if a drug is provided without a prescription, it would mean that drug products compounded under section 503A of the FD&C Act are excluded from regulation under the MOU and the 5 percent limit, because to qualify for the exemptions under section 503A, a compounder must obtain a valid prescription order for an individually identified patient. For the reasons stated previously in this document, we believe this would achieve the opposite of what Congress intended. A compounded drug product may be eligible for the exemptions under section 503A of the FD&C Act only if it is, among other things, "compounded for an identified individual patient based on the receipt of a valid prescription order or a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient."

Nor is there anything to suggest that Congress understood "distributed" and "dispensed" to be mutually exclusive categories rather than overlapping categories for purposes of section 503A. Section 503A(b)(3)(B) of the FD&C Act does not define "distribution" to exclude dispensing, which Congress has done elsewhere when that was its intention.[3] The definition proposed by comments would write an exclusion for dispensing, in its entirety, into the statute where Congress did not. Indeed, with respect to comments suggesting that drugs dispensed pursuant to prescriptions could not also be "distributed," we note that, in section 503A(b)(3)(B), Congress specifically contemplated that prescription orders could be "distributed" when it directed the Agency to count the number of prescription orders that pharmacists and prescribers distributed.

## IV. Other Issues

### *A. Authority of State Boards of Pharmacy or Other Appropriate State Agencies*

The 2018 revised draft standard MOU proposed that "States" would be the signatories of the MOU. In the final standard MOU, FDA clarifies the State party to the agreement, which is described as the "State Board of Pharmacy or other appropriate State agency." FDA received comments expressing concerns that the State entity signing the MOU (*e.g.*, the State Board of Pharmacy) may not have regulatory authority over physician compounding and could not agree to the MOU provisions regarding physicians as they appeared in the 2018 revised draft standard MOU. With regard to physician compounding, FDA has revised certain provisions from the 2018 revised draft standard MOU. Under the final standard MOU, a State Board of Pharmacy or other appropriate State agency would enter into the MOU on behalf of the State and agree to (1) notify FDA and the appropriate regulator of physicians within the State when it receives a complaint about adverse drug experiences or product quality issues associated with a human drug product compounded by a physician and distributed outside the State; and (2) if it becomes aware of a physician distributing any amount of compounded human drug products interstate, notify FDA and the appropriate regulator of physicians within the State.

### *B. Physician Compounding*

It is FDA's understanding that physicians who compound drugs generally do so for their own patients, within their own professional practice, and provide them intrastate. FDA believes that, generally, physicians are not engaged in compounding that results in routine distribution of compounded drug products interstate.

Additionally, several comments advised that State Boards of Pharmacy do not oversee physician compounding and would not be able to agree to the provisions under the 2018 revised draft standard MOU with respect to oversight of physician compounding (collecting additional information to identify whether a physician compounder is distributing inordinate amounts of compounded drug products interstate, etc.). Accordingly, under the final standard MOU, State Boards of Pharmacy or other appropriate State agencies would agree to (1) notify FDA and the appropriate regulator of physicians within the State when they receive complaints about adverse drug experiences or product quality issues associated with a human drug product compounded by a physician and distributed outside the State; and (2) if they become aware of a physician distributing any amount of compounded human drug products interstate, notify FDA and the appropriate regulator of physicians within the State. The information provided to FDA will help inform Agency inspectional priorities with respect to physicians who compound human drug products and provide information to State regulators of physicians for appropriate action.

[3] In other (non-compounding) contexts, where it would further a regulatory purpose, Congress and the Agency have specifically defined "distribute" to exclude dispensing. See, for example, section 581(5) of the FD&C Act (21 U.S.C. 360eee(5)), which applies to Title II of the DQSA, and 21 CFR 208.3, which applies to 21 CFR part 208. Section 503A of the FD&C Act does not contain a similar definition, or a similar specific direction to exclude dispensing from the meaning of distribution. We also note that these definitions were adopted for provisions that focus on conventionally manufactured drug products, which assign different obligations to dispensers than to wholesalers, packagers, or other intermediaries in light of the different role that dispensers play with respect to product labeling and the drug distribution chain. In contrast, section 503A of the FD&C Act focuses on compounded drugs, and the reasons for defining "distribution" to exclude dispensing in Title II of the DQSA or part 208 do not apply.

*C. Development of a Standard MOU*

A number of comments on the 1999 draft standard MOU, the 2013 draft 503A guidance, the 2015 draft standard MOU, and the 2018 revised draft MOU suggested that FDA negotiate MOUs with individual States, rather than develop a standard MOU. Section 503A of the FD&C Act requires the Agency to develop a standard MOU for use by the States. Furthermore, it would be impractical to develop an individualized MOU with every State, and creating individualized MOUs would create a patchwork of regulation of distribution of compounded human drug products interstate by compounders seeking for their drug products to qualify for the exemptions under section 503A of the FD&C Act. This would be confusing to the healthcare community, as well as regulators.

*D. Exemptions From the Provisions Related to Distribution of Inordinate Amounts of Compounded Human Drug Products Interstate*

Some comments on the 2013 draft 503A guidance, the 2015 draft standard MOU, and the 2018 revised draft standard MOU requested that we consider exempting certain drug products or types of compounding entities from the threshold in the MOU and the 5 percent limit. For example, some comments recommended that we exempt nonsterile products.

American consumers rely on the FDA drug approval process to ensure that medications have been evaluated for safety and effectiveness before they are marketed in the United States. Drugs made by compounders, including those made at outsourcing facilities, are not FDA-approved. This means that they have not undergone premarket review of safety, effectiveness, or manufacturing quality. Therefore, when an FDA-approved drug is commercially available, FDA recommends that practitioners prescribe the FDA-approved drug rather than a compounded drug product unless the prescribing practitioner has determined that a compounded product is necessary for the particular patient and would provide a significant difference for the patient as compared to the FDA-approved commercially available drug product.

In section 503A of the FD&C Act, Congress enacted several conditions to differentiate compounders from conventional manufacturers and provided that only if the compounders meet those conditions can they qualify for the exemptions from the drug approval requirements in section 505 of the FD&C Act. One of those conditions relates to limitations and other measures to address distribution of compounded drug products interstate, and FDA intends to enforce those provisions to differentiate compounding that qualifies for the exemptions from conventional manufacturing in the guise of compounding that does not and will apply the conditions to all types of drugs and all categories of compounding.

*E. Information Sharing Between the State Boards of Pharmacy or Other Appropriate State Agencies and FDA*

The final standard MOU provides that State Boards of Pharmacy or other appropriate State agencies will agree to notify FDA of a complaint relating to a compounded human drug product distributed outside the State involving a serious adverse drug experience or serious product quality issue and provide information about those experiences and issues. The final standard MOU also provides that State Boards of Pharmacy or other appropriate State agencies will notify FDA if they identify a pharmacy that has distributed inordinate amounts of compounded human drug products interstate. In addition, State Boards of Pharmacy or other appropriate State agencies will notify FDA and the appropriate regulator of physicians within the State if the State entity becomes aware of a physician who is distributing any amount of compounded human drug products interstate, or if the State entity receives a complaint involving an adverse experience or product quality issue relating to a human drug product compounded by a physician and distributed outside the State.

FDA has entered into a cooperative agreement with NABP to establish an information sharing network that is intended to, in part, facilitate State information reporting to FDA by State Boards of Pharmacy or other appropriate State agencies that enter into the MOU with FDA addressing distribution of compounded drugs interstate.[4] The goal of this information-sharing and research initiative is to improve the management and sharing of information available to State regulators and FDA regarding State-licensed compounders and the distribution of compounded human drug products interstate to support better and more targeted regulation and oversight of compounding activities to help reduce risk to patients. This information will be important to help States to focus their limited resources on compounders for which they have primary oversight responsibility that present the greatest risk. It will also facilitate FDA's ability to determine when additional Federal oversight is warranted, such as when a large-scale compounder distributes drug products to multiple States, potentially causing significant and widespread harm if its products are substandard. FDA expects that the information sharing network will be designated by FDA for purposes of the MOU to collect, assess, and allow review and sharing of information pursuant to the MOU. FDA regularly posts, on its compounding website, information about enforcement and other actions related to compounders that violate the FD&C Act, and it is obligated to share certain information with States under section 105 of the DQSA. In addition to these measures, FDA is taking steps to proactively share information with States about complaints that it receives regarding compounded drug products, consistent with Federal laws governing information disclosure.

*F. Enforcement of the 5 Percent Limit on Distribution of Compounded Human Drug Products Out of the State in Which They Are Compounded*

In the 2013 draft 503A guidance, FDA stated that it does not intend to enforce the 5 percent limit on distribution of compounded human drug products outside of the State in which they are compounded until 90 days after FDA has finalized a standard MOU and made it available to the States for their consideration and signature. Most comments on the 2013 draft 503A guidance that raised this issue said this period was too short but did not recommend a specific alternative. A few comments recommended a different timeframe, one recommending 120 days and another recommending 365 days. The 1997 Senate Committee Report for the Food and Drug Administration Modernization Act suggests that a 180-day period for States to decide whether to sign might be appropriate.[5] In the notice of availability for the 2018 revised draft standard MOU, consistent with the 2015 draft standard MOU, the Agency proposed a 180-day period after

[4] See RFA–FD–19–025, available at *https://grants.nih.gov/grants/guide/rfa-files/RFA-FD-19-025.html*.

[5] "[U]ntil the State . . . enters into a memorandum of understanding (MOU) with the Secretary or 180 days after the development of the standard MOU, whichever comes first, the [section 503A] exemption shall not apply if inordinate quantities of compounded products are distributed outside of the State in which the compounding pharmacy or physician is located." (U.S. Senate Committee Report)

the final standard MOU is made available for signature before FDA will enforce the 5 percent limit in States that have not signed the MOU, and invited public comment on whether this was an appropriate timeframe. Some commenters on the 2018 revised draft standard MOU stated that more time may be necessary because some States may be required to enact new laws and promulgate new regulations before entering the MOU. Therefore, in response to these comments, FDA is providing a 365-day period for States to decide whether to sign the MOU before FDA intends to begin enforcing the 5 percent limit in States that do not sign. It is FDA's understanding that this extended timeframe corresponds to a full legislative cycle for most States and should, therefore, afford sufficient time for States to modify their laws and regulations, if necessary.

### V. Paperwork Reduction Act of 1995

This MOU refers to previously approved collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information have been approved under OMB control number 0910–0800.

### VI. Electronic Access

Persons with access to the internet may obtain the final standard MOU at either *https://www.fda.gov/drugs/human-drug-compounding/regulatory-policy-information*, *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs*, or *https://www.regulations.gov*.

Dated: October 21, 2020.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

[FR Doc. 2020–23687 Filed 10–26–20; 8:45 am]

BILLING CODE 4164–01–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Meeting of the Tick-Borne Disease Working Group

**AGENCY:** Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

**ACTION:** Notice.

**SUMMARY:** As required by the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) is hereby giving notice that the Tick-Borne Disease Working Group (TBDWG) will hold a virtual meeting. The meeting will be open to the public. For this meeting, the TBDWG will review chapters and the template for the 2020 report to the HHS Secretary and Congress. The 2020 report will address ongoing tick-borne disease research, including research related to causes, prevention, treatment, surveillance, diagnosis, diagnostics, and interventions for individuals with tick-borne diseases; advances made pursnant to such research; federal activities related to tick-borne diseases; and gaps in tick-borue disease research.

**DATES:** The meeting will be held online via webcast on November 17, 2020 from approximately 9:00 a.m. to 5:30 p.m. ET (times are tentative and subject to change). The confirmed times and agenda items for the meeting will be posted on the TBDWG web page at *https://www.hhs.gov/ash/advisory-committees/tickbornediseasc/meetings/2020-11-17/index.html* when this information becomes available.

**FOR FURTHER INFORMATION CONTACT:** James Berger, Designated Federal Officer for the TBDWG; Office of Infectious Disease and HIV/AIDS Policy, Office of the Assistant Secretary for Health, Department of Health and Human Services, Mary E. Switzer Building, 330 C Street SW, Suite L600, Washington, DC, 20024. Email: *tickbornedisease@hhs.gov;* Phone: 202–795–7608.

**SUPPLEMENTARY INFORMATION:** The registration link will be posted on the website at *https://www.hhs.gov/ash/advisory-committees/tickbornedisease/meetings/2020-11-17/index.html* when it becomes available. After registering, you will receive an email confirmation with a personalized link to access the webcast on November 17, 2020.

The public will have an opportunity to present their views to the TBDWG orally during the meeting's public comment session or by submitting a written public comment. Comments should be pertinent to the meeting discussion. Persons who wish to provide verbal or written public comment should review instructions at *https://www.hhs.gov/ash/advisory-committees/tickbornedisease/meetings/2020-11-17/index.html* and respond by midnight November 6, 2020 ET. Verbal comments will be limited to three minutes each to accommodate as many speakers as possible during the 30 minute session. Written public comments will be accessible to the public on the TBDWG web page prior to the meeting.

*Background and Authority:* The Tick-Borne Disease Working Group was established on August 10, 2017, in accordance with Section 2062 of the 21st Century Cures Act, and the Federal Advisory Committee Act, 5 U.S.C. App., as amended, to provide expertise and review federal efforts related to all tick-borne diseases, to help ensure interagency coordination and minimize overlap, and to examine research priorities. The TBDWG is required to submit a report to the HHS Secretary and Congress on their findings and any recommendations for the federal response to tick-borne disease every two years.

Dated: October 13, 2020.

**James J. Berger,**

*Designated Federal Officer, Tick-Borne Disease Working Group, Office of Infectious Disease and HIV/AIDS Policy.*

[FR Doc. 2020–23693 Filed 10–26–20; 8:45 am]

BILLING CODE 4150–28–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Indian Health Service

### Notice of Listing of Members of the Indian Health Service's Senior Executive Service Performance Review Board (PRB)

**AGENCY:** Indian Health Service, HHS.

**ACTION:** Notice; correction of Performance Review Board Membership.

**SUMMARY:** The Indian Health Service published a notice in the **Federal Register** on October 14, 2020 listing members of the Indian Health Service's Senior Executive Service Performance Review Board. The membership listing failed to include Mr. Christopher Mandregan as a member of the Performance Review Board.

**FOR FURTHER INFORMATION CONTACT:** Nathan Anderson, Human Resources Specialist, 5600 Fishers Lane, Rockville, MD 20857, Phone: (605) 681–4940.

### Correction

In the FR notice of October, 14, 2020, (85 FR 65062), the correction is to the alphabetical listing of Performance Review Board members:

Buchanan, Chris
Cooper, Jennifer
Cotton, Beverly
Curtis, Jillian
Driving Hawk, James
Grinnell, Randy (Chair)
Gyorda, Lisa
LaRoche, Darrell
Mandregan, Christopher
Redgrave, Bryce
Smith, Ben

# Compounding Pharmacy Information-Sharing Project

**Through the expansion of our e-Profile system, NABP will soon accommodate the collection, management, and sharing of information related to compounding pharmacies in the United States.**

Frequently Asked Questions

Download the Info Sheet

In June 2020, development of a means to gather and share compounding pharmacy information began as part of a three-year pilot project with Food and Drug Administration (FDA). Funded by FDA, the project builds upon our existing NABP e-Profile with the addition of data fields and functionality specific to compounding activities. This new network will increase the amount of compounding data available to member state boards of pharmacy and FDA. With more compounding data available, regulators are better positioned to help reduce the risk of injury to patients from improperly compounded drug products.

This project provides a mechanism for the data collection and reporting outlined in the "Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products" (MOU)." The MOU was developed in accordance with Section 503A(b)(3) of the Food, Drug and Cosmetic Act, which directs FDA to work with us to develop a standard MOU for use by states in complying with section 503A(b)(3)(B)(i).

Over the next year and a half, we will evaluate the usability of the system and the accuracy of the information collected during the pilot and present a final analysis to the FDA. **This pilot project focuses on three goals:**

1

Expand e-Profile to collect, manage, and exchange data pertaining to state-licensed pharmacies engaged in human drug compounding.

2

Improve and increase information available to the state boards of pharmacy and FDA about compounding pharmacies that distribute across state lines.

3

Foster better and more targeted regulation and oversight of compounding pharmacies to reduce risk for patients.

# Benefits for the Boards

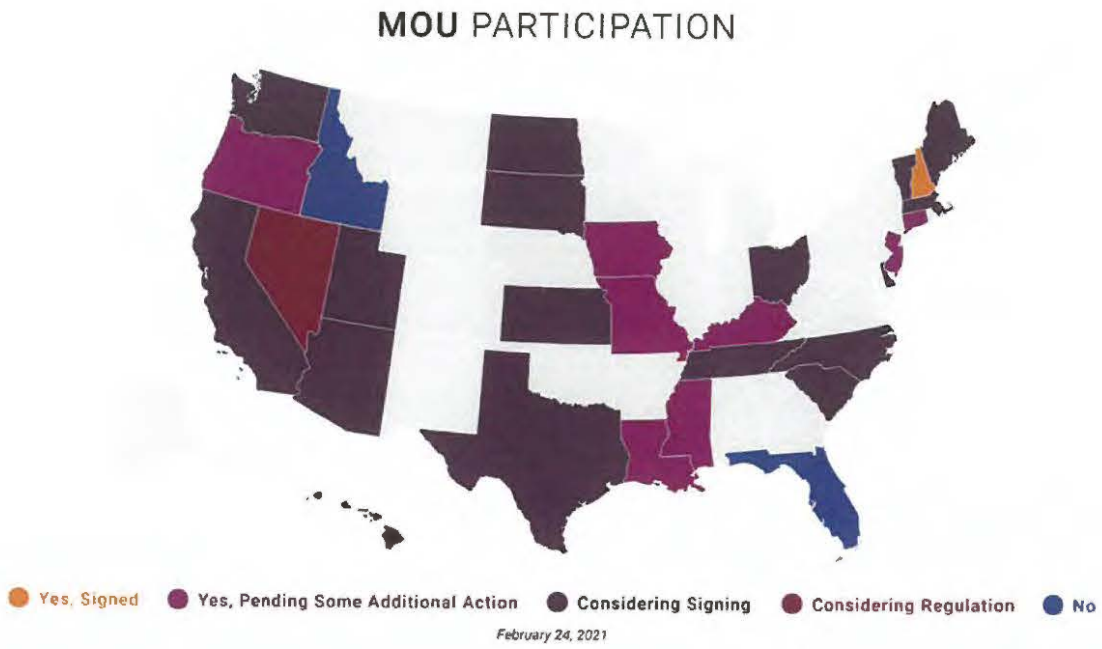
Our expanded information sharing network delivers a tool to report interstate compounding information to the other state boards of pharmacy and FDA. The tool will organize and make available information and data needed to make informed oversight determinations and provide the following benefits for the boards:

- **Reduced administrative burden –** enables the boards to prioritize their already limited resources to address the compounding pharmacies that pose the greatest risks to patients.
- **Real-time data –** improves upon the information currently available to the boards and FDA about compounding pharmacies, allowing the boards and FDA to gain a better understanding of the interstate distribution of compounded drugs.
- **Uniform tracking –** enables the boards to uniformly track pharmacies that ship inordinate amounts of compounded drug products out of state and the kinds of compounded drug products that they are shipping and flag these pharmacies for FDA.
- **Seamless information sharing –** allows the boards to collect and share information about complaints concerning compounded drugs and compounding pharmacies and physicians on an ongoing, year-round basis.

The MOU does not require boards to enter data into the information sharing network, but boards may do so if they have the data and resources. In addition, the MOU does allow boards to rely exclusively on the data that has been reported to the system by their licensees. Using that data, boards will be able to meet the requirement to identify for FDA, on an annual basis, pharmacies that distribute inordinate amounts of compounded human drug products interstate. State boards that do not sign the FDA MOU will still have access to the information sharing network. The information will be part of each pharmacy's business e-Profile, which boards can currently access.

In addition to information provided by the boards, we will capture compounding pharmacy data through our VPP and accreditation applications. Pharmacies that do not participate in these programs will be encouraged to self-report this data in NABP e-Profile. Boards who prefer to input pharmacy data into the system can work with us to streamline and automate the process.

Sign the FDA MOU for the Data Sharing Project




**For more information about NABP's compounding data sharing project or the MOU, email NABP Professional Affairs at prof-affairs@nabp.pharmacy.**

# Data Collection

The following information will be collected from participating pharmacies that distribute or dispense compounded human drug products:

- Whether the pharmacy engages in the following activities during an identified calendar year:
  - Human drug compounding – sterile and/or nonsterile
  - Patient-specific compounding
  - Non-patient-specific compounding
- If a pharmacy is compounding sterile or nonsterile human drug products, the following information will also be collected or calculated. (*Note: The "total number of prescription orders for compounded human drug products that were sent out of or dispensed from the facility in which the drug products were compounded"* ***and*** *"the percentage of compounded human drug products distributed interstate" will be calculated by the system.*) All information will be collected per calendar year:
  - The number of prescription orders for compounded human drug products that the pharmacy sent out of (or caused to be sent out of) the facility in which the drug products were compounded
  - The number of prescription orders for compounded human drug products that were dispensed (eg, picked up by a patient) at the facility in which the drug products were compounded
  - The total number of prescription orders for compounded human drug products that were sent out of or dispensed from the facility in which the drug products were compounded (this number will be calculated by the system)
  - The total number of prescription orders for compounded human drug products distributed interstate
  - The percentage of compounded human drug products distributed interstate (this number will be calculated by the system) (Note: this percentage will provide a benchmark for determining "inordinate amounts.")
  - The number of prescription orders for sterile compounded human drug products distributed interstate
  - Names of states in which the pharmacy is licensed

- Names of states into which the pharmacy distributed compounded human drug products during the identified calendar year
- Whether or not compounded human drug products are being distributed without patient-specific prescriptions

It is expected that the system will be ready for licensees and the boards of pharmacy to begin entering information in early 2021.

Further information on compounding data collection can be obtained in the *Compounding Pharmacy Data Sharing Project FAQs*.

Information for boards of pharmacy in preparation for the FDA MOU can be found in this presentation.

If you have any questions about additional compounding data that could be collected, email prof-affairs@nabp.pharmacy.

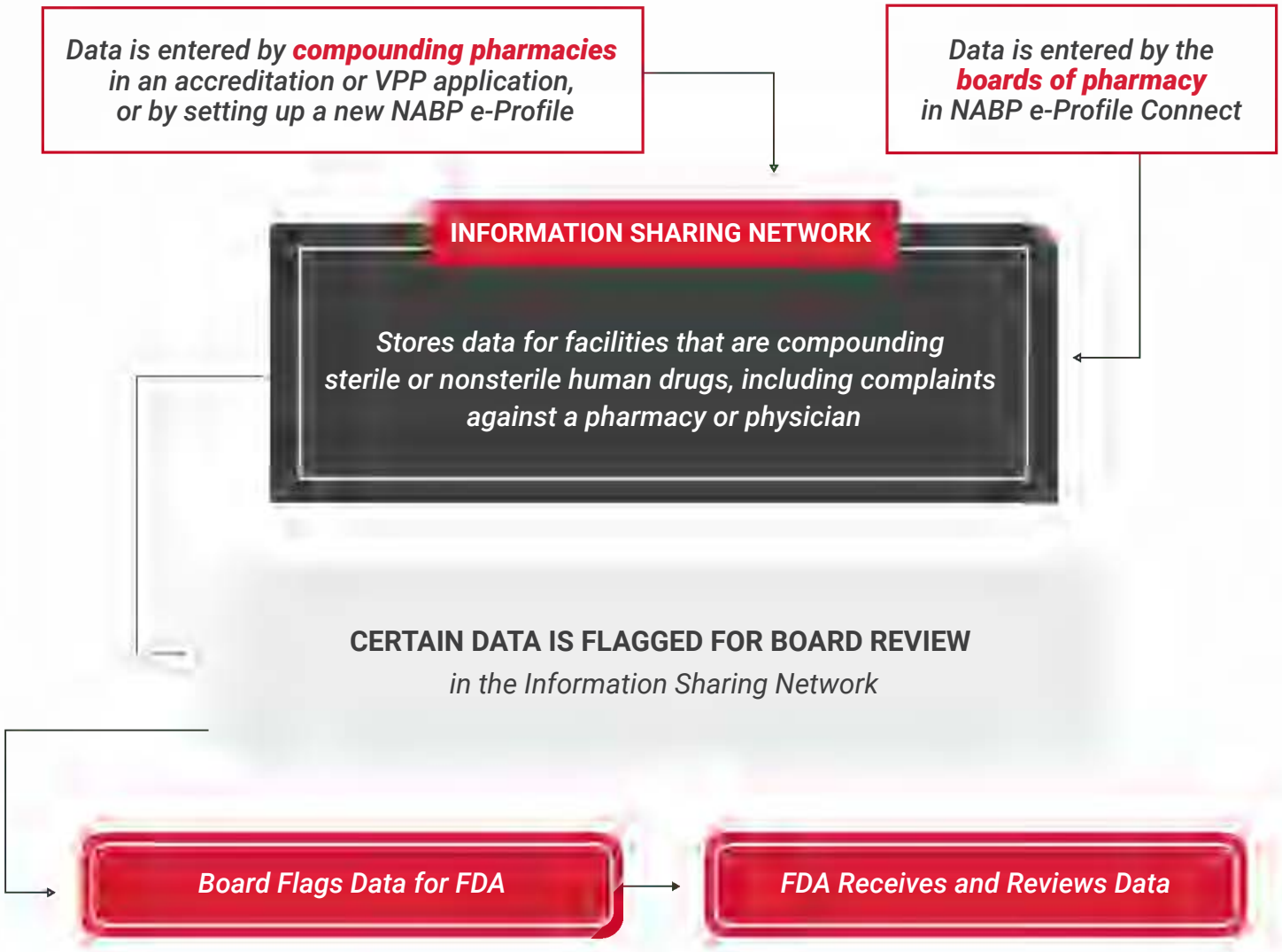
# Collect and Share Compounding Data With NABP's Information Sharing Network

NABP's Information Sharing Network helps state boards of pharmacy collect, manage, and share data related to compounding pharmacies with Food and Drug Administration (FDA). Access to the network is free and allows your board to meet the obligations outlined in the memorandum of understanding (MOU) on compounded human drug products. https://www.fda.gov/media/145283/download?utm_medium=email&utm_source=govdelivery

## PATHWAYS FOR DATA ENTRY

*& the flow of data through NABP e-Profile Connect*

*Developed as an expansion of NABP e-Profile Connect, the Information Sharing Network will be available for boards of pharmacy to begin entering data in early 2021.*




Visit *www.nabp.pharmacy/Compounding-Project* for more information on how the Information Sharing Network works or to access the FDA MOU.

## Data Collected

***The Information Sharing Network collects the following pharmacy and complaint data.***

***General Pharmacy Information*** *– Entered by the Pharmacy or the Board*

- Name and address of state-licensed entity
- Whether the pharmacy participates in the following activities during an identified calendar year:
  - Human drug compounding — sterile or nonsterile
  - Patient-specific or non-patient-specific compounding
- If a pharmacy is compounding sterile or nonsterile human drug products, additional data is collected related to licensing, prescription orders, and distribution numbers

***Complaint Information*** *– Entered by the Board*

Complaints of adverse drug experiences or product quality issues relating to human drug products that are compounded by a physician and distributed interstate are also entered by the board. Data collected includes:

- Name and contact information of the complainant or notifier
- Description of the complaint, including a description of any compounded human drug product that is the subject of the complaint
- The board's assessment of whether the complaint was substantiated, if available
- Description of any actions that the board has taken to address the complaint

Complaints of adverse drug experiences, product quality issues, or distribution of human drug products that are compounded by a physician are also entered by the board.

For a complete list of data collected in the Information Sharing Network, visit ***www.nabp.pharmacy/Compounding-Project.***

## Data for Board Review

***The Information Sharing Network flags data for the boards of pharmacy to review based on certain criteria.***

- Pharmacies that are compounding human drug products and distributing inordinate amounts interstate.
- Complaints of serious adverse experiences or quality issues relating to drugs compounded by pharmacies and distributed interstate.
- Complaints of adverse experiences or quality issues relating to drugs compounded by a physician and distributed interstate.

By logging in to e-Profile Connect, https://dashboard.clearinghouse/ the boards can review and submit the information to FDA with the click of a button.

***Sending Data to FDA***

Boards must submit the required information to FDA in accordance with the timelines outlined in the MOU, which can be as little as five days depending on the type of complaint.

A list of the data transmitted to FDA and the associated timelines can be found at ***www.nabp.pharmacy/Compounding-Project.***

# Frequently Asked Questions

Following are answers to frequently asked questions regarding this data sharing project. Question categories include data/information sharing, pharmacy participation, project audits, and the FDA MOU. If you have any additional questions see the Compounding Pharmacy Information-Sharing Project overview page or contact prof-affairs@nabp.pharmacy.



## Data/Information Sharing

**What volume of compounded human drug products distributed interstate is considered an inordinate amount?**

A pharmacy has distributed an inordinate amount of compounded human drug products interstate if the number of prescription orders for compounded human drug products that the pharmacy distributed interstate during any calendar year is greater than 50% of the sum of:

1. the number of prescription orders for compounded human drug products that the pharmacy sent out of (or caused to be sent out of) the facility in which the drug products were compounded during that same calendar year; plus
2. the number of prescription orders for compounded human drug products that were dispensed (eg, picked up by a patient) at the facility in which they were compounded during that same calendar year.

The distribution of inordinate amounts of compounded human drug products interstate is a threshold for the board of pharmacy to identify and report certain information to FDA, not a limit on the distribution of compounded human drug products interstate. Pharmacies whose data are reported to FDA will not necessarily be subject to in inspection by FDA.

**What information will be collected about compounding pharmacy complaints?**

Regarding complaints relating to human drug products compounded by a pharmacy and distributed outside a state, the system will collect the following information from the board of pharmacy:

name and contact information of the complainant, if available;
name and address of the pharmacy that is the subject of the complaint;
a description of the complaint, including a description of any compounded human drug product that is the subject of the complaint;
the board or state agency's assessment of whether the complaint was substantiated, if available; and

- a description and the date of any actions that the board or state agency has taken to address the complaint.

**What information about compounding physician complaints and notifications will NABP collect from boards of pharmacy and provide to FDA?**

Regarding complaints relating to human drug products compounded by a physician, or regarding the distribution of any amount of human drug products compounded by a physician and distributed outside a state, the system will collect the following information, if available, from the board of pharmacy and provide it to FDA:

- name and contact information of the complainant or notifier;
- name and address of the physician who is the subject of the complaint or notification; and
- a description of the complaint or notification, including a description of any compounded human drug product that is the subject of the complaint.

**What types of complaints does the MOU obligate the board of pharmacy to investigate?**

The board of pharmacy or state agency **will investigate complaints of adverse drug experiences and product quality issues relating to human drug products compounded at a pharmacy** in that state and distributed outside the state.

- An adverse drug experience is any adverse event associated with the use of a drug in humans, whether or not considered drug related, including the following: an adverse event occurring in the course of the use of a drug product in professional practice; an adverse event occurring from drug overdose, whether accidental or intentional; an adverse event occurring from drug abuse; an adverse event occurring from drug withdrawal; and any failure of expected pharmacological action (21 CFR 310.305(b)).
- A product quality issue is Information concerning (1) any incident that causes the drug product or its labeling to be mistaken for, or applied to, another article; or (2) any bacteriological contamination; any significant chemical, physical, or other change or deterioration in the distributed drug product; or any failure of one or more distributed batches of the drug product to meet the applicable specifications (21 CFR 314.81(b)(1)). Contamination in general, including but not limited to mold, fungal, bacterial, or particulate contamination, is a product quality issue.

Any investigations will be performed pursuant to the board of pharmacy or state agency's established investigatory policies and procedures, including those related to prioritizing complaints, provided they are not in conflict with the terms of the MOU.

Any investigations performed by the board of pharmacy or state agency under the MOU will include taking steps to assess (1) whether there is a public health risk associated with the compounded drug product; and (2) whether any public health risk associated with the product is adequately contained.

**There is no obligation for the board of pharmacy to investigate complaints regarding compounding physicians.**

**What information will be provided to FDA?**

Upon approval by a board of pharmacy, the system will provide FDA with:

- information about compounders for which the number of prescription orders for compounded drug products distributed interstate is greater than 50% of the number of prescription orders for compounded drug products distributed or dispensed both intrastate and interstate by such compounder; and
  information provided by a board of pharmacy about:
  complaints of serious adverse drug experiences and product quality issues relating to human drug products compounded at a pharmacy and distributed interstate; and
  complaints relating to an adverse drug experience or product quality issue relating to human drug products compounded by a physician and distributed interstate.



**Will NABP provide training on the use of the information-sharing network?**

Yes. Information on training will be forthcoming.

**What is included in "the number of prescription orders for compounded human drug products that the pharmacy sent out of (or caused to be sent out of) the facility in which the drug products were compounded during that same calendar year"?**

This statement refers to the number of prescription orders that were shipped or mailed out of the facility, *regardless of whether the products went in state or out of state.*

Note that this is added to "the number of prescription orders for compounded human drug products that were dispensed (eg, picked up by a patient) at the facility in which they were compounded during that same calendar year" to calculate the TOTAL number of prescription drug orders dispensed/distributed. This total is used as the denominator to determine the inordinate amount percentage.

**What is included in "the total number of prescription orders for compounded human drug products distributed interstate during that same calendar year"?**

This statement refers to the number of prescription orders that were sent (or caused to be sent) *out of the state* in which the drug was compounded.

This number is used as the numerator to determine the inordinate amount percentage. Then, the calculation is made. If the result is greater than 50%, the amount is considered inordinate and the data needs to be sent to FDA. (The calculation is shown at the top of page 6 of the MOU.)

**Figure 1. Calculating an Inordinate Amount**

$\frac{A}{B} = X$, where:

A = Number of prescription orders for compounded human drug products that the pharmacy distributed interstate during any calendar year

B = The sum of the number of prescription orders for compounded human drug products (i) that the pharmacy sent out of (or caused to be sent out of) the facility in which the drug products were compounded during that same calendar year; plus (ii) the number of prescription orders for compounded human drug products that were dispensed (e.g., picked up by a patient) at the facility in which they were compounded during that same calendar year

**If *X* is greater than 0.5, it is an inordinate amount and is a threshold for certain information identification and reporting under the MOU.**

# Pharmacy Participation

**Why would a pharmacy voluntarily enter the requested information?**

The information requested in the MOU will be incorporated into the application for many NABP accreditation and inspection programs, including VPP. As a result, all applicants seeking accreditation or a VPP inspection will voluntarily submit the requested information – regardless of whether their primary intent is to participate in the pilot project. Compounding pharmacies also will be able to enter the requested information, outside of the VPP application process, for a chance to receive a VPP inspection at no cost to them. The VPP inspection in this scenario will be adapted to serve the dual purpose of a traditional blueprint inspection and an audit for the pilot project. If pharmacies that submit the requested information through the NABP program application are chosen for an audit, they will receive either a refund or a future VPP inspection at no cost to them.

Some pharmacies already have a profile in NABP's e-Profile Connect system and would only need to provide the additional information related to compounding. Others would need to create a new profile. All entities providing the requested data would be entered into the pool of possible compounding pharmacies to be audited through a VPP inspection.

**Under the pilot project, what will NABP do with the information that the pharmacies provide?**

NABP will consult with FDA to select 150 eligible pharmacies to be audited for the project. The pharmacies will be prioritized based on factors including the volume of compounded drug products distributed interstate and other considerations. Those selected to be audited will receive a VPP inspection developed for entities engaged in sterile compounding. These VPP inspections will be modified to gather the additional information needed for the project. NABP will engage its team of seasoned and knowledgeable surveyors to conduct the audits, after providing them with the appropriate training to gather the necessary information.

**How do compounding pharmacies submit the requested data?**

Pharmacies that already have a business e-Profile can log into their account and add the information in the Compounding Details tab. If you do not yet have an e-Profile for your business, you will need to create one before you can enter the requested data. For more details, review the Instructions for Entering Pharmacy Compounding Data.

**How many pharmacies are expected to voluntarily submit their information?**

Participation by compounding pharmacies is voluntary; therefore, a specific number of pharmacies submitting information has not been determined. NABP plans to conduct 150 pharmacy audits over the course of the pilot program to evaluate the system and assess the information it produces.

**Will the free VPP inspection still be available after the pilot project is over?**

The funding from FDA includes the cost of these inspections. Thus, once the funding has been exhausted, VPP will no longer be available free of charge.

## Project Audits

**What will the audits entail?**

The audits will, among other things, assess the accuracy of the information provided, including the total number of prescription orders for compounded drug products distributed interstate and distributed or dispensed intrastate, and whether the pharmacy distributes compounded drugs without patient-specific prescriptions, such as for office stock. Audits also will evaluate the compounding facility for issues such as those related to production quality.

**What will NABP do with the audit findings?**

NABP will conduct research to analyze the information that the pharmacies self-reported in the data system, as compared with the audit findings. The analysis will assess the quality and reliability of the data collected in the system. This research will provide the following information:

- an assessment of the extent of interstate distribution of compounded drugs;
- a descriptive analysis of the characteristics of compounders engaging in interstate distribution, including the number of states into which they distribute compounded drugs, scale of production, distribution of office stock, and production quality factors;
- an assessment of the prevalence of data inaccuracies;
- an assessment of remaining data gaps and other factors that may inform risk-based oversight; and
- an analysis of complaints submitted to the information-sharing network.

**How will NABP determine which pharmacies to audit?**

NABP will select pharmacies for audits in consultation with FDA, prioritizing pharmacies based on several factors, including the volume of compounded drug products distributed interstate.

## FDA MOU

**Does the board of pharmacy have an obligation under the MOU to input compounding pharmacy data to the information-sharing network?**

No. Per the memorandum of understanding (MOU), the board is obligated to identify for FDA those pharmacies that are compounding human drug products and distributing inordinate amounts of such products interstate. The board will identify the pharmacies using surveys **or** reviews of records during inspections **or** an information-sharing network (NABP's system) **or** other available mechanisms. The MOU does not obligate the board to input the data into the

information-sharing network. It does, however, allow the board to meet its obligation solely through the use of the information-sharing network. So, if a board does not input any pharmacy compounding data, it is not in breach. It can exclusively rely on the data that has been reported to the system. With this in mind, NABP will put forth great effort to encourage pharmacies to voluntarily self-report the data and will incorporate the requirement to input this data into the Association's VPP program application and certain other accreditation program applications. Note that the obligation to identify this information for FDA is an annual one, but NABP intends for the system to allow for boards to report information on an ongoing, year-round basis, not just once a year.

If a board is able to and would like to input the information, NABP will work with the board to do that in a way that expends as few resources as possible in an automated fashion.

**Have any states signed the MOU?**

The final MOU was released in October 2020. States can now begin signing the MOU. One year after the release date, FDA will begin enforcing the 5% limitation on interstate distribution.

THE Compounding CENTER Rx

March 5, 2021

Dear members of the Board of Pharmacy:

Our compounding pharmacy is located in the very northern tip of the state. We are close to Maryland, D.C. and West Virginia and provide compounded medications to patients in those states. We ship about 25 percent of our compounded preparations out of state – all pursuant to a patient specific prescription.

I'm writing about FDA's Memorandum of Understanding. I do not like the wording in the MOU, but I am also concerned how it might impact access to compounded medications if not signed.

This feels like a no win situation. In the MOU the FDA has chosen to combine the definitions of 'distribute' and 'dispense'. Patient specific prescriptions that are dispensed should not count as being distributed across state lines.

I can also understand the Board may have concerns of increased workload that will occur if you sign the MOU, but if Virginia doesn't sign, we will be limited to shipping 5% of our compounds out of state. That will leave lots of people searching for medication. As an example, we compound a diluted Atropine eye drop for children and based on feedback from area physicians we seem to be one of the few accredited pharmacies where they can get this medication for their patients. We've also heard that other pharmacies cannot compound with chemotherapy agents, so when a patient needs a liquid or different dose they have a hard time finding a pharmacy to help them.

I wish we could get the FDA to amed the MOU, but if they do not then I ask you to consider signing it. I don't like it, and you may not like it either, but the alternative is worse.

If I can provide any additional insight into the ramifications of the MOU, I'd welcome an opportunity to talk with the board further. I appreciate your time and consideration.

Sincerely,

Cheri Garvin, RPh

Owner

www.compoundingcenter.com

36-C Catoctin Circle, SE
Leesburg, VA 20175
(703) 779-3301

**Agenda Item: Amend Pharmacist Workforce Survey to Include Question about Statewide Protocols**

**Background:**

Request received from VCU School of Pharmacy, Center for Pharmacy Practice Innovation to include question on annual pharmacy workforce survey to monitor use of statewide protocols.

**Board Action:**

Motion to amend the pharmacist workforce survey to include the question below as presented or as amended.

22c. If you initiate patient treatment in accordance with statewide protocols, which of the statewide protocols below do you utilize? Check all that apply:

- Hormonal contraception
- Emergency contraception
- Prenatal vitamins
- Naloxone
- Epinephrine
- Lowering out-of-pocket expenses

Virginia Board of Pharmacy
Inspection Report
March 30, 2021
Licenses Issued

| | 8/1/19-10/31/19 | 11/1/19-1/31/20 | 2/1/20-4/30/30 | 5/1/20-7/30/20 | 8/1/20-10/31/20 | 11/1/20-1/31/21 | License Count 2/18/2021 |
|---|---|---|---|---|---|---|---|
| Business CSR | 32 | 23 | 25 | 28 | 23 | 8 | 1,462 |
| CE Courses | 0 | 0 | 0 | 2 | 0 | 0 | 9 |
| Limited Use Pharmacy Technician | 0 | 0 | 0 | 0 | 0 | 0 | 8 |
| Medical Equipment Supplier | 7 | 1 | 4 | 5 | 4 | 2 | 235 |
| Nonresident Manufacturer | 11 | 10 | 7 | 6 | 3 | 1 | 201 |
| Nonresident Medical Equipment Supplier | 12 | 14 | 9 | 5 | 11 | 9 | 372 |
| Non-resident Outsourcing Facility | 0 | 1 | 0 | 3 | 2 | 0 | 33 |
| Non-resident Pharmacy | 18 | 21 | 33 | 22 | 29 | 31 | 855 |
| Non-resident Third Party Logistics Provider | 42 | 17 | 14 | 5 | 12 | 15 | 165 |
| Non-resident Warehouser | 16 | 6 | 19 | 5 | 11 | 9 | 79 |
| Non-resident Wholesale Distributor | 13 | 8 | 8 | 11 | 5 | 10 | 635 |
| Non-restricted Manufacturer | 0 | 0 | 1 | 1 | 0 | 0 | 33 |
| Outsourcing Facility | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Permitted Physician | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Pharmaceutical Processor | | 1 | 1 | 1 | 1 | 0 | 4 |
| Pharmacist | 328 | 187 | 120 | 309 | 301 | 168 | 15,569 |
| Pharmacist Volunteer Registration | 1 | 0 | 0 | 0 | 0 | 0 | 0 |
| Pharmacy | 10 | 11 | 10 | 12 | 7 | 7 | 1,769 |
| Pharmacy Intern | 225 | 43 | 160 | 76 | 177 | 99 | 1,414 |
| Pharmacy Technician | 433 | 485 | 345 | 333 | 447 | 482 | 12,450 |
| Pharmacy Technician Trainee | | | | | | 149 | 298 |
| Pharmacy Technician Training Program | 3 | 1 | 0 | 2 | 7 | 2 | 124 |
| Physician Selling Controlled Substances | 18 | 23 | 28 | 22 | 24 | 16 | 548 |
| Physician Selling Drugs Location | 4 | 3 | 6 | 5 | 4 | 2 | 159 |
| Pilot Programs | 0 | 1 | 0 | 1 | 0 | 1 | 24 |
| Registered Physician For CBD/THC-A Oil | 59 | 39 | 58 | 68 | 106 | 140 | 583 |
| Repackaging Training Program | 0 | 0 | 0 | 0 | 0 | 0 | 2 |
| Restricted Manufacturer | 0 | 0 | 1 | 1 | 0 | 0 | 41 |
| Third Party Logistics Provider | 0 | 0 | 1 | 0 | 0 | 0 | 6 |
| Warehouser | 1 | 3 | 2 | 1 | 4 | 1 | 120 |
| Wholesale Distributor | 3 | 0 | 0 | 2 | 1 | 0 | 67 |
| **Total** | **1,236** | **898** | **852** | **926** | **1,179** | **1,152** | **37,265** |

# Virginia Board of Pharmacy
## Inspection Report
## March 30, 2021
## Inspections Completed

| | 8/1/19-10/31/19 | | 11/1/19-1/31/20 | | 2/1/20-4/30/20 | | 5/1/20-7/31/20 | | 8/1/20-10/31/20 | | 11/1/20-1/31/21 | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **License Type** | | | | | | | | | | | Total | Virtual |
| Controlled Substances Registration | 177 | | 111 | | 145 | | 153 | | 192 | | 110 | 86 |
| Medical Equipment Supplier | 19 | | 36 | | 33 | | 35 | | 25 | | 22 | 10 |
| Non-restricted Manufacturer | 0 | | 0 | | 1 | | 2 | | 0 | | 0 | 0 |
| Permitted Physician | 0 | | 1 | | 0 | | 0 | | 0 | | 0 | 0 |
| Physician Selling Drugs Location | 30 | | 39 | | 18 | | 9 | | 8 | | 20 | 7 |
| Restricted Manufacturer | 0 | | 0 | | 2 | | 1 | | 0 | | 1 | 0 |
| Third Party Logistics Provider | 2 | | 0 | | 3 | | 2 | | 0 | | 0 | 0 |
| Warehouse | 7 | | 11 | | 16 | | 27 | | 16 | | 11 | 5 |
| Wholesale Distributor | 7 | | 5 | | 5 | | 15 | | 12 | | 5 | 2 |
| Pharmacy | 284 | | 274 | | 184 | | 73 | | 98 | | **170** | 12 |
| Pilot | 0 | | 0 | | 6 | | 8 | | 0 | | **3** | 2 |
| Pharmaceutical Processor | | | 6 | | 1 | | 4 | | 4 | | 4 | 0 |
| **Total** | **526** | | **483** | | **414** | | **329** | | **355** | | **346** | **124** |
| | | | | | | | | | | | | |
| **Pharmacy (0201) Inspections** | | | | | | | | | | | | |
| Change of Location | 5 | | 5 | | 4 | | 6 | | 7 | | 8 | 3 |
| New | 10 | | 10 | | 9 | | 11 | | 9 | | 6 | 1 |
| Reinspection | 15 | | 10 | | 7 | | 8 | | 6 | | 7 | 3 |
| Remodel | 49 | | 39 | | 42 | | 30 | | 31 | | 36 | 5 |
| Routine | 193 | | 207 | | 121 | | 15 | | 45 | | **109** | 0 |
| Focus | 3 | | 2 | | 1 | | 2 | | 0 | | **1** | 0 |
| Federal Agency | 9 | | 0 | | 0 | | 0 | | 0 | | 0 | 0 |
| Compliance | 0 | | 1 | | 0 | | 1 | | 0 | | 2 | 0 |
| Pilot | 0 | | 0 | | 0 | | 0 | | 0 | | **1** | 0 |
| **Total** | **284** | | **274** | | **184** | | **73** | | **98** | | **170** | **12** |
| | | | | | | | | | | | | |
| **Pharmacy Routine Inspections** | | | | | | | | | | | | |
| No Deficiency | 64 | 33% | 73 | 35% | 42 | 35% | 7 | 47% | 11 | 24% | 28 | 26% |
| Deficiency | 66 | 34% | 70 | 34% | 34 | 28% | 3 | 20% | 17 | 38% | 39 | 36% |
| Deficiency & IPHCO | 63 | 33% | 64 | 31% | 45 | 37% | 5 | 33% | 17 | 38% | 42 | 38% |
| **Total** | **193** | | **207** | | **121** | | **15** | | **45** | | **109** | |

Virginia Board of Pharmacy
December 10, 2020
Frequently Cited Deficiencies
August 2019 - January 2021

| Deficiencies Numbered Less 1-100 (Formerly Major Deficiency) | Cumulative Total |
|---|---|
| 15. Perpetual inventory not being maintained as required, to include not accurately indicating "physical count" on-hand at time of performing inventory or not noting explanation for any difference between "physical count" and "theoretical count"; perpetual inventory performed more than 7 days prior or more than 7 days after designated calendar month for which an inventory is required | 71 |
| 2. Pharmacist-in-Charge in place, inventory taken, but application not filed with Board within the required timeframe | 40 |
| 14. No incoming change of Pharmacist-in-Charge inventory , inventory taken or over 5 days late, or substantially incomplete, i.e., did not include all drugs in Schedules II-V (12/12/13 Cite Minor 13 if only expired drugs not included) | 37 |
| 16. Theft/unusual loss of drugs not reported to the Board as required or report not maintained | 25 |
| 9a. Alarm incapable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational. Alarm is operational but does not fully protect the prescription department and/or is not capable of detecting breaking by any means when activated. (12/12/13 New Minor 44 if no drug loss) | 21 |
| 26. No documentation of initial and annual (12 months) media-fill testing for persons performing low and medium-risk level compounding of sterile preparations. | 21 |
| 32. Have clean room, but not all physical standards in compliance, e.g., flooring, ceiling | 21 |
| 7. Change of location or remodel of pharmacy without submitting application or Board approval | 17 |
| 20. Pharmacist not checking and documenting repackaging or bulk packaging | 16 |
| 13. No biennial inventory, or over 30 days late, or substantially incomplete, i.e., did not include all drugs in Schedules II-V (12/12/13 Cite Minor 13 if only expired drugs not included) AND 5. Pharmacy technicians, pharmacy interns performing duties without monitoring by a pharmacist, or unlicensed persons engaging in acts restricted to pharmacists. | 14 |
| **Deficiencies Numbered Greater Than 100 (Formerly Minor Deficiency)** | **Cumulative Total** |
| 109. Expired drugs in working stock, dispensed drugs being returned to stock not in compliance, dispensed drugs returned to stock container or automated counting device not in compliance. (i.e. appropriate expiration date not placed on label of returned drug, mixing lot numbers in stock container) | 101 |
| 123. Engaging in remote processing not in compliance | 74 |
| 127. Repackaging records and labeling not kept as required or in compliance | 57 |
| 113. Inventories taken on time, but not in compliance, i.e., no signature, date, opening or close, Schedule II drugs not separate, failure to include expired drugs. | 54 |
| 124. Labels do not include all required information | 48 |
| 108. Emergency access alarm code/key not maintained in compliance | 42 |
| 142. No record maintained and available for 12 months from date of analysis of dispensing errors or submission to patient safety organization, to include any zero reports. Record maintained and available for 12 months from date of analysis of dispensing error, to include any zero reports, but is not in compliance | 40 |
| 122. Engaging in alternate delivery not in compliance | 39 |
| 130a. Compounded products not properly labeled | 38 |
| 116. Prescriptions do not include required information. Prescriptions not transmitted as required (written, oral, fax, electronic, etc.) AND 119. Not properly documenting partial filling of prescriptions | 36 |

Virginia Board of Pharmacy
Inspection Report
December 30, 2021

Deficiencies 1 - 100
(Formerly Major Deficiency)

| | 8/19-10/19 | 11/19-1/20 | 2/20-4/20 | 5/20-7/20 | 8/20-10/20 | 11/20-1/21 | Total | 11/20-1/21 | Cumulative |
|---|---|---|---|---|---|---|---|---|---|
| **Routine Inspections Completed** | **193** | **207** | **121** | **73** | **73** | **73** | **740** | **Repeat** | **Repeat** |
| **Total Deficiencies** | **119** | **111** | **74** | **8** | **34** | **69** | **415** | **8** | **275** |
| **Average Deficiencies per Inspection** | **0.6** | **0.5** | **0.6** | **0.1** | **0.5** | **0.9** | **0.6** | | |
| 1. No Pharmacist-in-Charge or Pharmacist-in-Charge not fully engaged in practice at pharmacy location | 0 | 4 | 1 | 0 | 0 | 0 | 5 | | |
| 2. Pharmacist-in-Charge in place, inventory taken, but application not filed with Board within the required timeframe | 7 | 15 | 6 | 0 | 5 | 7 | 40 | | 3 |
| 3. Unregistered persons performing duties restricted to pharmacy technician when not enrolled in a Board-approved pharmacy technician training program or beyond 9 months from the initial enrollment date in a Board-approved pharmacy technician training program | 4 | 4 | 2 | 0 | 0 | 2 | 12 | | |
| 4. Pharmacists/pharmacy technicians/pharmacy interns performing duties on an expired license/registration | 0 | 0 | 0 | 0 | 0 | 2 | 2 | | |
| 5. Pharmacy technicians, pharmacy interns performing duties without monitoring by a pharmacist, or unlicensed persons engaging in acts restricted to pharmacists | 6 | 5 | 2 | 0 | 1 | 0 | 14 | | 1 |
| 6. Exceeds pharmacist to pharmacy technician ratio (12/12/13 New Minor 43 for first offense) | 0 | 1 | 0 | 0 | 0 | 1 | 2 | | 1 |
| 7. Change of location or remodel of pharmacy without submitting application or Board approval | 4 | 2 | 5 | 2 | 1 | 3 | 17 | | 1 |
| 8. Refrigerator/freezer temperature out of range greater than +/- 4 degrees Fahrenheit. | 0 | 3 | 0 | 0 | 0 | 0 | 3 | | 1 |
| 9. Alarm not operational or not being set | 0 | 1 | 1 | 0 | 0 | 0 | 2 | | |
| 9a. Alarm incapable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational. Alarm is operational but does not fully protect the prescription department and/or is not capable of detecting breaking by any means when activated. (12/12/13 New Minor 44 if no drug loss) | 11 | 5 | 1 | 1 | 1 | 2 | 21 | | 1 |

Virginia Board of Pharmacy
Inspection Report
December 30, 2021

Deficiencies 1 - 100
(Formerly Major Deficiency)

| | 8/19-10/19 | 11/19-1/20 | 2/20-4/20 | 5/20-7/20 | 8/20-10/20 | 11/20-1/21 | Total | 11/20-1/21 | Cumulative |
|---|---|---|---|---|---|---|---|---|---|
| 10. Unauthorized access to alarm or locking device to the prescription department | 7 | 3 | 0 | 0 | 0 | 3 | 13 | | 1 |
| 11. Insufficient enclosures or locking devices (12/12/13 New Minor 45 if no drug loss) | 1 | 3 | 2 | 0 | 0 | 2 | 8 | | |
| 12. Storage of prescription drugs not in the prescription department | 5 | 3 | 1 | 1 | 0 | 1 | 11 | | 11 |
| 12a. Schedule II drugs are not dispersed with other schedules of drugs or maintained in a securely locked cabinet, drawer, or safe. (12/12/13 New Minor 46 if no drug loss) | 2 | 4 | 0 | 0 | 0 | 1 | 7 | | 4 |
| 13. No biennial inventory, or over 30 days late, or substantially incomplete, i.e., did not include all drugs in Schedules II-V (12/12/13 Cite Minor 13 if only expired drugs not included) | 5 | 4 | 3 | 0 | 0 | 2 | 14 | | 5 |
| 14. No incoming change of Pharmacist-in-Charge inventory , inventory taken or over 5 days late, or substantially incomplete, i.e., did not include all drugs in Schedules II-V (12/12/13 Cite Minor 13 if only expired drugs not included) | 7 | 8 | 6 | 1 | 6 | 9 | 37 | | 8 |
| 15. Perpetual inventory not being maintained as required, to include not accurately indicating "physical count" on-hand at time of performing inventory or not noting explanation for any difference between "physical count" and "theoretical count"; perpetual inventory performed more than 7 days prior or more than 7 days after designated calendar month for which an inventory is required | 19 | 17 | 18 | 2 | 7 | 8 | 71 | 3 | 123 |
| 16. Theft/unusual loss of drugs not reported to the Board as required or report not maintained | 5 | 3 | 6 | 0 | 2 | 9 | 25 | | 4 |
| 17. Hard copy prescriptions not maintained or retrievable as required (i.e. hard copy of fax for Schedule II, III, IV & V drugs and refill authorizations) | 3 | 0 | 2 | 0 | 1 | 0 | 6 | | |
| 18. Records of dispensing not maintained as required | 4 | 1 | 0 | 0 | 0 | 0 | 5 | | 1 |
| 19. Pharmacists not verifying or failing to document verification of accuracy of dispensed prescriptions | 3 | 2 | 1 | 0 | 1 | 0 | 7 | | 3 |

Virginia Board of Pharmacy
Inspection Report
December 30, 2021

Deficiencies 1 - 100
(Formerly Major Deficiency)

| | 8/19-10/19 | 11/19-1/20 | 2/20-4/20 | 5/20-7/20 | 8/20-10/20 | 11/20-1/21 | Total | 11/20-1/21 | Cumulative |
|---|---|---|---|---|---|---|---|---|---|
| 20. Pharmacist not checking and documenting repackaging or bulk packaging | 5 | 5 | 3 | 0 | 2 | 1 | 16 | | 18 |
| 20a. Pharmacist not documenting final verification of non-sterile compounding | 1 | 2 | 2 | 0 | 0 | 3 | 8 | | 4 |
| 20b. Pharmacist not documenting final verification of sterile compounding | 3 | 4 | 0 | 0 | 1 | 2 | 10 | | 16 |
| 21. No clean room | 0 | 0 | 0 | 1 | 0 | 0 | 1 | | |
| 21a. Performing sterile compounding outside of a clean room (Added 12/12/13) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| 22. Certification of the direct compounding area (DCA) for compounded sterile preparations indicating ISO Class 5 not performed by a qualified individual no less than every 6 months and whenever the device or room is relocated, altered, or major service to the facility is performed | 1 | 0 | 1 | 0 | 0 | 0 | 2 | | |
| 23. Certification of the buffer or clean room and ante room indicating ISO Class 7 / ISO Class 8 or better not performed by a qualified individual no less than every six months and whenever the device or room is relocated, altered, or major service to the facility is performed. | 0 | 0 | 1 | 0 | 0 | 0 | 1 | | 1 |
| 24. Sterile compounding of hazardous drugs performed in an area not physically separated from other preparation areas. | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| 25. No documentation of sterilization methods or endotoxin pyrogen testing for high-risk level compounded sterile preparations or high risk compounded sterile preparations assigned inappropriate beyond use date (BUD) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | 2 |
| 25a. No documentation of initial and semi-annual (6 months) media-fill testing for persons performing high-risk level compounding of sterile preparations. | 1 | 0 | 0 | 0 | 0 | 0 | 1 | | 1 |
| 25b. . High-risk compounded sterile preparations intended for use are improperly stored | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |

Virginia Board of Pharmacy
Inspection Report
December 30, 2021

Deficiencies 1 - 100
(Formerly Major Deficiency)

| | 8/19-10/19 | 11/19-1/20 | 2/20-4/20 | 5/20-7/20 | 8/20-10/20 | 11/20-1/21 | Total | 11/20-1/21 | Cumulative |
|---|---|---|---|---|---|---|---|---|---|
| 25c. Documentation that a person who failed a media-fill test has performed high-risk level compounding of sterile preparations after receipt of the failed test result and prior to retraining and receipt of passing media-fill test | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| 26. No documentation of initial and annual (12 months) media-fill testing for persons performing low and medium-risk level compounding of sterile preparations. | 5 | 6 | 3 | 0 | 2 | 5 | 21 | 3 | 36 |
| 26a. Documentation that a person who failed a media-fill test has performed low or medium risk level compounding of sterile preparations after receipt of the failed test result and prior to retraining and receipt of passing media-fill test | 0 | 1 | 0 | 0 | 0 | 0 | 1 | | 1 |
| 27. Compounding using ingredients in violation of 54.1-3410.2. | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | 1 |
| 28. Compounding copies of commercially available products | 2 | 0 | 0 | 0 | 1 | 0 | 3 | | 1 |
| 29. Unlawful compounding for further distribution by other entities | 1 | 0 | 1 | 0 | 1 | 0 | 3 | | |
| 30. Security of after-hours stock not in compliance | 0 | 0 | 1 | 0 | 0 | 0 | 1 | | |
| 31. Drugs removed and administered to a patient from an automated dispensing device in a nursing home prior to review of the order and authorization by a pharmacist. | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| 32. Have clean room, but not all physical standards in compliance, e.g., flooring, ceiling | 6 | 4 | 4 | 0 | 2 | 5 | 21 | 2 | 24 |
| 33. Low or medium-risk compounded sterile preparations assigned inappropriate beyond use date (BUD) | 1 | 0 | 1 | 0 | 0 | 1 | 3 | | 1 |
| 34. Combined with Minor 42 – 12/2013. | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| 35. Schedule II through VI drugs are being purchased from a wholesale distributor or warehouse not licensed or registered by the board or from another pharmacy in a non-compliant manner | 0 | 1 | 0 | 0 | 0 | 0 | 1 | | 1 |

Virginia Board of Pharmacy
Inspection Report
March 30, 2021

Deficiencies Above 100
(Formerly Minor Deficiency)

| | 8/19-10/19 | 11/19-1/20 | 2/20-4/20 | 5/20-7/20 | 8/20-10/20 | 11/20-1/21 | Total | 11/20-1/21 | Cumulative |
|---|---|---|---|---|---|---|---|---|---|
| **Routine Inspections Completed** | **193** | **207** | **121** | **73** | **73** | **73** | **740** | **Repeat** | **Repeat** |
| **Total Deficiencies** | **239** | **208** | **97** | **5** | **53** | **151** | **602** | **9** | **394** |
| **Average Deficiencies per Inspection** | **1.2** | **1.0** | **0.8** | **0.1** | **0.7** | **2.1** | **0.8** | | |
| 101. Repealed 6/2011 | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| 102. Special/limited-use scope being exceeded without approval | 1 | 0 | 0 | 0 | 0 | 1 | 2 | | 1 |
| 103. Repealed 12/12/2013 - Decreased hours of operation without public/Board notice | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| 104. Sink with hot and cold running water not available within the prescription department. | 1 | 3 | 2 | 0 | 0 | 3 | 9 | 1 | 8 |
| 105. No thermometer or non-functioning thermometer in refrigerator/freezer, but temperature within range, +/-4 degrees Fahrenheit | 0 | 4 | 1 | 0 | 0 | 1 | 6 | | 7 |
| 106. Prescription department substantially not clean and sanitary and in good repair | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | 2 |
| 107. Current dispensing reference not maintained | 2 | 2 | 0 | 0 | 1 | 1 | 6 | | 11 |
| 108. Emergency access alarm code/key not maintained in compliance | 10 | 11 | 4 | 2 | 3 | 12 | 42 | 1 | 20 |
| 109. Expired drugs in working stock, dispensed drugs being returned to stock not in compliance, dispensed drugs returned to stock container or automated counting device not in compliance. (i.e. appropriate expiration date not placed on label of returned drug, mixing lot numbers in stock container) | 38 | 37 | 11 | 0 | 4 | 11 | 101 | 3 | 59 |
| 110. Storage of paraphernalia/Rx devices not in compliance | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| 111. Storage of prescriptions awaiting delivery outside of the prescription department not in compliance | 0 | 0 | 0 | 0 | 1 | 1 | 2 | | 2 |
| 112. Biennial taken late but within 30 days | 0 | 1 | 0 | 0 | 1 | 4 | 6 | | |
| 113. Inventories taken on time, but not in compliance, i.e., no signature, date, opening or close, Schedule II drugs not separate, failure to include expired drugs. | 16 | 15 | 6 | 0 | 7 | 10 | 54 | | 63 |

Virginia Board of Pharmacy
Inspection Report
March 30, 2021

Deficiencies Above 100
(Formerly Minor Deficiency)

| | 8/19-10/19 | 11/19-1/20 | 2/20-4/20 | 5/20-7/20 | 8/20-10/20 | 11/20-1/21 | Total | 11/20-1/21 | Cumulative |
|---|---|---|---|---|---|---|---|---|---|
| 114. Records of receipt (e.g. invoices) not on site or retrievable | 2 | 0 | 3 | 0 | 0 | 3 | 8 | | |
| 115. Other records of distributions not maintained as required | 0 | 1 | 1 | 0 | 0 | 1 | 3 | | |
| 116. Prescriptions do not include required information. Prescriptions not transmitted as required (written, oral, fax, electronic, etc.) | 11 | 7 | 5 | 1 | 3 | 9 | 36 | | 2 |
| 117. Minor 17 combined with Minor 16 – 6/2011 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| 118. Schedule II emergency oral prescriptions not dispensed in compliance | 1 | 0 | 0 | 0 | 0 | 0 | 1 | | |
| 119. Not properly documenting partial filling of prescriptions | 10 | 11 | 4 | 0 | 2 | 9 | 36 | | 28 |
| 120. Offer to counsel not made as required | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| 121. Prospective drug review not performed as required | 0 | 0 | 0 | 0 | 1 | 0 | 1 | | 1 |
| 122. Engaging in alternate delivery not in compliance | 13 | 6 | 4 | 0 | 5 | 11 | 39 | 2 | 13 |
| 123. Engaging in remote processing not in compliance | 23 | 14 | 14 | 0 | 9 | 14 | 74 | 1 | 12 |
| 124. Labels do not include all required information | 14 | 12 | 5 | 0 | 5 | 12 | 48 | | 16 |
| 125. Compliance packaging or labeling does not comply with USP-NF standards for customized patient medication packages | 10 | 7 | 2 | 1 | 0 | 6 | 26 | | 10 |
| 126. Special packaging not used or no documentation of request for non-special packaging | 1 | 0 | 0 | 0 | 0 | 0 | 1 | | 5 |
| **Repackaging, specialty dispensing, compounding:** | | | | | | | | | |
| 127. Repackaging records and labeling not kept as required or in compliance | 20 | 19 | 10 | 1 | 2 | 5 | 57 | | 38 |
| 128. Unit dose procedures or records not in compliance | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| 129. Robotic pharmacy systems not in compliance | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| 130. Required compounding/dispensing/distribution records not complete and properly maintained | 8 | 9 | 2 | 0 | 2 | 12 | 33 | | 16 |
| 130a. Compounded products not properly labeled | 14 | 15 | 5 | 0 | 1 | 3 | 38 | | 17 |

Virginia Board of Pharmacy
Inspection Report
March 30, 2021

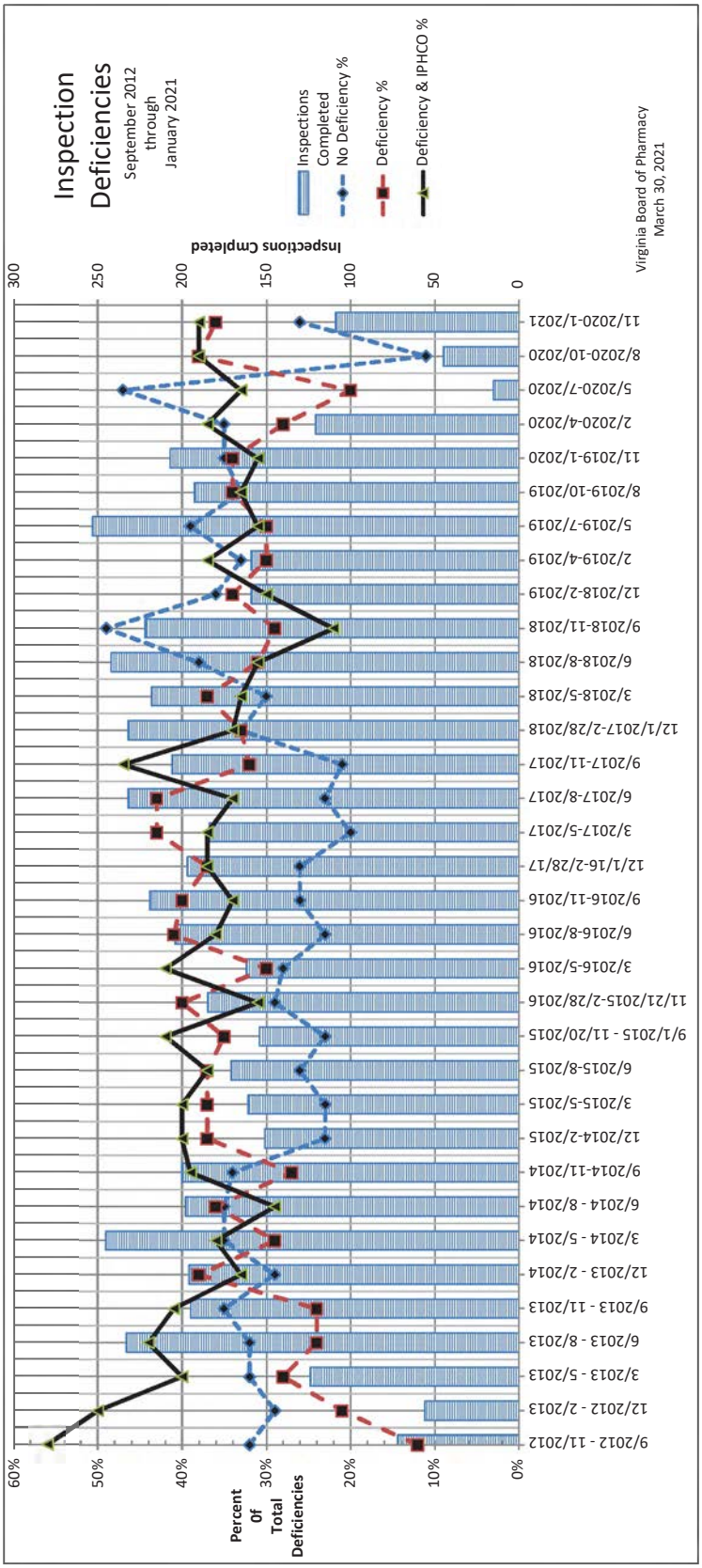
Deficiencies Above 100
(Formerly Minor Deficiency)

| | 8/19-10/19 | 11/19-1/20 | 2/20-4/20 | 5/20-7/20 | 8/20-10/20 | 11/20-1/21 | Total | 11/20-1/21 | Cumulative |
|---|---|---|---|---|---|---|---|---|---|
| 131. Required "other documents" for USP-NF 797 listed on the pharmacy inspection report are not appropriately maintained | 7 | 7 | 2 | 0 | 2 | 2 | 20 | | 1 |
| 132. Personnel preparing compounded sterile preparations do not comply with cleansing and garbing requirements | 8 | 6 | 0 | 0 | 1 | 4 | 19 | | 8 |
| 133. Compounding facilities and equipment used in performing non-sterile compounds not in compliance with 54.1-3410.2 | 1 | 0 | 0 | 0 | 0 | 0 | 1 | | |
| **Hospital specific or long-term care specific:** | | | | 0 | | | | | |
| 134. Policies and procedures for proper storage, security and dispensing of drugs in hospital not established or assured | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| 135. Policies and procedures for drug therapy reviews not maintained or followed | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| 136. After hours access to a supply of drugs or records not in compliance | 0 | 1 | 0 | 0 | 0 | 0 | 1 | | |
| 137. Floor stock records not in compliance, pharmacist not checking, required reconciliations not being done | 1 | 0 | 1 | 0 | 0 | 1 | 3 | | 2 |
| 138. Automated dispensing device loading, records, and monitoring/reconciliation not in compliance | 3 | 0 | 1 | 0 | 1 | 2 | 7 | | 1 |
| 139. Emergency medical services procedures or records not in compliance | 2 | 2 | 0 | 0 | 0 | 0 | 4 | | 5 |
| 140. Emergency kit or stat-drug box procedures or records not in compliance | 3 | 2 | 1 | 0 | 0 | 1 | 7 | 1 | 8 |
| 141. Maintaining floor stock in a long-term care facility when not authorized | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| 142. No record maintained and available for 12 months from date of analysis of dispensing errors or submission to patient safety organization, to include any zero reports. Record maintained and available for 12 months from date of analysis of dispensing error, to include any zero reports, but is not in compliance | 14 | 12 | 6 | 0 | 2 | 6 | 40 | | 20 |
| 143. Exceeds pharmacist to pharmacy technician ratio (Added 12/12/13) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |

Virginia Board of Pharmacy
Inspection Report
March 30, 2021

Deficiencies Above 100
(Formerly Minor Deficiency)

| | 8/19-10/19 | 11/19-1/20 | 2/20-4/20 | 5/20-7/20 | 8/20-10/20 | 11/20-1/21 | Total | 11/20-1/21 | Cumulative |
|---|---|---|---|---|---|---|---|---|---|
| 144. Alarm incapable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational. Alarm is operational but does not fully protect the prescription department and/or is not capable of detecting breaking by any means when activated. (Added 12/12/13) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | 6 |
| 145. Insufficient enclosures or locking devices (Added 12/12/13) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | 4 |
| 146. Schedule II drugs are not dispersed with other schedules of drugs or maintained in a securely locked cabinet, drawer, or safe. (Added 12/12/13) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | 2 |
| 147. Particle counts, environmental sampling, and smoke pattern testing not performed under dynamic conditions. (Added 12/12/13) | 1 | 0 | 1 | 0 | 0 | 0 | 2 | | 3 |
| 148. Theft/unusual loss of drugs reported to board but report not maintained by pharmacy (Added 6/21/18) | 4 | 4 | 6 | 0 | 0 | 6 | 20 | | 3 |


Inspection Deficiencies
September 2012 through January 2021
Inspections Completed
No Deficiency %
Deficiency %
Deficiency & IPHCO %
Virginia Board of Pharmacy
March 30, 2021
Inspections Completed
Percent Of Total Deficiencies
300
250
200
150
100
50
0
60%
50%
40%
30%
20%
10%
0%
9/2012 - 11/2012
12/2012 - 2/2013
3/2013 - 5/2013
6/2013 - 8/2013
9/2013 - 11/2013
12/2013 - 2/2014
3/2014 - 5/2014
6/2014 - 8/2014
9/2014-11/2014
12/2014-2/2015
3/2015-5/2015
6/2015-8/2015
9/1/2015 - 11/20/2015
11/21/2015-2/28/2016
3/2016-5/2016
6/2016-8/2016
9/2016-11/2016
12/1/16-2/28/17
3/2017-5/2017
6/2017-8/2017
9/2017-11/2017
12/1/2017-2/28/2018
3/2018-5/2018
6/2018-8/2018
9/2018-11/2018
12/2018-2/2019
2/2019-4/2019
5/2019-7/2019
8/2019-10/2019
11/2019-1/2020
2/2020-4/2020
5/2020-7/2020
8/2020-10/2020
11/2020-1/2021

## Pharmaceutical Processors Report-March 30, 2021

- All four pharmaceutical processors have begun dispensing cannabis oil products.
- Columbia Care of Eastern Virginia, LLC (Portsmouth) and Dalitso, LLC (Manassas) continue in the cultivation phase.
- The RFA for a pharmaceutical processor permit in Health Service Area I that was posted from September 25, 2020 to December 4, 2020 resulted in 26 applications being received. Currently the application review process is on hold due to a court order.
- The Board is receiving, on average, 800 patient applications per week
- The Board has two temporary staff employees assisting with the processing of applications and has begun the recruitment process for two full time administrative specialist to support the program. Additionally, agency staff have been providing assistance with processing patient applications by working overtime hours for the Board.
- The Board is continuing to explore a new patient registration platform/process to address the increase in patient registrations currently and expected due to anticipated legislative changes.

Pharmaceutical Processors Program-By the Numbers
As of 3/11/2021

| | |
|---|---|
| Registered Practitioners | 666 |
| Registered Patients | 15,076 |
| Registered Parents/Guardians | 119 |
| Registered Agents | 46 |
| Registered Cannabis Oil Products | 183 |

# Discipline Program Report

Open Cases as of 3-12-2021:

| | PC | APD | Investigation | FH | IFC | Entry | Pending Closure | OAG | TOTALS |
|---|---|---|---|---|---|---|---|---|---|
| **Patient Care Cases** | 57 | 10 | 76 | 1 | 11 | 2 | 0 | 1 | 158 |
| **Non-Patient Care Cases** | 73 | 2 | 14 | 1 | 7 | 0 | 9 | 0 | 106 |
| | | | | | | | | **TOTAL:** | **264** |

- ❖ Patient care cases:
  - There are fifty-seven (57) patient care cases at Probable Cause compared to sixty-five (65) reported for November 2020. Twelve (12) of these cases are pending an IFC or FH.
  - There are thirty (30) fewer cases compared to November 2020.

- ❖ There are nine (9) cases > 365 days – all but one case is at Formal Hearing or Informal Conference status.

**Upcoming Disciplinary Proceedings: <u>All proceedings will be held virtually until further notice.</u>**

| | | |
|---|---|---|
| April 14, 2021 | Virtual IFC-B | Glenn Bolyard/Ryan Logan |
| April 27, 2021 | Virtual Formal Hearings | All Board Members |
| May 6, 2021 | Virtual IFC-C | Cheryl Nelson/Dale St. Clair |
| May 7, 2021 | Virtual Formal Hearings | All Board Members |
| May 13, 2021 | Virtual IFC-A | Patricia Richards-Spruill/Bill Lee |
| June 3, 2021 | Virtual IFC-B | Glenn Bolyard/Ryan Logan |
| June 4, 2021 | Virtual Full Board Mtg/FHs | All Board Members |

**Executive Director's Report** – March 30, 2021

*Recent Meetings Attended:*

- Various VDH COVID-19 Meetings
- NABP Monthly Executive Directors Meeting
- NABP Executive Committee
- NABP Solutions Board of Managers
- VPhA Mid-year Meeting

*Staffing:*

- Retirement of Sammy Johnson, Deputy Executive Director – April 1, 2021
- Recruiting for Deputy Executive Director and two licensing administrative assistants for pharmaceutical processor program
- Continuing to telework with limited hours on-site

*E-newsletter:*

- Next publication early April

*Scam Alert:*

- Recent Warning from DHP

*Statewide Protocols:*

- Regulations became effective January 3, 2021
- Protocols listed on homepage of board website

*Applications for New Licensing Categories Implemented in January 2021:*

- Pharmacy technician trainees
- Individual license and permit for limited-use practitioner of the healing arts to sell Schedule VI drugs in a non-profit facility
- Cannabis dispensing facility permits

*NABP Virtual Annual Meeting*

- May 13 - 14, 2021