COMMONWEALTH OF VIRGINIA
Meeting of the Board of Pharmacy

Perimeter Center, 9960 Mayland Drive, Second Floor
Henrico, Virginia 23233
(804) 367-4456 (Tel)
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Tentative Agenda of Public Hearings and Full Board Meeting
December 12, 2016
9:00AM

TOPIC	PAGES
Call to Order of Public Hearings for Scheduling Certain Substances, Emergency Regulations for Permitting Facilities for Practitioners of the Healing Arts to Sell Controlled Substances, Emergency Regulations for Permitting Outsourcing Facilities, and Regulations for Prohibition Against Incentives to Transfer Prescriptions: Ryan Logan, Vice-Chairman • Welcome & Introductions • Reading of Emergency Evacuation Script	1-10
Call for Public Comment: • Possible Scheduling of the Certain Chemicals in Schedule I of the Drug Control Act • Emergency Regulations for Permitting Facilities for Practitioners of the Healing Arts to Sell Controlled Substances • Emergency Regulations for Permitting Outsourcing Facilities • Regulations for Prohibition Against Incentives to Transfer Prescriptions	
Adjournment of Public Hearings	
Call to Order of Full Board Meeting: Ryan Logan, Vice-Chairman • Approval of Agenda • Approval of Previous Board Meeting Minutes:	
○ September 7, 2016, Full Board Meeting	11-20
○ September 7, 2016, Public Hearing for Scheduling Certain Chemicals	21-22
○ September 7, 2016, Formal Hearing	23-25
○ September 8, 2016, Special Conference Committee	26-28
○ September 20, 2016, Special Conference Committee	29-31
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○ October 3, 2016, Panel Formal Hearing	37-38
○ November 14, 2016, Telephone Conference Call	39-40
○ November 16, 2016, Special Conference Committee	41-43
○ November 29, 2016, Regulation Committee	Handout
○ December 6, 2016, Special Conference Committee	Handout
Call for Public Comment: The Board will receive public comment at this time. The Board will not receive comment on any regulation process for which a public comment period has closed or any pending disciplinary matters.	
DHP Director's Report: David Brown, DC	

Regulatory Actions: Elaine Yeatts

- Regulatory Update — 44
- Legislative Update
- Adoption of Regulation to Schedule Certain Chemicals in Schedule I — 45-50
- Adoption of Chapter 21 Recommendations from Regulation Committee — 51-68
- Adoption of Regulatory Amendment to Allow CE credit for Voluntary Hours — 69-74
- Consideration of Request to Delay Enforcement of USP Chapter <800> — 75-124
- Amend Guidance Document 110-38, Requirement for Non-resident Pharmacies to Submit Current Inspection Report — 125-128, 129-131
- Adopt Amendments to Naloxone Protocol

New Business:

- Consideration for NABP E-profile Participation — 132-133
- Consideration for Requiring CE in a Specific Subject Area in 2017 — 134

Reports:

- Chairman's Report – Ryan Logan, Vice-Chairman
- Report on Board of Health Professions – Ryan Logan
- Report on PMP Advisory Panel – Ryan Logan/Jody Allen
- Report on NABP Telepharmacy Task Force – Freeda Cathcart
- Report on NABP International Membership Task Force – Cindy Warriner
- Report on NABP Interactive Member Forum – Jody Allen
- Report on Licensure Program – J. Samuel Johnson, Jr.
- Report on Disciplinary Program – Cathy M. Reiniers-Day — Handout
- Executive Director's Report – Caroline D. Juran — Handout

Handout

Consideration of consent orders & summary suspension, if any

Adjourn

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

****A panel of the board will convene at 1:30pm or immediately following adjournment of the meeting, whichever is later.****

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 public hearing will be conducted at **9:00 a.m. on December 12, 2016** at the Perimeter Center, 9960 Mayland Drive, Suite 201, Richmond, VA 23233. Public comment may also be submitted electronically or in writing prior to December 1, 2016 to Caroline Juran, Executive Director of the Board of Pharmacy to caroline.juran@dhp.virginia.gov.

As specified in § 54.1-3443, the Virginia Department of Forensic Science (DFS) has identified eight (8) compounds for recommended inclusion by the Board of Pharmacy into Schedule I in the Code of Virginia. A brief description and chemical name for each compound is as follows:

The following compounds are classified as research chemicals. Drugs of this type have been placed in Schedule I (§ 54.1-3446(3)) in previous legislative sessions.

1. 1-(1,3-benzodioxol-5-yl)-2-(dimethylamino)-1-pentanone (other names: N,N-Dimethylpentylone, Dipentylone)

2. 4-chloro-alpha-Pyrrolidinovalerophenone (other name: 4-chloro-alpha-PVP)

3. 4-methyl-alpha-Pyrrolidinohexiophenone (other name: MPHP)

4. 4-fluoro-alpha-Pyrrolidinoheptiophenone (other name: 4-fluoro-PV8)

5. 1-(4-methoxyphenyl)-2-(pyrrolidin-1-yl)octan-1-one (other name: 4-methoxy-PV9)

6. 4-allyloxy-3,5-dimethoxyphenethylamine (other name: Allylescaline)

7. 4-methyl-alpha-ethylaminopentiophenone

The following compound is a powerful synthetic opioid. DFS recommends placing this compound into Schedule I (§ 54.1-3446(1)).

8. N-(4-fluorophenyl)-2-methyl-N-[1-(2-phenylethyl)-4-piperidinyl]-propanamide (other name: para-fluoroisobutyryl fentanyl)

If approved by the Board of Pharmacy, the placement of these substances in Schedule I in the Virginia Drug Control Act shall remain in effect for a period of 18 months from the date of Board action and shall then be de-scheduled unless the Drug Control Act is amended by enactment of legislation by the General Assembly.

Proposed Regulations for Public Hearings

Proposed Text - Permits for facilities

18VAC110-30-15. Fees.

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

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

1. ~~The application fee for initial licensure shall be $240~~ License for practitioner of the healing arts to sell controlled substances: $180.

2. ~~The application fee for reinstatement of a license that has been revoked or suspended indefinitely shall be $500~~ Permit for facility in which practitioners of the healing arts sell controlled substances: $240.

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

1. ~~The annual fee for renewal of an active license shall be $90. For the annual renewal due on December 31, 2009, the fee shall be $50~~ License for practitioner of the healing arts to sell controlled substances: $90.

2. ~~The late fee for renewal of a license within one year after the expiration date is $30 in addition to the annual renewal fee~~ Permit for facility in which practitioners of the healing arts sell controlled substances: $240.

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

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

1. License for practitioner of the healing arts to sell controlled substances: $30.

2. Permit for facility in which practitioners of the healing arts sell controlled substances: $40.

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

1. License for practitioner of the healing arts to sell controlled substances: $150.

2. Permit for facility in which practitioners of the healing arts sell controlled substances: $240.

3. Application fee for reinstatement of a license or permit that has been revoked or suspended indefinitely: $500.

F. Facilities in which only one practitioner of the healing arts is licensed by the board to sell controlled substances shall be exempt from fees associated with obtaining and renewing a facility permit.

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

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

Part II
Licensure Requirements

18VAC110-30-20. Application for 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. Any disciplinary action taken by the Board of Medicine against the practitioner's license to practice shall constitute grounds for the board to deny, restrict, or place terms on the license to sell.

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

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

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

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.

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.

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

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

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

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

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

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

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

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

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

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

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

Part III
Inspection Requirements, Standards, and Security for Storage Areas; Disposal of Controlled Substances

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

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

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

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

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

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

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

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

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

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

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

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

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

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

18VAC110-30-90. Physical standards.

Physical standards for the controlled substance selling and storage area:

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

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

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

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

5. A sink with hot and cold running water shall be available within ~~the immediate vicinity~~ 20 feet of the selling and storage area and not located within an examination room or restroom; and

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

Proposed Text - Outsourcing facilities

18VAC110-20-20. Fees.

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

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

C. Initial application fees.

1. Pharmacist license	$180
2. Pharmacy intern registration	$15
3. Pharmacy technician registration	$25
4. Pharmacy permit	$270
5. Permitted physician licensed to dispense drugs	$270

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

D. Annual renewal fees.

1. Pharmacist active license due no later than December 31	$90
2. Pharmacist inactive license due no later than December 31	$45
3. Pharmacy technician registration due no later than December 31	$25
4. Pharmacy permit due no later than April 30	$270
5. Physician permit to practice pharmacy due no later than February 28	$270
6. Medical equipment supplier permit due no later than February 28	$180
7. Humane society permit due no later than February 28	$20
8. Outsourcing facility permit due no later than April 30	$270
~~8.~~ 9. Nonresident pharmacy registration due no later than the date of initial registration	$270
10. Nonresident outsourcing facility registration due no later than the date of initial registration	$270
~~9.~~ 11. Controlled substances registrations due no later than February 28	$90
~~10.~~ 12. Innovative program continued approval based on board order not to exceed $200 per approval period.	
~~11.~~ 13. Approval of a pharmacy technician training program	$75 every two years
~~12.~~ 14. Approval of a repackaging training program	$30 every two years

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

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

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

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

~~e.~~ f. Nonresident pharmacy registration	$115
g. Nonresident outsourcing facility registration	$240
~~f.~~ h. Controlled substances registration	$180
~~g.~~ i. Approval of a pharmacy technician training program	$75
~~h.~~ j. Approval of a repackaging training program	$50

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

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

H. Miscellaneous fees.

1. Duplicate wall certificate	$25
2. Returned check	$35
3. Duplicate license or registration	$10
4. Verification of licensure or registration	$25

18VAC110-20-215. Outsourcing facilities.

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

B. In order to obtain or renew a permit or registration, outsourcing facilities shall submit to the board (i) documentation that the facility is registered as an outsourcing facility under the Federal Food, Drug, and Cosmetic Act and (ii) a copy of a current inspection report consistent with § 54.1-3434.05 or 54.1-3434.5 of the Code of Virginia. Outsourcing facilities that fail to demonstrate that the facility is registered as an outsourcing facility under the Federal Food, Drug, and Cosmetic Act or submit a copy of a current inspection report consistent with § 54.1-3434.05 or 54.1-3434.5 shall not meet the requirements for an initial permit or registration or for renewal of a permit or registration.

C. An outsourcing facility shall comply with all provisions of this chapter relating to a pharmacy in Parts IV (18VAC110-20-110 et seq.) and VI (18VAC110-20-240 et seq.), with the following exceptions:

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

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

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

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

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

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

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

2. Records.

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

b. Compounding records shall include identification and strength of the drugs and shall provide the ingredients, expiration dates, and the source of such ingredients. Records shall also include the national drug code number of the source drug or bulk active ingredient, if available; the strength of the active ingredient per unit; the dosage form and route of administration; the package description; the number of individual units produced; the national drug code number of the final product, if assigned, or lot number; and an appropriately assigned expiration date or beyond-use date.

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

E. No outsourcing facility may distribute or dispense any drug to any person pursuant to a prescription unless it also maintains a current active pharmacy permit. The pharmacy shall comply with all state and federal laws, regulations, and requirements, except it shall compound in compliance with current good manufacturing practices under § 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (21 USC § 351(a)(2)(B)).

Part VIII
Labeling and Packaging Standards for Prescriptions

18VAC110-20-321. Compounding.

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

B. The compounding of sterile drug products by an outsourcing facility or by a pharmacy sharing the same physical space with an outsourcing facility shall be performed in accordance with current good manufacturing practices under § 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (21 USC § 351(a)(2)(B)).

Proposed Text - Prohibition against incentives to transfer prescriptions

18VAC110-20-25. 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 provision of patient records to another practitioner or to the patient or his personal representative;

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

3. Failing to maintain 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 his family, including but not limited to sexual misconduct with a patient or a member of his 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 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 PIC to ensure that pharmacy interns and pharmacy technicians working in the pharmacy are registered and that such registration is current; ~~or~~

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

11. Advertising or soliciting in a manner that may jeopardize the health, safety, and welfare of a patient, including incentivizing or inducing the transfer of a prescription absent professional rationale by use of coupons, rebates, or similar offerings.

DRAFT/UNAPPROVED

VIRGINIA BOARD OF PHARMACY
MINUTES OF BOARD MEETING

September 7, 2016
Second Floor
Board Room 2

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: The meeting was called to order at 9:07am

PRESIDING: Rebecca Thornbury, Chairman

MEMBERS PRESENT:
Jody H. Allen
Melvin L. Boone, Sr.
Freeda Cathcart (arrived at 9:55am)
Michael I. Elliott
Sheila K. W. Elliott (arrived at 9:35am)
Ryan K. Logan
Rafael Saenz
Ellen B. Shinaberry
Cynthia Warriner (arrived 9:10am)

STAFF PRESENT:
Caroline D. Juran, Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director
David Brown, Director, DHP
James Rutkowski, Assistant Attorney General
Elaine J. Yeatts, Senior Policy Analyst, DHP
Beth O'Halloran, Individual Licensing Manager

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

APPROVAL OF AGENDA: The agenda was amended to include new business, a request for waivers of the 91-day waiting period for retaking the NAPLEX examination after receiving a failing score. The agenda was approved as amended.

APPROVAL OF MINUTES: The following minutes were considered for approval:

- June 8, 2016, Special Conference Committee
- June 14, 2016, Full Board Meeting
- June 14, 2016, Public Hearing for Scheduling Certain Chemicals
- June 15, 2016, Inspection Special Conference Committee
- June 14, 2016, Special Conference Committee, 9am and 1pm
- August 15, 2016, Telephone Conference Call

MOTION: **The Board voted unanimously to adopt the minutes from June 8, 2016 through August 15, 2016 as presented.**
(motion by Warriner, second by Boone)

PUBLIC COMMENTS:

Marla Watson, legislative chair for Community Coalitions of Virginia and concerned parent, provided comment on the recommended language for the regulations regarding THC-A oil and cannabidiol oil. She reminded the Board that Cannabis is not an FDA-approved product and that the allowance for THC-A and cannabidiol oils for epilepsy will open the door to approval of other conditions in the future. Ms. Watson is concerned with comments made during the Regulatory Advisory Panel meeting regarding desires for the ability to dispense a 90-day supply, the ability for manufacturing and dispensing to occur at separate locations, and the ability to deliver the dispensed oils to the patient's residence.

John Lubkowski, Director, Augusta Health, provided comments regarding the new pilot inspection process using the draft NABP uniform inspection report. Mr. Lubkowski was pleased with the process, however, suggested that the flow of the inspection may be smoother if the pharmacy were to have the ability to fill out the interview portion prior to the inspection. Mr. Lubkowski stated that advance notice of 24-48 hours would be helpful as the interview portion may create a safety concern if the pharmacist were taken away from patient care for a period of time to be interviewed by the inspector.

Lennice Wirth, drug policy advocate, stated that the marijuana oils were much less toxic than other drugs for seizures. Ms. Wirth feels the allowance for 90-day supply is appropriate.

DHP DIRECTOR'S REPORT:

Dr. Brown offered his thanks to the Regulatory Advisory Panel for all their work and commended Ryan Logan for chairing the Panel and doing a tremendous job. Dr. Brown also thanked Ms. Juran and Ms. Yeatts for their work on the regulations.

Dr. Brown spoke about the Task Force on Heroin and Prescription Drug Abuse and its outcomes:

- The Board of Medicine convened a workgroup on buprenorphine. Best practices are scheduled to be presented to the Board of Medicine at its October meeting.
- PMP will have an advisory panel to establish criteria for identifying suspicious prescribing and dispensing activities which can be forwarded to the Enforcement Division for investigation.
- PMP also in a regulatory process to allow additional elements to be reported.
- Department of Health Professions (DHP) has taken the lead to establish a website on prescription drug abuse. DHP currently working with the Governor's office regarding implementation.

Dr. Brown also provided information regarding the upcoming board member training on October 24, 2016. He then reported that the two legislative proposals adopted by the board in June regarding collaborative practices and requiring PTCB certification received considerable negative feedback from key stakeholders and therefore, they would not be

advancing to the Secretary's office for consideration for the 2017 General Assembly session.

REGULATORY ACTIONS:

- Regulatory Update: Ms. Yeatts provided a handout with updated information regarding the status of pending regulatory actions.

- Legislative Update: Ms. Yeatts did not have any additional information to provide regarding a legislative update.

- Adoption of Regulation to Schedule Certain Chemicals in Schedule I: There was a public hearing conducted at 9:00am this morning pursuant to requirements of §54.1-3443 of the Drug Control Act. No comment was received during the hearing.

MOTION:

The Board voted unanimously to adopt an exempt action amendment of Regulation 18VAC110-20-322 as presented by adding subsection C which places the following chemicals into Schedule I:

Classified as research chemicals:

- **1-propionyl lysergic acid diethylamide (other name: 1P-LSD)**
- **(2-methylaminopropyl)benzofuran (other name: MAPB)**

Classified as stimulants:

- **Ethyl phenyl(piperidin-2-ly)acetate (other name: Ethylphenidate)**
- **2-(3-flurophenyl)-3-methylmorpholine (other name: 3-flurophenmetrazine)**

Classified as powerful synthetic opioids:

- **N-(4-fluorophenyl)-N-[1-(2-phenylethyl)-4-piperidinyl] – butanamide (other name: para-fluorobutyrylfentanyl), its optical, positional, and geometric isomers, salts and salts of isomers. (motion by Warriner, second by Boone)**

REPORT FROM REGULATORY ADVISORY PANEL FOR ADOPTION OF EMERGENCY REGULATIONS FOR PHARMACEUTICAL PROCESSORS TO PRODUCE AND DISPENSE CANNABIDIOL OIL AND THC-A OIL:

In response to SB701, the Regulatory Advisory Panel met on three occasions during the summer of 2016 to draft emergency regulations for consideration by the full board for pharmaceutical processors to cultivate, produce, and dispense cannabidiol oil and THC-A oil for the treatment of intractable epilepsy. These emergency regulations must be adopted within 280 days from the signing of the bill. However, an enactment clause on the bill requires the issue to be reconsidered by the 2017 General Assembly prior to the law or regulations becoming effective. If the bill changes, this Board will likely need to amend its regulations. The Board reviewed the recommended regulatory language and offered several amendments.

MOTION:

The Board voted 9 to 1 to amend the proposed emergency Regulation

18VAC110-60-310 H by striking the words "in consultation with the certifying physician". (motion by Shinaberry, second by Warriner; Cathcart opposed)

MOTION:

The Board voted 8 to 0 with two abstentions to adopt the emergency regulations for pharmaceutical processors to cultivate, produce, and dispense cannabidiol oil and THC-A oil for the treatment of intractable epilepsy as amended and with the following additional amendments:

- **18VAC110-60-30, correct numbering sequence;**
- **18VAC110-60-170 (B), after "A pharmacist with a current, unrestricted license issued by the Virginia board shall provide personal supervision on the premises of the pharmaceutical processor at all times during hours of operation" insert "and at any time the facility is accessed";**
- **18VAC110-60-170 F, after "Persons who do not maintain licensure as a pharmacist or registration as a pharmacy technician, but have received a degree in chemistry, pharmacology, or have at least two years of experience extracting chemicals from plants may perform duties associated with the extraction of cannabidiol oil and THC-A oil" insert ", as authorized by the pharmacist-in-charge" to the end.**
- **18VAC110-60-170 H, after "At no time shall a pharmaceutical processor operate" insert "or be accessed". (motion by Allen, second by Saenz; Warriner and Cathcart abstained)**

ACTION ITEM:

There was consensus that an educational presentation should be provided to the board members on cannabidiol oil and THC-A oil and the associated law and regulations prior to issuing licenses for pharmaceutical processors. (recommend by S. Elliott)

ADOPT FAST TRACK REGULATIONS FOR THIRD-PARTY LOGISTIC PROVIDERS, NONRESIDENT MANUFACTURERS, AND TRACK AND TRACE REQUIREMENTS:

Ms. Yeatts explained that HB528 passed during the 2016 General Assembly conformed several sections of state law to Title II of the Drug Quality and Security Act. The bill authorized the Board to license in-state third-party logistics providers and non-resident manufacturers, struck requirements for a pedigree and required compliance with the federal track and trace requirements. The federal law precludes the individual states from licensing third-party logistic providers as wholesale distributors.

MOTION:

The Board voted unanimously to adopt as presented the fast-track regulatory amendments of 18VAC110-50-10 et seq. regarding third-party logistics providers, non-resident manufacturers and track and trace requirements. (motion by Warriner, second by S. Elliott)

ADOPT EXEMPT REGULATIONS FOR NONRESIDENT MEDICAL

Ms. Yeatts reviewed HB527 which created a new licensing category for nonresident medical equipment suppliers. She explained that the existing applicable fees for medical equipment suppliers would apply to the

EQUIPMENT SUPPLIERS:

nonresident medical equipment suppliers and there was no need to specifically delineate this in the fees section. The only suggested amendment is in 18VAC110-20-680 E which states, "A nonresident medical equipment supplier shall register and practice in accordance with 54.1-3435.3:1 of the Code of Virginia." The amendment could be made through an exempt action.

MOTION:

The Board voted unanimously to adopt the exempt regulatory action as presented regarding nonresident medical equipment suppliers by creating a subsection E which states "A nonresident medical equipment supplier shall register and practice in accordance with 54.1-3435.3:1 of the Code of Virginia." (motion by Warriner, second by S. Elliott)

PETITIONS FOR RULEMAKING

- Permit pharmacists to dispense quantity of Schedule VI greater than face amount prescribed, up to total amount authorized

The Board reviewed a request from Derek Phillips to permit a pharmacist to dispense a quantity of a Schedule VI drug greater than the face amount prescribed, up to the total amount authorized in refills. During the comment period which ended June 29, 2016, the board received one comment which supported the request. Currently a pharmacist may not dispense more than the specific quantity prescribed at each dispensing and may not exceed that quantity by taking authorized refills into consideration.

MOTION

The Board voted unanimously to accept the petition for rulemaking authorizing a pharmacist, when deemed appropriate in his professional judgement and upon request by the patient, to dispense a quantity of a Schedule VI drug, excluding psychotherapeutic drugs, in excess of the specific quantity prescribed for a dispensing, not to exceed the total amount authorized in refills and to adopt a notice of intended regulatory action (NOIRA). (motion by Warriner, second by Saenz)

- Permit the use of electronic devices in lieu of manual emergency kits and stat drug boxes

The Board reviewed a request from Roger StClair to amend 18VAC110-20-540, 18VAC110-20-550 and 18VAC110-20-555 to authorize the use of electronic devices in lieu of manual emergency drug kits and stat-drug boxes. The petition states that current regulation does not distinguish between automated dispensing devices being utilized for first dose non-routine administration vs routine drug administration. Ms. Juran explained that DEA does not require a provider pharmacy to a long term care facility to obtain DEA registration for the use of an automated dispensing device in the facility if the device is used solely for obtaining drugs for non-routine "emergency" administration. DEA does require the provider pharmacy to obtain a DEA registration at the address of the long term care facility for the automated dispensing device if the device is for obtaining drugs for routine administration. Currently, 18VAC110-20-555 authorizes the use of an automated dispensing device in a nursing home and requires a nursing home without an in-house pharmacy to obtain

a controlled substances registration prior to using an automated dispensing system, regardless of its intended use for obtaining routine or non-routine drugs. Additionally, while 18VAC110-20-555 3c does allow access to drugs in the device that would be stocked in an emergency drug kit pursuant to 18VAC110-20-540, it does not specifically authorize access to drugs that would be stocked in a stat-drug box in 18VAC110-20-550. However, the board has historically applied the regulation in a manner to permit such. Lastly, Mr. Johnson indicated the quantity limitations of Schedule II-V drugs in 18VAC110-20-550 5b may not be appropriate when using an automated dispensing device.

MOTION:

The Board voted unanimously to accept the petition for rulemaking and adopt a notice of intended regulatory action (NOIRA) for amending Regulation 18VAC110-20-555 to specifically authorize the use of an automated dispensing device in a nursing home for obtaining drugs that would be stocked in a stat-drug box and to clarify the quantity of drugs in Schedules II-V that may be stocked in the device for this purpose, and to consider the appropriateness of requiring a provider pharmacy to the nursing home to obtain a controlled substances registration at the location of the facility for the purpose of placing an automated dispensing device in the facility. (motion by Saenz, second by M. Elliott)

OLD BUSINESS:

- Consideration for accepting inspection from Bestech GMP Contracting, Inc. in lieu of FDA inspection for outsourcing facility

Matthew Bestercy, Owner and Principal Consultant for Bestech GMP Contracting, Inc., provided a handout with additional information for board consideration in follow-up to the discussion during the June 2016 full board meeting. He is requesting the board to accept an inspection report of outsourcing facilities resulting from inspections performed by his company for satisfying the requirement for an outsourcing facility to submit a current inspection report when the FDA has not performed an inspection in the required timeframe as authorized in 54.1-3434.05 and 54.1-3434.5. Bestech would provide the board with the complete inspection report, collect a written corrective action plan from the outsourcing facility within 15 days of the inspection, and provide the board with a written opinion regarding the appropriateness of the written corrective action plan. Mr. Bestercy indicated his inspectors would be able to provide testimony during a disciplinary case, if necessary. It was stated that all inspection reports of outsourcing facilities resulting from an FDA inspection must be considered by the board and that an inspection from Bestech would not preclude this requirement. However, the board could consider accepting an inspection from Bestech for licensure purposes when the FDA had not performed an inspection in the required timeframe.

MOTION:

The board voted 7 to 3 in support of accepting an inspection report

from Bestech GMP Contracting, Inc. for licensure purposes of outsourcing facilities when the FDA has not performed an inspection within the required timeframe for a "current" inspection report pursuant to 54.1-3434.05 and 54.1-3434.5. (motion by Saenz, second by Shinaberry; M. Elliott, Boone, and S. Elliott opposed)

NEW BUSINESS:

- Amend Bylaws

Ms. Juran stated the description of the Examination Administrator Selection Committee and Item Review Committee in the bylaws needed to be amended to reflect the change from no longer administering the Virginia Federal and State Drug Law Exam and the board's participation in the Multistate Pharmacy Jurisprudence Examination.

MOTION:

The Board voted unanimously to amend the bylaws as presented. (motion by S. Elliott, second by Cathcart)

- FDA Guidance Document, Insanitary Conditions at Compounding Facilities

The open comment period for an FDA proposed a Guidance Document regarding Insanitary Conditions at Compounding Facilities closes October 3, 2016. The board considered a draft comment supporting the publishing of the guidance document as written.

MOTION:

The Board voted unanimously to submit the draft comment as presented to support the FDA publishing the proposed guidance document for insanitary conditions at compounding facilities as written. (motion by Allen, second by Logan)

- Requests for Waivers of the 91-day Waiting Period between Retakes of the NAPLEX after Receiving a Failing Score

Ms. Juran stated that the National Association of Boards of Pharmacy (NABP) currently requires a candidate who fails the NAPLEX examination to wait 91 days before being eligible to sit for the exam again. However, NABP will decrease this waiting period to 45 days effective November 1, 2016. In the interim, NABP will allow a candidate to test after waiting 45 days if a board approves such a waiver. Board staff has received approximately 5 waiver requests. Most are residents who failed their first attempt at NAPLEX. They are requesting a shorter waiting period for retaking NAPLEX so as to remain eligible for their residency program or to progress through the residency program in a timeframe that is contemporary with their peers who passed NAPLEX.

MOTION:

The board voted 8 to 2 to reduce the waiting period between retakes of the NAPLEX examination to 45 days and to apply this approval retroactively to any candidates who recently received a failing score on the NAPLEX. (motion by M. Elliott, second by Cathcart; Warriner and S. Elliott opposed)

REPORTS:

- Chairman's Report

Ms. Thornbury provided a report to the Board mentioning that three

members, Allen, Warriner, and Cathcart, had been appointed by the NABP President to serve on NABP committees later this year, along with Ms. Juran who will serve as an NABP Executive Committee liason to one of committees. Ms. Thornbury reminded everyone of the upcoming NABP/AACP Districts 1 and 2 Meeting to be held in West Virginia on September 15, 16 and 17th. Ms. Warriner, Mr. Boone, Ms. Juran, Ms. Shinaberry, and Mr. Logan are planning to attend this meeting. Ms. Thornbury encouraged each member to attend the DHP board member training in October. Ms. Thornbury thanked Ms. Warriner for her service to the Board as the previous chairman.

- Report on the Board of Health Professions

Mr. Logan stated the agency is developing a website on prescription drug and heroin abuse which is an initiative resulting from the Governor's Task Force on Heroin and Prescription Drug Abuse. It will be unveiled in the near future.

- Report on Licensure Program:

Mr. Johnson provided a handout and reported the Board currently licenses 36,814 individuals and facilities. The Board issued 1,452 licenses and registrations for the period of June 1, 2016 through August 31, 2016. Inspectors conducted 492 facility inspections including 204 routine inspections of pharmacies: 46 (23%) resulted in no deficiency, 84 (41%) with deficiencies and 74 (36%) with deficiencies and a consent order. Mr. Johnson also discussed a chart providing a graphic display of inspection deficiencies by quarter since September 2012. Mr. Johnson reviewed the report of Inspection Deficiencies. It was noted that deficiency 142, regarding compliance with CQI requirements, is the most frequently cited deficiency. Other frequently cited deficiencies include deficiency 15 regarding the perpetual inventory, deficiency 109 regarding expired drugs, deficiency 113 regarding drug inventories, and deficiency 130a regarding the labeling of compounded drug products

- Report on Disciplinary Program:

Ms. Juran stated that Ms. Reiniers-Day is on approved leave. No handout of a report is available at this time. However, she reported that the clearance rate for cases is down from previous reporting periods due to staffing shortages. Anne Joseph from the Administrative Proceedings Division is currently assisting board staff on a temporary basis with the processing of cases in an effort to improve the clearance rate.

- Executive Director's Report:

Ms. Juran provided a handout of her report which summarizes outside meetings attended recently or presentations provided and those scheduled in the near future. Additionally, she reported that the transition to the MPJE examination occurred July 1, 2016 and occurred smoothly. There has been no significant change in the passing rate for Virginia applicants and staff has recently completed its annual review of the item pool for the MPJE. She also reported that the Enforcement Division recently piloted the draft NABP uniform inspection form in approximately 10 pharmacies and is providing feedback to NABP on the form. Lastly, she reported that staff is currently recruiting for two vacant P-14 administrative assistant positions and

one full-time administrative assistant to support the disciplinary program. Two temporary workers were also recently hired, one of which is dedicated to a scanning project for scanning the facility licensure files so as to move toward an electronic recordkeeping system.

MEETING DATES FOR 2017:

The Board discussed meeting dates for 2017 and decided upon the dates as follows:

Full Board meetings:

- March 21, 2017
- June 27, 2017
- September 26, 2017
- December 11, 2017

Regulation Committee Meetings:

- May 10th or 31st, 2017
- November 2, 2017

SUMMARY SUSPENSION:

SHERRI A. KNOX
Registration No: 0230-018157

Wayne Halbleib, Senior Assistant Attorney General, presented a summary of the evidence in the case for the Board to consider a summary suspension. Mykl D. Egan, DHP Adjudication Specialist, was also present.

MOTION:

Upon a motion by Ms. Warriner, and duly seconded by Mr. Boone, the Board voted 8-0 in favor of the motion that, according to the evidence presented, the continued practice by Sherri A. Knox, as a pharmacy technician poses a substantial danger to the public; and therefore, the registration of Sherri A. Knox to practice as a pharmacy technician be summarily suspended. Further, in lieu of a formal hearing, a Consent Order shall be offered to Ms. Knox for the revocation of her pharmacy technician registration.

CONSIDERATION OF CONSENT ORDERS

Closed Meeting:

Upon a motion by Ms. Thornbury, and duly seconded by Ms. Warriner, the Board voted 9-0 to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia for the purpose of deliberation to reach a decision in the matter of a Consent Order. Additionally, she moved that Caroline D. Juran, J. Samuel Johnson, Jr., Beth O'Halloran, and James Rutkowski attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Board in its deliberations.

Reconvene:	The Board voted unanimously that only public business matters lawfully exempt from open meeting requirements under the Virginia Freedom of Information Act and only such public business matters as were identified in the motion for closed meeting were heard, discussed or considered during the closed meeting.
MOTION:	**Upon a motion by Ms. Warriner and duly seconded by Mr. Saenz, the Board voted 8-0 in favor of accepting the Consent Order as presented by Ms. Juran in the matter of Lindy M. Knight, a pharmacy technician.**
ADJOURN:	With all business concluded, the meeting adjourned at approximately 3:25pm.

Rebecca Thornbury, Chairman

DATE:

Caroline D. Juran, Executive Director

DATE:

VIRGINIA BOARD OF PHARMACY
PUBLIC HEARING FOR SCHEDULING CERTAIN SUBSTANCES

September 7, 2016
Second Floor
Board Room 2

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

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

PRESIDING: Rebecca Thornbury, Chairman

MEMBERS PRESENT:
Melvin L. Boone, Sr.
Ryan K. Logan
Raphael Saenz
Ellen B. Shinaberry
Jody H. Allen
Michael Elliott

MEMBERS ABSENT:
Sheila K. W. Elliott
Cindy Warriner
Freeda Cathcart

STAFF PRESENT:
Caroline D. Juran, Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director
Beth O'Halloran, Individual Licensing Manager
David E. Brown, D.C., Director, DHP
Elaine J. Yeatts, Senior Policy Analyst, DHP
James Rutkowski, Assistant Attorney General

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

Pursuant to subsection D of 54.1-3443 of the Code, a public hearing to consider placement of chemical substances in Schedule I of the Drug Control Act was held. If approved by the Board of Pharmacy, the placement of these substances in Schedule I in the Virginia Drug Control Act shall go into effect 30 days following publication of the proposed regulation and remain in effect for a period of 18 months. The chemicals will then be de-scheduled unless a general law is passed by the General Assembly placing the chemicals into Schedule I.

CALL FOR COMMENT: Ms. Thornbury called for comment to consider placement of the following chemical substances into Schedule I:

Classified as research chemicals:

- 1-propionyl lysergic acid diethylamide (other name: 1P-LSD)

- (2-methylaminopropyl)benzofuran (other name: MAPB)

Classified as stimulants:

- Ethyl phenyl(piperidin-2-ly)acetate (other name: Ethylphenidate)
- 2-(3-flurophenyl)-3-methylmorpholine (other name: 3-flurophenmetrazine)

Classified as powerful synthetic opioid:

- N-(4-fluorophenyl)-N-[1-(2-phenylethyl)-4-piperidinyl] – butanamide (other name: para-fluorobutyrylfentanyl), its optical, positional, and geometric isomers, salts and salts of isomers

No public comment was provided.

ADJOURN: The public hearing adjourned at 9:07am.

Rebecca Thornbury, Chairman

Caroline D. Juran, Executive Director

Date

Date

VIRGINIA BOARD OF PHARMACY
MINUTES OF A PANEL OF THE BOARD

September 7, 2014
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 3:40 p.m.

PRESIDING: Cindy Warriner, Chair

MEMBERS PRESENT:
Jody H. Allen
Melvin L. Boone, Sr.
Freeda Cathcart
Michael I. Elliott
Sheila K. W. Elliott
Rafael Saenz
Ellen B. Shinaberry

STAFF PRESENT:
Caroline D. Juran, Executive Director
Beth O'Halloran, Individual Licensing Manager
James Rutkowski, Assistant Attorney General
Wayne T. Halbleib, Senior Assistant Attorney General
Mykl Egan, DHP Adjudication Specialist

QUORUM: With seven members of the Board present, a panel was established.

STUART L. BEASLEY
License No. 0202-009029

A formal hearing was scheduled in the matter of Stuart L. Beasley to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy in Virginia.

Wayne T. Halbleib, Senior Assistant Attorney General, was present to prosecute the case with the assistance of Mykl Egan, DHP Adjudication Specialist.

Mr. Beasley was represented by Hunter Jamerson, Esquire.

Following introductions, Mr. Jamerson presented the Board with a draft Consent Order for their consideration that Mr. Beasley would be willing to sign, in lieu of proceeding with

the formal hearing.

CLOSED MEETING: Upon a motion by Ms. Shinaberry, and duly seconded by Ms. Allen, the panel voted 8-0, 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 acceptance of a draft Consent Order from Stuart L. Beasley. Additionally, she moved that Caroline Juran, Beth O'Halloran, 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 in open meeting and announced the decision.

DECISION: Upon a motion by Ms. Shinaberry, and duly seconded by Mr. Saenz, the panel voted 8-0 to offer an amended Consent Order as its counteroffer as read by Mr. Rutkowski.

Mr. Beasley agreed to sign the Consent Order as offered by the Board.

ADJOURN: With all business concluded, the meeting adjourned at approximately 3:50p.m.

CALL TO ORDER: Following a brief adjournment, a panel of the Board was reconvened to reconsider the Consent Order offered to Stuart L. Beasley as he indicated after the adjournment that he and his counsel misunderstood the conditions when presented and he would not be able to sign the Consent Order as presented.

PRESIDING:

Cindy Warriner

MEMBERS PRESENT:

Jody H. Allen
Melvin L. Boone, Sr.
Freeda Cathcart
Michael I. Elliott
Sheila K. W. Elliott
Rafael Saenz

STAFF PRESENT:

Caroline D. Juran, Executive Director
Beth O'Halloran, Individual Licensing Manager (left 5pm)
James Rutkowski, Assistant Attorney General

Mykl Egan, DHP Adjudication Specialist
Wayne T. Halbleib, Senior Assistant Attorney General
Mykl Egan, DHP Adjudication Specialist

QUORUM: With seven members of the Board present, a panel was established.

CLOSED MEETING: With seven members present, a panel was established.

Upon a motion by Ms. Allen, and duly seconded by Mr. Elliott, 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 acceptance of a draft Consent Order from Stuart L. Beasley. Additionally, she moved that Caroline Juran, Beth O'Halloran, 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 in open meeting and announced the decision.

DECISION: Upon a motion by Ms. Allen, and duly seconded by Ms. Elliott, the panel voted 7-0 to offer an amended Consent Order as read by Mr. Rutkowski.

Mr. Beasley agreed to sign the Consent Order as presented.

ADJOURN: With all business concluded, the meeting adjourned at approximately 7:20pm.

Cindy Warriner, Presiding Chair

Caroline D. Juran
Executive Director

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
SPECIAL CONFERENCE COMMITTEE MINUTES

Wednesday, September 8, 2016
Commonwealth Conference Center
Second Floor
Board Room 1

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

CALL TO ORDER:	A meeting of a Special Conference Committee of the Board of Pharmacy was called to order at 9:00 a.m.
PRESIDING:	Rebecca Thornbury, Committee Chair
MEMBERS PRESENT:	Rafael Saenz, Committee Member Sheila K. W. Elliott, Committee Member
STAFF PRESENT:	J. Samuel Johnson, Deputy Executive Director Mykl D. Egan, DHP Adjudication Specialist Beth L. O'Halloran, Individual Licensing Manager
LAWRENCE PHARMACY, INC. Pharmacy Permit #0201000416	Christopher M. Mercer, Pharmacist-In-Charge, appeared to discuss allegations that Lawrence Pharmacy, Inc. may have violated certain laws and regulations governing the practice of pharmacy as stated in the August 8, 2016 Notice.
Closed Meeting:	Upon a motion by Mr. Saenz, and duly seconded by Ms. Thornbury, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Lawrence Pharmacy, Inc. Additionally, he moved that Sheila K. W. Elliott, J. Samuel Johnson, Mykl D. Egan and Beth L. O'Halloran attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the Committee re-convened in open meeting and announced the decision.
Decision:	Upon a motion by Mr. Saenz, and duly seconded by Ms. Thornbury, the Committee accepts certain

Findings of Facts and Conclusions of Law and unanimously voted to enter an Order that imposes a $3750 monetary penalty. Additional documentation of evidence of corrective action for all violations must be submitted to the Board within 30 days.

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

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

CVS PHARMACY #1656
Pharmacy Permit #0201004143

George Parcells, attorney, T. Huntley Thorpe, III, attorney and Joseph Lavino, Legal Counsel with CVS Pharmacy, appeared to discuss allegations that CVS Pharmacy #1656 may have violated certain laws and regulations governing the practice of pharmacy as stated in the August 8, 2016 Notice.

Closed Meeting:

Upon a motion by Mr. Saenz, and duly seconded by Ms. Thornbury, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of CVS Pharmacy #1656. Additionally, he moved that Sheila K. W. Elliott, J. Samuel Johnson, Mykl D. Egan and Beth L. O'Halloran attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

Reconvene:

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

Decision:	Upon a motion by Mr. Saenz, and duly seconded by Ms. Thornbury, the Committee finds no violation of law or regulation.
CVS PHARMACY #1836 Pharmacy Permit #0201004151	George Parcells, attorney, T. Huntley Thorpe, attorney and Joseph Lavino, Legal Counsel for CVS Pharmacy, appeared to discuss allegations that CVS Pharmacy #1856 may have violated certain laws and regulations governing the practice of pharmacy as stated in the August 8, 2016 Notice.
Closed Meeting:	Upon a motion by Mr. Saenz, and duly seconded by Ms. Thornbury, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of CVS Pharmacy #1836. Additionally, he moved that Sheila K. W. Elliott, J. Samuel Johnson, Mykl D. Egan and Beth L. O'Halloran attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the Committee re-convened in open meeting and announced the decision.
Decision:	Upon a motion by Mr. Saenz, and duly seconded by Ms. Thornbury, the Committee finds that there was no violation of law or regulation.
ADJOURN:	With all business concluded, the meeting adjourned at 11:30am

Rebecca Thornbury, Chair

J. Samuel Johnson, Deputy Executive Director

Date

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
SPECIAL CONFERENCE COMMITTEE MINUTES

Tuesday, September 20, 2016
Commonwealth Conference Center
Second Floor
Board Room 1

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

CALL TO ORDER: A meeting of a Special Conference Committee of the Board of Pharmacy was called to order at 9:10 a.m.

PRESIDING: Jody H. Allen, Committee Chair

MEMBERS PRESENT: Michael Elliott, Committee Member

STAFF PRESENT: J. Samuel Johnson, Jr. Deputy Executive Director
Mykl D. Egan, DHP Adjudication Specialist

Charlotte Michelle Lawrence
Registration Number 0230-002216

Charlotte Michelle Lawrence appeared to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the August 19, 2016, Notice.

Closed Meeting: Upon a motion by Mr. Elliott, and duly seconded by Ms. Allen, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Charlotte Michelle Lawrence. Additionally, he moved that J. Samuel Johnson, Jr., and Mykl Egan attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

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

Decision: Upon a motion by Mr. Elliott, and duly seconded by Ms. Allen, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to issue an Order with certain terms and conditions.

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

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

Rima Shurbaji
Permit Number 0202-206984

Rima Shurbaji appeared with her attorney, Margaret F. Hardy, to discuss allegations that Ms. Shurbaji may have violated certain laws and regulations governing the practice of pharmacy as stated in the August 19, 2016, Notice.

Closed Meeting:

Upon a motion by Mr. Elliott, and duly seconded by Ms. Allen, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Rima Shurbaji. Additionally, he moved that J. Samuel Johnson, Jr., and Mykl Egan attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations

Reconvene:

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

Decision:

Upon a motion by Mr. Elliott, and duly seconded by Ms. Allen, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to issue an Order that reprimands Ms. Shurbaji and orders that she obtain eight additional hours of continuing education in the subject of medication error, and report any medication errors to the Board.

As provided by law, this decision shall become a final Order thirty (30) days after service of such Order on Ms. Shurbaji, unless a written request is

made to the Board requesting a formal hearing on the allegations made against her is received from Ms. Shurbaji within such time. If service of the Order is made by mail, three (3) additional days shall be added to that period.

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

Dayna M. Pontzer
Permit Number 0202-211624

Dayna M. Pontzer did not appear to discuss allegations that Ms. Pontzer may have violated certain laws and regulations governing the practice of pharmacy as stated in the August 19, 2016, Notice.

Closed Meeting:

Upon a motion by Mr. Elliott, and duly seconded by Ms. Allen, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Dayna M. Pontzer. Additionally, he moved that J. Samuel Johnson, Jr., and Mykl Egan attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations

Reconvene:

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

Decision:

Upon a motion by Mr. Elliott, and duly seconded by Ms. Allen, the Committee voted to refer this matter to a formal hearing.

ADJOURN:

With all business concluded, the meeting adjourned at 11:45 a.m.

Jody H. Allen , Chair

J. Samuel Johnson
Deputy Executive Director

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF PILOT INFORMAL CONFERENCE COMMITTEE

Tuesday, September 27, 2016
Commonwealth Conference Center
Second Floor
Board Room 3

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

CALL TO ORDER: The meeting was called to order at 9:00 a.m.

PRESIDING: Ellen B. Shinaberry, Committee Chairperson

MEMBERS PRESENT: Cynthia Warriner

STAFF PRESENT: Caroline D. Juran, Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director
Beth O'Halloran, Individual Licensing Manager
Anne G. Joseph, Administrative Proceedings Division
Mykl D. Egan, Administrative Proceedings Division

Partners Pharmacy of Virginia, LLC
Permit #0201004141

The purpose of the informal conference was to act upon the Application of Partners Pharmacy of Virginia, LLC for approval of an innovative (pilot) program ("Application") and waiver of compliance with certain provisions of Board of Pharmacy Regulations. Present for the meeting from Partners Pharmacy of Virginia, LLC were Cheri Inman Luster, Pharmacist-In-Charge of Partners Pharmacy of Virginia, LLC, Shakema Poulson, Director of Partners Pharmacy of Virginia, LLC, Bill Gleason, Vice President of Cubex, and Karen Nishi, Consultant Pharmacist at Cubex

Partners Pharmacy of Virginia, LLC, requested a waiver of Regulation 18 VAC 110-20-555 (6) requiring that the drugs loaded in the device must be by a pharmacist or pharmacy technician trained in proper loading of the system.

For the purpose of this pilot program, Partners Pharmacy of Virginia is requesting approval of an innovative program to allow non-pharmacy personnel to reload the automated drug dispensing systems that are located at various nursing homes in the Commonwealth, and to use the automated drug dispensing systems as emergency and stat drug devices. Partners Pharmacy will fill the "cubies" that will be sent to the nursing homes and be loaded in to the automated dispensing devices using Cubex software by non-pharmacy personnel. In

addition, the automated dispensing devices will be used both for stat meds as well as emergency meds and a waiver of Regulation 18VAC110-20-550 (5b) for the 20 dosage limit will be required if approved.

Closed Meeting:

Upon a motion by Ms. Warriner, and duly seconded by Ms. Shinaberry, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A (7) of the Code of Virginia, for the purpose of briefing by staff members pertaining to probable litigation and to act upon the application for approval of an innovative (pilot) program for Partners Pharmacy of Virginia, LLC. Additionally, she moved that Caroline D. Juran, J. Samuel Johnson, Jr., Beth O'Halloran, Anne G. Joseph, and Mykl D. Egan attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

Reconvene:

Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3711 of the Code, the Committee re-convened in open meeting and announced the decision.

Decision:

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

- The innovative pilot program shall apply to two nursing homes of Partners Pharmacy's choosing.
- The Cubex system may be used for stat and emergency kit purposes.
- Partners Pharmacy shall provide evidence to the Board that it has obtained controlled substances registrations for all nursing homes it services, without an in-house pharmacy, that contain the Cubex system.
- The Cubex system may contain more than 20 solid dosage units per schedule and more than 30 ml of liquid dosage units.
- Designated nursing personnel may load the pharmacist-verified "cubies" into the automated dispensing device.

- Partners Pharmacy and the designated nursing homes shall be subject to one unannounced inspection by an inspector of the Department of Health Professions within 12 months from the date that the Board approves Partners Pharmacy's policies and procedures as set forth in Term 1(a) of this Order.
- The inspection shall be conducted during normal business hours and shall include a review of policies and procedures in the use of the Cubex system in the pilot program.
- Partners Pharmacy shall be responsible for the payment of the inspection fee, to be paid to the Board within 30 days of the inspection. Any fee not paid in a timely manner will be sent for collection. In the event that any inspection reveals a possible violation of the laws or regulations pertaining to the practice the conduct of a pharmacy in Virginia or the Virginia Drug Control Act (Virginia Code §§ 54.1-3400 et seq.), the Board may notice Partners Pharmacy to appear for an administrative proceeding.
- Partners Pharmacy may request to expand the program to additional nursing homes under the above terms and conditions 12 months after the initiation of the program. Any operational changes or modifications to the innovative (pilot) program shall be approved by the Board prior to initiation or modification.
- Reports of significant errors or other problems, or failure to comply with the terms and conditions described above in this Order or any statute or regulation governing the practice of pharmacy, shall constitute grounds for the rescission of the approval, and an administrative proceeding shall be convened to determine whether the approval should be rescinded or modified.

Central Virginia Training Center Pharmacy
Permit #0201000997

The purpose of the informal conference was to act upon the Application of Central Virginia Training Center (CVTC) Pharmacy for approval of an innovative (pilot) program ("Application") and waiver of compliance with certain provisions of Board of Pharmacy Regulations. Present for the meeting from Central Virginia Training Center Pharmacy was Teresa Graham, Pharmacist-In-Charge for CVTC Pharmacy.

CVTC Pharmacy requested a waiver of various sections of Regulation 18 VAC 110-20-555 as their automated dispensing device is incapable of meeting the requirements and the facility is scheduled to close in the near future. The pending closure of the facility precludes the facility's ability to purchase a new automated dispensing device.

For the purpose of this pilot program, CVTC Pharmacy is requesting the ability to use a Documed dispensing cabinet, "an older semi-computerized automatic dispensing machine" for retrieving drugs for stat box and emergency drug kit purposes when the local backup pharmacy is closed.

Closed Meeting:

Upon a motion by Ms. Warriner, and duly seconded by Ms. Shinaberry, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A (7) of the Code of Virginia, for the purpose of briefing by staff members pertaining to probable litigation and to act upon the application for approval of an Innovative (pilot) program for CVTC Pharmacy. Additionally, she moved that Caroline D. Juran, J. Samuel Johnson, Jr., Beth O'Halloran, Anne G. Joseph, and Mykl D. Egan attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

Reconvene:

Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3711 of the Code, the Committee re-convened in open meeting and announced the decision

Decision:

After consideration of the Application and statements concerning the innovative (pilot) program, Ms. Shinaberry stated the Committee approved CVTC Pharmacy's use of a Documed machine to retrieve medications for stat box and emergency drug kit purposes under the following terms and conditions:

- Pilot program begins on date the order is entered and ends either when CVTC has closed or December 31, 2020, whichever occurs first.
- The Documed machine may be used only for stat and emergency purposes. It may not be used to store drugs for routine administration.
- Restriction in Regulation 18VAC110-20-550(5)(b) for a stat box to contain no more than

20 solid dosage units per schedule and more than 30ml of liquid dosage units is waived.

- CVTC shall fully comply with 18VAC110-20-550 except as provided below:
  - Requirements in Regulation 18VAC110-20-555(1) and (3) are waived.
  - In lieu of the requirements of 18VAC110-20-555(8) of the Regulations, CVTC shall conduct daily counts of all C-II through C-V controlled substances dispensed from the Documed.
  - In lieu of the requirements of 18VAC110-20-555(9)(c) of the Regulations, CVTC shall conduct a monthly audit of all C-II through C-V controlled substances dispensed from the Documed by comparing the medications dispensed with residents' medication administration records.
- Any operational changes or modifications to the innovative (pilot) program shall be approved by the Board prior to initiation or modification.
- Reports of significant errors or other problems, or failure to comply with the terms and conditions described above in this Order or any statute or regulation governing the practice of pharmacy, shall constitute grounds for the recission of the approval, and an administrative proceeding shall be convened to determine whether the approval should be rescinded or modified.

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

Ellen B. Shinaberry, Committee Chairman

J. Samuel Johnson, Jr.
Deputy Executive Director

Date

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF A PANEL OF THE BOARD

October 3, 2016
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 9:30a.m.

PRESIDING: Michael I. Elliott, Chair

MEMBERS PRESENT: Melvin L. Boone, Sr.
Freeda Cathcart
Sheila K. W. Elliott
Rafael Saenz

STAFF PRESENT: Caroline D. Juran, Executive Director
James Rutkowski, Assistant Attorney General
James E. Schliessmann, Senior Assistant Attorney General
Mykl Egan, DHP Adjudication Specialist

QUORUM: With five members of the Board present, a panel was established.

Angela-Fee Lynch
License No. 0230-026930

A formal hearing was scheduled in the matter of Angela-Fee Lynch to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians in Virginia. Her registration was recently summarily suspended.

James E. Schliessmann, Senior Assistant Attorney General, was present to prosecute the case with the assistance of Mykl Egan, DHP Adjudication Specialist.

Ms. Lynch was not present.

CLOSED MEETING: Upon a motion by Mr. Boone, and duly seconded by Mr. Saenz, the panel voted 5-0, 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 Angela-Fee Lynch. Additionally, he moved that Caroline Juran 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 in open meeting and announced the decision.

DECISION: Upon a motion by Mr. Saenz, and duly seconded by Mr. Boone, the panel voted 5-0 to revoke the pharmacy technician held by Angela-Fee Lynch.

ADJOURN: With all business concluded, the meeting adjourned at approximately 11:30a.m.

Michael I. Elliott, Presiding Chair

Caroline D. Juran
Executive Director

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF TELEPHONE CONFERENCE CALL

Monday, November 14, 2016

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

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

TIME & PURPOSE: Pursuant to § 54.1-2400(13) of the Code of Virginia, a telephone conference call of the Virginia Board of Pharmacy ("TCC") was held on November 14, 2016, at 2:00p.m., to consider the summary suspension of the registration of Kelly Lantz Pierre to practice as a pharmacy technician in the Commonwealth of Virginia.

PRESIDING: Ryan K. Logan, Chair

MEMBERS PRESENT:
Ellen Shinaberry
Cindy Warriner
Rafael Saenz
Sheila K.W. Elliott
Michael I. Elliott

STAFF PRESENT:
Caroline D. Juran, Executive Director
Rose E. DeMatteo, Compliance Case Manager
Mykl Egan, DHP Adjudication Specialist
James Rutkowski, Assistant Attorney General
Wayne Halbleib, Senior Assistant Attorney General

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

With six (6) members participating and four (4) members unable to participate, it was established that a quorum could not have been convened in a regular meeting to consider this matter.

KELLY LANTZ PIERRE
Registration No. 0230026886

Wayne Halbleib presented a summary of the evidence in this case.

Upon a motion by Ms. Warriner and duly seconded by Mr. Elliott, the Board unanimously voted that, with the evidence presented, the practice as a pharmacy technician by Kelly Lantz Pierre poses a substantial danger to the public; and therefore, the registration of Ms. Pierre shall be summarily suspended. Further, with the Notice of Hearing, a Consent Order shall be offered to Ms. Pierre for the suspension of her registration for a period of not less than two years.

ADJOURN: With all business concluded, the meeting adjourned at 2:18p.m.

Caroline D. Juran
Executive Director

Ryan K. Logan, Chair

Date

DRAFT

VIRGINIA BOARD OF PHARMACY
SPECIAL CONFERENCE COMMITTEE MINUTES

Wednesday, November 16, 2016
Commonwealth Conference Center
Second Floor
Board Room 1

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

CALL TO ORDER:	A meeting of the Special Conference Committee of the Board of Pharmacy was called to order at 9:07 a.m.
PRESIDING:	Michael Elliott, Committee Chair
MEMBERS PRESENT:	Jody H. Allen, Committee Member
STAFF PRESENT:	J. Samuel Johnson, Deputy Executive Director Anne G. Joseph, Acting Deputy Executive Director Mykl D. Egan, DHP Adjudication Specialist
Jacquelyn S. Johnson Registration Number 0230-025531	Jacquelyn S. Johnson appeared to discuss allegations that she may have violated certain laws governing the practice of pharmacy as stated in the October 14, 2016, Notice.
Closed Meeting:	Upon a motion by Ms. Allen, and duly seconded by Mr. Elliott, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(28) for the purpose of deliberation to reach a decision in the matter of Jacquelyn S. Johnson. Additionally, she moved that J. Samuel Johnson, Anne G. Joseph, and Mykl D. Egan attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.
Decision:	Upon a motion by Ms. Allen, and duly seconded by Mr. Elliott, the Committee unanimously voted to offer Ms. Allen a Consent Order for the indefinite

suspension of her pharmacy technician registration.

Brad F. Wooten
License Number 0202-012550

Brad F. Wooten appeared to discuss allegations that he may have violated certain laws governing the practice of pharmacy as stated in the October 14, 2016, Notice.

Closed Meeting:

Upon a motion by Ms. Allen, and duly seconded by Mr. Elliott, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(28) for the purpose of deliberation to reach a decision in the matter of Jacquelyn S. Johnson. Additionally, she moved that J. Samuel Johnson, Anne G. Joseph, and Mykl D. Egan attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

Reconvene:

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

Decision:

Upon a motion by Ms. Allen, and duly seconded by Mr. Elliott, the Committee made certain Findings of Fact and Conclusions of Law and unanimously voted to issue an Order requiring Mr. Wooten to comply with the terms and conditions of the Health Practitioners' Monitoring Program ("HPMP") for the period specified by the HPMP.

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

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

ADJOURN:

With all business concluded, the meeting adjourned at 12:10 p.m.

Michael Elliott, Chair

Anne G. Joseph
Acting Deputy Executive Director

Date

Date

Agenda Item: Regulatory Actions - Chart of Regulatory Actions

Chapter		Action / Stage Information
[18 VAC 110 - 11]	Public participation guidelines	Conforming to Code [Action 4594] Fast-Track - *Register Date: 10/31/16* *Effective 12/15/16*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Periodic review result of Chapters 20 and 50; Promulgation of Chapters 16 and 25 [Action 4538] NOIRA - *Register Date: 7/11/16*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Response to petitions for rulemaking [Action 4694] NOIRA - *Register Date: 11/28/16* *Comment closes: 12/28/16*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Outsourcing facilities [Action 4452] Proposed - *Register Date: 10/31/16* *Comment closes: 12/30/16*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Prohibition against incentives to transfer prescriptions [Action 4186] Proposed - *Register Date: 12/12/16* *Comment closes: 2/10/16*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Addressing hours of continuous work by pharmacists [Action 3755] Final - *At Governor's Office for 18 days*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Registration of non-resident medical equipment suppliers [Action 4656] Final - *Register Date: 10/17/16* *Effective: 11/16/16*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Schedling of chemicals in Schedule I [Action 4657] Final - *Register Date: 10/17/16* *Effective: 11/16/16*
[18 VAC 110 - 30]	Regulations for Practitioners of the Healing Arts to Sell Controlled Substances	Permits for facilities [Action 4451] Proposed - *Register Date: 10/17/16* *Comment closes: 12/16/16*
[18 VAC 110 - 50]	Regulations Governing Wholesale Distributors, Manufacturers and Warehousers	Permitting of third party logistics providers and registration of nonresident manufacturers [Action 4678] Fast-Track - *DPB Review in progress*
[18 VAC 110 - 60]	Regulations Governing Pharmaceutical Processors	New regulations [Action 4695] Emergency/NOIRA - *AT Attorney General's Office*

Agenda Item: Adoption of Regulation to Schedule certain chemicals in Schedule I of the Drug Control Act

Staff Note:

There was a Public Hearing conducted at 9:00 this morning pursuant to requirements of § 54.1-3443 of the Drug Control Act.

Included in your packet:

Notice of hearing and request for comment (none received)

Copy of regulation to schedule certain chemicals

Board action:

Adoption of amendments to section 18VAC110-20-322. Placement of chemicals in Schedule I. (Note: the action is exempt from the requirements of the Administrative Process Act pursuant to §2.2-4006)

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 public hearing will be conducted at **9:00 a.m. on December 12, 2016** at the Perimeter Center, 9960 Mayland Drive, Suite 201, Richmond, VA 23233. Public comment may also be submitted electronically or in writing prior to December 1, 2016 to Caroline Juran, Executive Director of the Board of Pharmacy to caroline.juran@dhp.virginia.gov.

As specified in § 54.1-3443, the Virginia Department of Forensic Science (DFS) has identified eight (8) compounds for recommended inclusion by the Board of Pharmacy into Schedule I in the Code of Virginia. A brief description and chemical name for each compound is as follows:

The following compounds are classified as research chemicals. Drugs of this type have been placed in Schedule I (§ 54.1-3446(3)) in previous legislative sessions.

1. 1-(1,3-benzodioxol-5-yl)-2-(dimethylamino)-1-pentanone (other names: N,N-Dimethylpentylone, Dipentylone)

2. 4-chloro-alpha-Pyrrolidinovalerophenone (other name: 4-chloro-alpha-PVP)

3. 4-methyl-alpha-Pyrrolidinohexiophenone (other name: MPHP)

4. 4-fluoro-alpha-Pyrrolidinoheptiophenone (other name: 4-fluoro-PV8)

5. 1-(4-methoxyphenyl)-2-(pyrrolidin-1-yl)octan-1-one (other name: 4-methoxy-PV9)

6. 4-allyloxy-3,5-dimethoxyphenethylamine (other name: Allylescaline)

7. 4-methyl-alpha-ethylaminopentiophenone

The following compound is a powerful synthetic opioid. DFS recommends placing this compound into Schedule I (§ 54.1-3446(1)).

8. N-(4-fluorophenyl)-2-methyl-N-[1-(2-phenylethyl)-4-piperidinyl]-propanamide (other name: para-fluoroisobutyryl fentanyl)

If approved by the Board of Pharmacy, the placement of these substances in Schedule I in the Virginia Drug Control Act shall remain in effect for a period of 18 months from the date of Board action and shall then be de-scheduled unless the Drug Control Act is amended by enactment of legislation by the General Assembly.

Project 4992 - none

BOARD OF PHARMACY

Scheduling of chemicals

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. N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-butanamide (other name: butyryl fentanyl).

2. Flubromazolam.

3. 5-methoxy-N,N-methylisopropyltryptamine (Other name: 5-MeO-MIPT).

4. Cannabimimetic agents:

a. N-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-[(4-fluorophenyl)methyl]-1H-indazole-3-carboxamide (other name: ADB-FUBINACA);

b. Methyl 2-[1-[(4-fluorophenyl)methyl]-1H-indazole-3-carboxamido]-3,3-dimethylbutanoate (other name: MDMB-FUBINACA); and

c. Methyl 2-[1-(5-fluoropentyl)-1H-indazole-3-carboxamido]-3,3-dimethylbutanoate (other names: 5-fluoro-ADB, 5-Fluoro-MDMB-PINACA).

The placement of drugs listed in this subsection shall remain in effect until December 14, 2017, 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. Beta-keto-N,N-dimethylbenzodioxolylbutanamine (other names: Dibutylone, bk-DMBDB);

2. 1-(1,3-benzodioxol-5-yl)-2-(ethylamino)-1-pentanone (other name: N-ethylpentylone);

3. 1-[1-(3-methoxyphenyl)cyclohexyl]piperidine (other name: 3-methoxy PCP);

4. 1-[1-(4-methoxyphenyl)cyclohexyl]piperidine (other name: 4-methoxy PCP);

5. 4-Chloroethcathinone (other name: 4-CEC);

6. 3-Methoxy-2-(methylamino)-1-(4-methylphenyl)-1-propanone (other name: Mexedrone);

7. 3,4-dichloro-N-[2-(dimethylamino)cyclohexyl]-N-methyl-benzamide (other name: U-47700);

8. 3,4-dichloro-N-{[1-(dimethylamino)cyclohexyl]methyl}benzamide (other name: AH-7921);

9. N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-pentanamide (other name: Pentanoyl fentanyl);

10. N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-2-furancarboxamide (other name: Furanyl fentanyl);

11. N-(3-fluorophenyl)-N-[1-(2-phenethyl)-4-piperidinyl]-propanamide (other name: 3-fluorofentanyl);

12. Clonazolam; and

13. Cannabimimetic agents:

a. Methyl 2-({1-[(4-fluorophenyl)methyl]-1H-indazole-3-carbonyl}amino)-3-methylbutanoate (other names: AMB-FUBINACA, FUB-AMB);

b. N-(adamantan-1-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (other name: FUB-AKB48);

c. N-(adamantan-1-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide (other name: 5F-AKB48);

d. Naphthalen-1-yl 1-pentyl-1H-indazole-3-carboxylate (other name: SDB-005); and

e. N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)indole-3-carboxamide (other name: AB-CHMICA).

The placement of drugs listed in this subsection shall remain in effect until March 7, 2018, 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. 1-propionyl lysergic acid diethylamide (other name: 1P-LSD);

2. (2-Methylaminopropyl)benzofuran (other name: MAPB);

3. Ethyl phenyl(piperidin-2-yl)acetate (other name: Ethylphenidate);

4. 2-(3-fluorophenyl)-3-methylmorpholine (other name: 3-fluorophenmetrazine); and

5. N-(4-fluorophenyl)-N-[1-(2-phenylethyl)-4-piperidinyl]-butanamide (other name: para-fluorobutyrylfentanyl), its optical, positional, and geometric isomers, salts and salts of isomers.

The placement of drugs listed in this subsection shall remain in effect until May 10, 2018, 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. 1-(1,3-benzodioxol-5-yl)-2-(dimethylamino)-1-pentanone (other names: N,N-Dimethylpentylone, Dipentylone);

2. 4-chloro-alpha-Pyrrolidinovalerophenone (other name: 4-chloro-alpha-PVP);

3. 4-methyl-alpha-Pyrrolidinohexiophenone (other name: MPHP);

4. 4-fluoro-alpha-Pyrrolidinoheptiophenone (other name: 4-fluoro-PV8);

5. 1-(4-methoxyphenyl)-2-(pyrrolidin-1-yl)octan-1-one (other name: 4-methoxy-PV9);

6. 4-allyloxy-3,5-dimethoxyphenethylamine (other name: Allylescaline);

7. 4-methyl-alpha-ethylaminopentiophenone; and

8. N-(4-fluorophenyl)-2-methyl-N-[1-(2-phenylethyl)-4-piperidinyl]-propanamide (other name: para-fluoroisobutyryl fentanyl).

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

Agenda Item: Periodic Review of Regulations

Included in your agenda package are:

A copy of the Appendix, showing amendments considered during periodic review at meeting of Regulation Committee on November 3, 2015

A copy of the amendments recommended by the Regulation Committee at meeting on November 29, 2016

Staff Note: The Board adopted a NOIRA which was published on July 11, 2016 with a comment period until August 10, 2016. There were 5 comments; none relating to sections being amended at this meeting.
Included in the NOIRA was a recommendation to divide Chapter 20 into two chapters: 1) Governing the Licensure of Pharmacists and Registration of Pharmacy Technicians; and 2) Governing the Practice of Pharmacy

Board action:

Recommendation of the Regulation Committee to adopt amendments to regulations for pharmacists and pharmacy technicians

FINAL/APPROVED
Attachment 1

Below are regulations in Chapter 20, Parts I-IV and XIII-XVII identified by the Regulation Committee to be considered by the full board for inclusion in the Notice of Intended Regulatory Action (NOIRA) as part of the periodic regulatory review.

Part I. General Provisions

18VAC110-20-10 Definitions.

18VAC110-20-15 Criteria for delegation of informal fact-finding proceedings to an agency subordinate

- Should be moved to its own separate chapter

18VAC110-20-20 Fees

- Consider staggering renewals for pharmacist licenses and pharmacy technician registrations. Committee recommended no change to facility renewals. (Note: a change in renewals for pharmacists and pharmacy technicians necessitates amendments of 18VAC110-20-80 A and B and 18VAC110-20-105.)

18VAC110-20-25 Unprofessional conduct

- Ms. Reiniers-Day to research other boards' language.

Part II. Licensure Requirements For Pharmacists

18VAC110-20-50 Curriculum and approved schools of pharmacy

- Consider striking subsection B to eliminate language for "first" professional degree. Staff to do further research on implications of this recommendation and will discuss at future meeting.

18VAC110-20-60 Content of the examination and grades required; limitation on admittance to examination

- Discussed limiting validity of law exam score to 2 years, but recommended limiting to 3 years based on record retention.

18VAC110-20-80 Renewal and reinstatement of license

- Recommended clarifying language in E that the required payment should equal the difference between the active and inactive renewal fee as staff is currently requiring and not the current active renewal fee.
- Staff will review to ensure the terms "reactivate" and "reinstate" are being used correctly.

18VAC110-20-90 Requirements for continuing education

- Consider ability to accept inter-professional continuing education; staff to research how it is currently being awarded and by whom.

FINAL/APPROVED
Attachment 1

- Suggested wording in (B) (2) be changed from "Category I Continuing Medical Education" to "American Medical Association" which appears to be the current title for this type of CE
- Consider striking ability for board to approve and accept board-approved CE programs
- Committee discussed recommendations for requiring live CE and having ability to carry over hours into subsequent year, but concluded a statutory amendment would be necessary. Staff will research what other state boards of pharmacy may require live CE.
- Committee discussed recommendation for requiring CE annually in the subject of opioids. Statutory ability to specify topic for CE annually also discussed. No final recommendation was made.

18VAC110-20-100 Approval of continuing education programs

- Suggestion to remove ability for board to approve CE programs.

PART III Requirements For Pharmacy Technician Registration

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

- Consider including training program approval number to be printed on certificate awarded by training program.
- Consider requiring copy of sample certificate with application for approval of training program and requirement to notify board of changes to certificate.

18VAC110-20-106 Requirements for continued competency

- Consider changing "certificates" to "documentation" in both sentences of subsection D.

18VAC110-20-110 Pharmacy permits generally

- Consider specifying minimum number of hours PIC must practice at the location listed on the pharmacy permit application
- Consider requiring minimum number of years of experience for PIC eligibility. There was discussion for a possible ability for exceptions, but no final recommendation made.

18VAC110-20-130 Pharmacy closings; going out of business; change of ownership

- Clarify requirements for acquisitions with regard to inspection and inventory
- Consider requirement for inspection during change of ownership.

18VAC110-20-140 New pharmacies, acquisitions and changes to existing pharmacies

- Clarify requirements for acquisitions with regard to inspection and inventory
- Consider amending to allow Board to rescind pharmacy permit if not opened within 60 days of issuing permit. Concern raised that board counsel may recommend criteria if the term "may" is used as proposed in the agenda packet

Commonwealth of Virginia

REGULATIONS

GOVERNING THE LICENSURE OF PHARMACISTS AND REGISTRATION OF PHARMACY TECHNICIANS

Title of Regulations: 18 VAC 110-21-10 et seq.

Statutory Authority: § 54.1-2400 and Chapters 33 and 34 of Title 54.1 of the *Code of Virginia*

Revised Date:

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Chapter 21
REGULATIONS GOVERNING THE LICENSURE OF PHARMACISTS AND REGISTRATON OF PHARMACY TECHNICIANS

Part I. General Provisions

18VAC110-21-10. Definitions.

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.

"Board" means the Virginia Board of Pharmacy.

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

"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, 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.

"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.

"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 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	$180
2. Pharmacy intern registration	$15

3. Pharmacy technician registration	$25
4. Pharmacy permit	$270
5. Approval of a pharmacy technician training program	$150
6. Approval of a continuing education program	$100

D. Annual renewal fees.

1. Pharmacist active license – due no later than December 31	$90
2. Pharmacist inactive license – due no later than December 31	$45
3. Pharmacy technician registration – due no later than December 31	$25
4. Approval of a pharmacy technician training program	$75 every two years

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

1. Pharmacist license	$30
2. Pharmacist inactive license	$15
3. Pharmacy technician registration	$10
4. Approval of a pharmacy technician training program	$15

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

1. Pharmacist license	$210
2. Pharmacist license after revocation or suspension	$500
3. Pharmacy technician registration	$35
4. Pharmacy technician registration after revocation or suspension	$125
5. 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. A 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 $50	

H. Miscellaneous fees.

1. Duplicate wall certificate	$25
2. Returned check	$35
3. Duplicate license or registration	$10
4. Verification of licensure or registration	$25

18VAC110-21-21. Current address.

A. It shall be the duty and responsibility of each licensee to inform the board of his current address. A licensee shall notify the board within 14 days in writing or electronically of any change of an address of record. Properly updating address of record directly through the board's web-based application or other approved means shall constitute lawful notification.

B. All notices required by law or by these rules and regulations are deemed to be legally given when ~~mailed~~ sent to the address of record and shall not relieve the licensee of the obligation to comply.

(highlighted language moved from renewal section)

C. An individual licensed by or registered with the board who has provided the board with a public address that is different from the address of record shall notify the board in writing if there is a change in the address.

18VAC110-21-25. 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 provision of patient records to another practitioner or to the patient or his personal representative;

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

3. Failing to maintain 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 his family, including but not limited to sexual misconduct with a patient or a member of his 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 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 PIC to ensure that pharmacy interns and pharmacy technicians working in the pharmacy are registered and that such registration is current; ~~or~~

10. Failing to exercise professional judgment in determining whether a prescription meets 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 or Chapters 33 or 34 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 in another U. S. jurisdiction.

18VAC110-21-26. Kickbacks, fee-splitting, interference with supplier.

A. A pharmacist shall not solicit or foster prescription practice with a prescriber of drugs or any other person providing for rebates, "kickbacks," fee-splitting, or special charges in exchange for prescription orders unless fully disclosed in writing to the patient and any third party payor.

B. A pharmacist shall not interfere with the patient's right to choose his supplier of medication or cooperate with any person or persons in denying a patient the opportunity to select his supplier of prescribed medications.

Part II. Licensure Requirements for Pharmacists

18VAC110-21-30. Requirements for pharmacy practical experience.

A. Each applicant for licensure as a pharmacist shall have gained practical experience in the practice of pharmacy as set forth in this section and 18VAC110-21-40.

B. An applicant for licensure as a pharmacist shall attain a minimum of 1,500 hours of practical experience.

C. Practical experience that is gained within an ACPE-accredited school of pharmacy, that conforms to the current ACPE standards, and that allows the student to gain at least 1,500 hours of practical experience, shall meet the board's practical experience requirements for licensure as a pharmacist.

D. All practical experience credit gained outside of an ACPE-accredited school of pharmacy program shall only be gained after successful completion of the equivalent of at least two semesters in an ACPE-accredited school of pharmacy. Credit shall not be given for more than 50 hours in one week and not less than an average of 20 hours per week averaged over a month. The board may grant an exception to the minimum number of hours for good cause shown.

E. In accordance with § 54.1-3312 of the Code of Virginia, all practical experience required by this section shall be gained within the United States.

18VAC110-21-40. Procedure for gaining practical experience.

A. Each person desiring to gain practical pharmacy experience in Virginia shall first register with the board as a pharmacy intern on a form provided by the board prior to becoming so engaged as a pharmacy

intern. This requirement shall apply to any person gaining practical experience within the Commonwealth whether for licensure in Virginia or in another state.

B. In order to be eligible to register as a pharmacy intern, an applicant shall meet at least one of the following criteria:

1. The applicant shall be enrolled in and have started course work in a professional degree program of a board-approved school of pharmacy. Such registration is only valid while the student is enrolled in the school of pharmacy and is satisfactorily progressing toward meeting the requirements for licensure as a pharmacist. An expiration date shall be assigned to the registration to cover the estimated time period for the student to complete the school program and pass the required examinations. If the student is no longer enrolled in the school program, takes a voluntary break from the program, or is otherwise not actively participating in the school program, except for regularly scheduled school breaks, the registration is no longer valid and shall be returned to the board immediately;

2. The applicant is a graduate of a board-approved school of pharmacy or a graduate of a foreign school of pharmacy, has established educational equivalency and proficiency in English by obtaining the FPGEC certificate, and desires to gain required practical experience required for licensure as a pharmacist. Such applicant shall provide documentation on a board-approved form of current employment or an employment start date within 90 days in a pharmacy in Virginia with approval by the supervising pharmacist. An expiration date shall be assigned to cover the estimated time period needed to obtain the required practical experience hours and take the required examinations to become licensed as a pharmacist;

3. The applicant has already gained the required practical experience, but is an otherwise qualified applicant awaiting examination for licensure. A three-month expiration date shall be assigned to allow the applicant time to take required examinations; or

4. The applicant is an applicant for reactivation or reinstatement of a previously issued pharmacist license and is meeting board requirements for relicensure. An expiration date shall be assigned to reasonably cover the period of time necessary to meet the board requirements.

C. For documented, good cause shown, the executive director of the board may extend the expiration date of the intern registration upon submission of an application form approved by the board and payment of the initial application fee.

D. A pharmacy intern shall be supervised by a pharmacist who holds a current, unrestricted license and assumes full responsibility for the training, supervision and conduct of the intern.

E. The intern registration of a pharmacy student shall be valid only while the student is enrolled in a school of pharmacy. The registration card issued by the board shall be returned to the board upon failure to be enrolled.

F. Practical experience gained within any other state must be registered with and certified by the board of that state in order to be accepted or certified by this board. In the event that a state relies on the pharmacy school to certify the hours of experience, an affidavit from the pharmacy school certifying the hours of experience gained in the United States may be accepted in lieu of board certification.

G. All practical experience of the pharmacy intern shall be evidenced by an affidavit approved by the board, which shall be filed prior to or with the application for examination for licensure.

H. An applicant for licensure by endorsement may provide verification acceptable to the board of practical experience hours worked as a pharmacist in another state within the United States in lieu of prelicensure intern hours in order to meet the practical experience requirement.

I. A pharmacy intern shall notify the board in writing of any change in address of record within 14 days of such change.

18VAC110-21-50. Curriculum and approved schools of pharmacy.

A. The following minimum educational requirements for the specified periods shall be recognized by the board for the purpose of licensure.

1. On and after June 1, 1936, but before June 1, 1964, the applicant for licensure shall have been graduated from a four-year course of study with a Bachelor of Science degree in pharmacy awarded.

2. On and after June 1, 1964, the applicant for licensure shall have been graduated from at least a five-year course of study with a Bachelor of Science degree in pharmacy or a Doctorate of Pharmacy degree awarded.

B. In order to be licensed as a pharmacist within this Commonwealth, the applicant shall have been granted the first professional degree from a program of a school of pharmacy which meets the requirements of §54.1-3312 of the Code of Virginia or shall satisfy the requirements of 18VAC110-21-70.

18VAC110-21-60. Content of the examination and grades required; limitation on admittance to examination.

A. Prior to admission to any examination required for licensure, the applicant shall have met all other requirements to include education and practical experience requirements, but in no case shall the applicant be admitted if grounds exist to deny licensure under §54.1-3316 of the Code of Virginia.

B. The applicant shall achieve a passing score as determined by the board on the licensure examination which is approved by the board and which shall consist of an integrated examination of pharmacy practice, pharmacology, pharmacy mathematics, and such other subjects as are necessary to assure that the candidate possesses the necessary knowledge and skills to practice pharmacy.

C. When an applicant for licensure by examination fails to meet the passing requirements of the board-approved integrated pharmacy examination on three occasions, he shall not be readmitted to the examination until he has completed an additional 1,000 hours of practical experience as a pharmacy intern as set forth in 18VAC110-21-40.

D. The applicant shall also achieve a passing score as determined by the board on an examination that tests the candidate's knowledge of federal and state laws related to pharmacy practice. If an applicant has not subsequently been issued a license by any U. S. jurisdiction within three years of achieving a passing score, he shall retake the examination in order to be licensed in Virginia.

E. When an applicant fails to pass the law examination, he shall not be allowed to retake it for a period of 30 days.

F. If an applicant requests a testing accommodation for either examination based on a physical or mental impairment that substantially limits one or more major life activities, subject to the Americans with Disabilities Act, the board may approve a reasonable accommodation that does not compromise the security or integrity of the examination.

1. Supporting documentation shall be provided by the applicant to include the following to be considered for review:

a. A letter of request from the candidate that specifies the testing accommodation requested;

b. A written report of an evaluation (educational, psychological, or physical) within the preceding two years from a qualified professional that states a diagnosis of the disability, describes the disability, recommends specific accommodations, and provides justification that the accommodation is appropriate and necessary for the diagnosed disability. If the comprehensive evaluation was done more than two years ago and the condition is one that is not subject to change, the original evaluation report may be submitted along with a current letter from the qualified professional stating that there has been no change in the condition since the time of the evaluation; and

c. A written statement from the appropriate person at the applicant's school of pharmacy that describes any testing accommodations made while the student was enrolled, if applicable.

2. The applicant will be notified in writing of the decision. If the request for accommodation is granted, the approval information will be forwarded to the examination contractor and the form of the accommodation will be coordinated with the contractor.

18VAC110-21-70. Requirements for foreign-trained applicants.

A. Applicants for licensure who were trained in foreign schools of pharmacy shall obtain the FPGEC certificate prior to being allowed to register as a pharmacy intern and gain required practical experience in Virginia.

B. After obtaining the FPGEC certificate, the applicant may apply for a pharmacy intern registration and shall fulfill the requirements for practical experience set forth in 18VAC110-21-30 and 18VAC110-21-40 before being admitted to examinations required by 18VAC110-21-60.

C. Applicants for licensure who were trained in foreign schools of pharmacy shall also complete and achieve passing scores on the examinations set forth in 18VAC110-21-60 before being licensed as a pharmacist.

D. Applicants for licensure who were trained in foreign schools of pharmacy, but who subsequently have been granted a professional degree from a program of a school of pharmacy which meets the requirements of §54.1-3312 of the Code of Virginia, as specified in18VAC110-21-50, shall be exempt from the requirement for a FPGEC certificate but shall fulfill the requirements for practical experience set forth in 18VAC110-21-30 and 18VAC110-21-40 before being admitted to examinations required by 18VAC110-21-60.

18VAC110-20-75. Registration for voluntary practice by out-of-state licensees.

Any pharmacist who seeks registration to practice on a voluntary basis pursuant to subdivision 12 of §54.1-3301 of the Code of Virginia under the auspices of a publicly supported, all volunteer, nonprofit organization that sponsors the provision of health care to populations of underserved people shall:

1. File a complete application for registration on a form provided by the board at least five business days prior to engaging in such practice;

2. Provide a complete list of each state in which he has held a pharmacist license and a copy of any current license;

3. Provide the name of the nonprofit organization and the dates and location of the voluntary provision of services;

4. Pay a registration fee of $10; and

5. Provide a notarized statement from a representative of the nonprofit organization attesting to its compliance with the provisions of subdivision 12 of §54.1-3301 of the Code of Virginia.

18VAC110-20-80. Renewal and reinstatement of license.

A. Pharmacist licenses expire on December 31 and shall be renewed annually prior to that date by the submission of a renewal fee, renewal form, and statement of compliance with continuing education requirements.

B. A pharmacist newly licensed on or after October 1 shall not be required to renew that license until December 31 of the following year.

C. A pharmacist who fails to renew his license by the expiration date may renew his license at any time within one year of its expiration by submission of the renewal fee and late fee, renewal form, and statement of compliance with continuing education requirements.

D. A pharmacist who fails to renew his license for more than one year following expiration and who wishes to reinstate such license 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.

E. A pharmacist who has been registered as inactive for more than one year must apply for ~~reinstatement~~ reactivation, submit documentation showing compliance with continuing education requirements, and pay the difference between the inactive fee and the current year active renewal fee in order to resume active licensure.

F. In order to reactivate or reinstate a license to active status, a pharmacist who holds an inactive license, who has allowed his license to lapse, or who has had his license suspended or revoked must submit evidence of completion of CEU's or hours equal to the requirements for the number of years in which his license has not been active, not to exceed a total of 60 hours of CE.

G. A pharmacist whose license has been lapsed, in inactive status, or suspended or revoked for more than five years shall, as a condition of reinstatement or reactivation in addition to 60 hours CE, take and receive a passing score on the board-approved law examination and furnish acceptable documentation of one of the following:

1. Active pharmacy practice within the past five years as a properly licensed pharmacist in another state; or

2. Practical experience as a pharmacy intern registered with the board of at least 160 hours within six months immediately prior to being reinstated or reactivated.

H. The practice of pharmacy without a current, active pharmacist license is unlawful and shall constitute grounds for disciplinary action by the board.

18VAC110-21-90. Requirements for continuing education.

A. A pharmacist shall be required to have completed a minimum of 1.5 CEUs or 15 contact hours of continuing pharmacy education in an approved program for each annual renewal of licensure. CEUs or hours in excess of the number required for renewal may not be transferred or credited to another year.

B. A pharmacy education program approved for continuing pharmacy education is:

1. One that is approved by the Accreditation Council for Pharmacy Education (ACPE);

2. One that is approved as a Category I Continuing Medical Education (CME) course, the primary focus of which is pharmacy, pharmacology or drug therapy; or

3. One that is approved by the board in accordance with the provisions of 18 VAC 110-21-100.

C. Of the 15 contact hours required for annual renewal, at least five hours shall be obtained in courses or programs that are live or real-time interactive. Included in the five hours, the following may be credited:

1. One hour for attendance at a board meeting or formal hearing; or

2. One hour for serving as a preceptor for a pharmacy student or resident in an accredited school or program.

~~C.~~D. The board may grant an extension pursuant to §54.1-3314.1 E of the Code of Virginia. Any subsequent extension shall be granted only for good cause shown.

~~D.~~E. Pharmacists are required to attest to compliance with CE requirements in a manner approved by the board at the time of their annual license renewal. Following each renewal period, the board may conduct an audit of the immediate past two years' CE documents to verify compliance with requirements. Pharmacists are required to maintain, for two years following renewal, the original certificates documenting successful completion of CE, showing date and title of the CE program or activity, the number of CEUs or contact hours awarded, and a certifying signature or other certification of the approved provider. Pharmacists selected for audit must provide these original documents to the board by the deadline date specified by the board in the audit notice.

18VAC110-21-100. Approval of continuing education programs.

A. The board will approve without application or further review any program offered by an ACPE-approved provider and will accept for credit certificates bearing the official ACPE logo and program number.

B. The board may approve an individual CE program under the following provisions:

1. An approved individual program is a course, activity, or lecture which includes subject matter related to the competency of the practice of pharmacy and which has been approved for CE credit by the board.

2. In order to receive approval for an individual program, the sponsor or provider must apply prior to the program offering on a form provided by the board. The information which must be provided shall include but not be limited to: name of provider, location, date and time of program, charges to participants, description of program content and objectives, credentials of speaker or author, method of delivery, evaluation procedure, evidence of a post assessment, credits requested, mechanism for recordkeeping, and any such information as the board deems necessary to assure quality and compliance.

3. The sponsor applying for board approval of an individual program must pay a fee as required in 18VAC110-21-20 C 6.

4. The board shall notify the provider or sponsor within 60 days following the receipt of a completed application of approval or disapproval of a program and the number of credits which may be awarded. The board shall also assign an expiration date for approval of the program not to exceed two years from the date of approval.

5. The provider of an approved program shall provide to each participant who completes the required hours and passes the post test a certification with the name of the provider, name of the participant, description of course and method of delivery, number of hours credited, date of completion, and program identification number.

6. The provider of an approved program shall maintain all records on that program, its participants, and hours awarded for a period of five years and shall make those records available to the board upon request.

7. The board shall periodically review and monitor programs. The provider of a CE program shall waive registration fees for a representative of the board for that purpose.

8. Any changes in the information previously provided about an approved program or provider must be submitted or the board may withdraw its approval. If a provider wants to give a live program more than once, all program dates must either be submitted on the original application or provided to the board in subsequent correspondence at least five days prior to giving the program.

Part III. Requirements for Pharmacy Technician Registration

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

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

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

1. Satisfactory completion of an approved training program, and

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

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

D. A pharmacy technician trainee 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 without becoming registered as a pharmacy technician. (Language differs from that recommended by Regulation Committee but is adapted for regulation of techs, not pharmacies.)

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

A. Any person wishing to apply for approval of a pharmacy technician training program shall submit the application fee, 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 his authorized agent provided there is no change to the original prescription.

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

revoked as a pharmacy technician in any jurisdiction; or (iii) other person approved and deemed qualified by the board to be a program director.

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

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

F. The program shall maintain records of program participants either on-site or at another location where the records are readily retrievable upon request for inspection. A program shall provide a certificate of completion, 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.

18VAC110-20-103. Examination.

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

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

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

D. Any requests for testing accommodations under the Americans with Disabilities Act shall be in accordance with the provisions of 18VAC110-21-60 F.

18VAC110-20-104. Address of record; maintenance of certificate.

A. It shall be the duty and responsibility of each pharmacy technician to inform the board of his current address. A pharmacy technician shall notify the board in writing or electronically of any change of an address of record within 14 days. Properly updating address of record directly through the board's web-based application or other approved means shall constitute lawful notification. All notices required by law

or by these rules and regulations are deemed to be legally given when mailed to the address of record and shall not relieve the registrant of the obligation to comply.

B. A pharmacy technician shall maintain his current registration certificate at his principal place of practice available for inspection upon request. A pharmacy technician who does not have a principal place of practice may maintain it at any pharmacy in which he practices or his address of record.

18VAC110-20-105. 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 and renewal form. 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 obtained of required continuing education.

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. Conducting tasks associated with 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.

18VAC110-20-106. 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 subsection B of 18VAC110-21-90 or subsection B of 18VAC110-21-100.

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. Original ~~certificates~~ 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 ~~original certificates~~ documentation to the board upon request in a manner to be determined by the board.

Agenda Item: Agenda Item: Adoption of Amendments to allow CE credit for voluntary hours

Included in the agenda package:

Copy of HB319 as passed by the 2016 General Assembly

Copy of proposed amendments to regulation as recommended by the Regulation Committee

Staff note:

Adoption of amendments to include acceptance of certain voluntary practice for CE credit in accordance with HB319 is mandatory; the Committee recommended language to fulfill the statutory mandate.

Action:

Adoption of proposed amendments allowing CE credit for voluntary service by pharmacists or pharmacy technicians as a fast-track action.

CHAPTER 82

An Act to amend and reenact § 54.1-2400 of the Code of Virginia, relating to continuing education requirements; volunteer health services.

[H 319]

Approved March 1, 2016

Be it enacted by the General Assembly of Virginia:

1. That § 54.1-2400 of the Code of Virginia is amended and reenacted as follows:

§ 54.1-2400. General powers and duties of health regulatory boards.

The general powers and duties of health regulatory boards shall be:

1. To establish the qualifications for registration, certification, licensure or the issuance of a multistate licensure privilege in accordance with the applicable law which are necessary to ensure competence and integrity to engage in the regulated professions.

2. To examine or cause to be examined applicants for certification or licensure. Unless otherwise required by law, examinations shall be administered in writing or shall be a demonstration of manual skills.

3. To register, certify, license or issue a multistate licensure privilege to qualified applicants as practitioners of the particular profession or professions regulated by such board.

4. To establish schedules for renewals of registration, certification, licensure, and the issuance of a multistate licensure privilege.

5. To levy and collect fees for application processing, examination, registration, certification or licensure or the issuance of a multistate licensure privilege and renewal that are sufficient to cover all expenses for the administration and operation of the Department of Health Professions, the Board of Health Professions and the health regulatory boards.

6. To promulgate regulations in accordance with the Administrative Process Act (§ 2.2-4000 et seq.) ~~which~~ *that* are reasonable and necessary to administer effectively the regulatory system, *which shall include provisions for the satisfaction of board-required continuing education for individuals registered, certified, licensed, or issued a multistate licensure privilege by a health regulatory board through delivery of health care services, without compensation, to low-income individuals receiving health services through a local health department or a free clinic organized in whole or primarily for the delivery of those health services*. Such regulations shall not conflict with the purposes and intent of this chapter or of Chapter 1 (§ 54.1-100 et seq.) and Chapter 25 (§ 54.1-2500 et seq.) ~~of this title~~.

7. To revoke, suspend, restrict, or refuse to issue or renew a registration, certificate, license or multistate licensure privilege which such board has authority to issue for causes enumerated in applicable law and regulations.

8. To appoint designees from their membership or immediate staff to coordinate with the Director and the Health Practitioners' Monitoring Program Committee and to implement, as is necessary, the provisions of Chapter 25.1 (§ 54.1-2515 et seq.) of this title. Each health regulatory board shall appoint one such designee.

9. To take appropriate disciplinary action for violations of applicable law and regulations, and to accept, in their discretion, the surrender of a license, certificate, registration or multistate licensure privilege in lieu of disciplinary action.

10. To appoint a special conference committee, composed of not less than two members of a health regulatory board or, when required for special conference committees of the Board of Medicine, not less than two members of the Board and one member of the relevant advisory board, or, when required for special conference committees of the Board of Nursing, not less than one member of the Board and one member of the relevant advisory board, to act in accordance with § 2.2-4019 upon receipt of information that a practitioner or permit holder of the appropriate board may be subject to disciplinary action or to consider an application for a license, certification, registration, permit or multistate licensure privilege in nursing. The special conference committee may (i) exonerate; (ii) reinstate; (iii) place the practitioner or permit holder on probation with such terms as it may deem appropriate; (iv) reprimand; (v) modify a previous order; (vi) impose a monetary penalty pursuant to § 54.1-2401, (vii) deny or grant an application for licensure, certification, registration, permit, or multistate licensure privilege; and (viii) issue a restricted license, certification, registration, permit or multistate licensure privilege subject to terms and conditions. The order of the special conference committee shall become final 30 days after service of the order unless a written request to the board for a hearing is received within such time. If service of the decision to a party is accomplished by mail, three days shall be added to the 30-day period. Upon receiving a timely written request for a hearing, the board or a panel of the board shall then proceed with a hearing as provided in § 2.2-4020, and the action of the committee shall be vacated.

This subdivision shall not be construed to limit the authority of a board to delegate to an appropriately qualified agency subordinate, as defined in § 2.2-4001, the authority to conduct informal fact-finding proceedings in accordance with § 2.2-4019, upon receipt of information that a practitioner may be subject to a disciplinary action. The recommendation of such subordinate may be considered by a panel consisting of at least five board members, or, if a quorum of the board is less than five members, consisting of a quorum of the members, convened for the purpose of issuing a case decision. Criteria for the appointment of an agency subordinate shall be set forth in regulations adopted by the board.

11. To convene, at their discretion, a panel consisting of at least five board members or, if a quorum of the board is less than five members, consisting of a quorum of the members to conduct formal proceedings pursuant to § 2.2-4020, decide the case, and issue a final agency case decision. Any decision rendered by majority vote of such panel shall have the same effect as if made by the full board and shall be subject to court review in accordance with the Administrative Process Act. No member who participates in an informal proceeding conducted in accordance with § 2.2-4019 shall serve on a panel conducting formal proceedings pursuant to § 2.2-4020 to consider the same matter.

12. To issue inactive licenses or certificates and promulgate regulations to carry out such purpose. Such regulations shall include, but not be limited to, the qualifications, renewal fees, and conditions for reactivation of licenses or certificates.

13. To meet by telephone conference call to consider settlement proposals in matters pending before special conference committees convened pursuant to this section, or matters referred for formal proceedings pursuant to § 2.2-4020 to a health regulatory board or a panel of the board or to consider modifications of previously issued board orders when such considerations have been requested by either of the parties.

14. To request and accept from a certified, registered or licensed practitioner or person holding a multistate licensure privilege to practice nursing, in lieu of disciplinary action, a confidential consent agreement. A confidential consent agreement shall be subject to the confidentiality provisions of § 54.1-2400.2 and shall not be disclosed by a practitioner. A confidential consent agreement shall include findings of fact and may include an admission or a finding of a violation. A confidential consent agreement shall not be considered either a notice or order of any health regulatory board, but it may be considered by a board in future disciplinary proceedings. A confidential consent agreement shall be entered into only in cases involving minor misconduct where there is little or no injury to a patient or the public and little likelihood of repetition by the practitioner. A board shall not enter into a confidential consent agreement if there is probable cause to believe the practitioner has (i) demonstrated gross negligence or intentional misconduct in the care of patients or (ii) conducted his practice in such a manner as to be a danger to the health and welfare of his patients or the public. A certified, registered or licensed practitioner who has entered into two confidential consent agreements involving a standard of care violation, within the 10-year period immediately preceding a board's receipt of the most recent report or complaint being considered, shall receive public discipline for any subsequent violation within the 10-year period unless the board finds there are sufficient facts and circumstances to rebut the presumption that the disciplinary action be made public.

15. When a board has probable cause to believe a practitioner is unable to practice with reasonable skill and safety to patients because of excessive use of alcohol or drugs or physical or mental illness, the board, after preliminary investigation by an informal fact-finding proceeding, may direct that the practitioner submit to a mental or physical examination. Failure to submit to the examination shall constitute grounds for disciplinary action. Any practitioner affected by this subsection shall be afforded reasonable opportunity to demonstrate that he is competent to practice with reasonable skill and safety to patients. For the purposes of this subdivision, "practitioner" shall include any person holding a multistate licensure privilege to practice nursing.

2. That the provisions of this act shall become effective on January 1, 2017.

Project 4990 - none

BOARD OF PHARMACY

CE credit for volunteer practice

18VAC110-20-90. Requirements for continuing education.

A. A pharmacist shall be required to have completed a minimum of 1.5 CEUs or 15 contact hours of continuing pharmacy education in an approved program for each annual renewal of licensure. CEUs or hours in excess of the number required for renewal may not be transferred or credited to another year.

B. A pharmacy education program approved for continuing pharmacy education is:

1. One that is approved by the Accreditation Council for Pharmacy Education (ACPE);

2. One that is approved as a Category I Continuing Medical Education (CME) course, the primary focus of which is pharmacy, pharmacology, or drug therapy; or

3. One that is approved by the board in accordance with the provisions of 18VAC110-20-100.

C. The board may grant an extension pursuant to § 54.1-3314.1 E of the Code of Virginia. Any subsequent extension shall be granted only for good cause shown.

D. Up to two hours of the 15 hours required for annual renewal may be satisfied through delivery of pharmacy services, without compensation, to low-income individuals receiving health services through a local health department or a free clinic organized in whole or primarily for the delivery of those 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.

~~D.~~ E. Pharmacists are required to attest to compliance with CE requirements in a manner approved by the board at the time of their annual license renewal. Following each renewal period, the board may conduct an audit of the immediate past two years' CE documents to verify compliance with requirements. Pharmacists are required to maintain, for two years following renewal, the original certificates documenting successful completion of CE, showing date and title of the CE program or activity, the number of CEUs or contact hours awarded, and a certifying signature or other certification of the approved provider. Pharmacists selected for audit must provide these original documents to the board by the deadline date specified by the board in the audit notice.

18VAC110-20-106. 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 subsection B of 18VAC110-20-90 or subsection B of 18VAC110-20-100.

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, 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.

~~D.~~E. Original certificates 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 original certificates to the board upon request in a manner to be determined by the board.

Consideration of Request to Delay Enforcement of USP Chapter <800>

Included in your packet:

- Letter requesting delay in enforcement
- USP Frequently Asked Questions
- USP Chapter <800> Published Text
- 2016 Presentation at ASHP Midyear Meeting

September 12, 2016

Caroline Juran
Executive Director
Virginia Board of Pharmacy
Perimeter Center, 9960 Mayland Drive, Suite 300
Henrico, VA 23233-1463

Dear Caroline Juran,

Our organizations are writing today in regards to a new general chapter from the U.S. Pharmacopeial Convention (USP), *General Chapter <800>, Hazardous Drugs—Handling in Healthcare Settings.* The purpose of the chapter, per USP, is "to describe practice and quality standards for handling hazardous drugs in healthcare settings and help promote patient safety, worker safety, and environmental protection."

Chapter <800> will apply to all healthcare personnel who handle hazardous drug preparations, including members of our organizations. Also impacted will be nurses, physicians, physician assistants, home healthcare workers, veterinarians, and veterinary technicians and the entities where they practice.

General Chapter <800> utilizes the National Institute for Occupational Safety and Health (NIOSH) list of antineoplastic and other hazardous drugs to define a hazardous drug preparation. There are multiple commonly dispensed drugs on this list, including estrogen and progestin containing drugs, anticonvulsants, immunosuppressive agents, antifungal agents, atypical antipsychotics and warfarin. The impact of General Chapter <800> on our members is substantial from both an economic and operational perspective and compliance with the new general chapter will require changes such as the use of Personal Protective Equipment (PPE) and the potential for reconstruction of facilities.

General Chapter <800> was published on February 1, 2016. In recognizing that it will take facilities time to conform to the new requirements, USP extended the official implementation date until July 1, 2018. However, given such highly complex, resource intensive, and time consuming compliance requirements, we respectfully request that the Virginia Board of Pharmacy carefully consider any actions related to pharmacy compliance with the standards.

Employee safety must always be a top priority. Our members are currently held to and comply with regulations and guidelines from entities such as the Environmental Protection Agency (EPA), the Occupational Safety and Health Administration (OSHA), and The Joint Commission (TJC), which detail the handling of hazardous material that serve to protect employees. We appreciate the intent of the proposed chapter <800>, however, the impact on our members and their patients in relation to a 2018 enforcement date is too great at this time and full compliance would be extremely difficult to the vast majority of our members.

In order to give our members the opportunity to perform the proper analyses, including budget implications and the impact upon the delivery of services to patients, and to fully integrate General Chapter <800> into their practice settings, we feel that a delay in enforcement is warranted, similar to the phased in approach that accompanied the introduction of USP *General Chapter <797> Pharmaceutical Compounding – Sterile.*

A delay in enforcement of USP <800> allows healthcare organizations sufficient time to plan and gradually implement changes. Budgeting capital expenses is a multistep, multi-year process that is not under the control of many pharmacies. Some organizations may have to justify their <800> project proposal to numerous organizational stakeholders, spread expenditures over more than one budget cycle, and integrate their project into existing organizational project timelines.

If the Virginia Board of Pharmacy agrees that a graduated approach to implementing General Chapter <800> is consistent with its mission and goals, we respectfully request that the Virginia Board of Pharmacy grant a five year delay in enforcement of General Chapter <800> until July 1, 2021. This grace period allows state-licensed practitioners to assess and plan for the significant operational and structural changes needed as well as budget and obtain the necessary resources in an already strained financial environment.

We appreciate your thoughtful consideration of our comments regarding *General Chapter <800>, Hazardous Drugs—Handling in Healthcare Settings.*

Sincerely,

American Pharmacists Association (APhA)
American Society of Consultant Pharmacists (ASCP)
College of Psychiatric and Neurologic Pharmacists (CPNP)
International Academy of Compounding Pharmacists (IACP)
National Alliance of State Pharmacy Associations (NASPA)
National Association of Chain Drug Stores (NACDS)
National Community Pharmacists Association (NCPA)

U.S. Pharmacopeial Convention

Frequently Asked Questions: <800> Hazardous Drugs—Handling in Healthcare Settings

The following are responses provided by members of the USP Compounding Expert Committee. Responses have been provided for informational purposes only, and should not be construed as an official interpretation of USP text or relied on to demonstrate compliance with USP standards or requirements.

General

1. **What is a hazardous drug?**
   A hazardous drug is any drug identified as hazardous or potentially hazardous by the National Institute for Occupational Safety and Health (NIOSH) on the basis of at least one of the following six criteria: carcinogenicity, teratogenicity or developmental toxicity, reproductive toxicity in humans, organ toxicity at low doses in humans or animals, genotoxicity, and new drugs that mimic existing hazardous drugs in structure or toxicity. NIOSH maintains a list of antineoplastic and other hazardous drugs used in healthcare settings.

2. **What is the purpose of this chapter?**
   The purpose of the chapter is to describe practice and quality standards for handling hazardous drugs in healthcare settings and help promote patient safety, worker safety, and environmental protection. The chapter defines processes intended to minimize the exposure to hazardous drugs in healthcare settings. The chapter was developed by the USP Compounding Expert Committee with the assistance of the USP Compounding with Hazardous Drugs Expert Panel and government liaisons from the U.S. Food and Drug Administration (FDA) and the U.S. Centers for Disease Control and Prevention (CDC) including NIOSH. The chapter was published for the first time for public comment in March 2014. Based on the public comments received, the chapter was revised and proposed for another round of public comments in December 2014. The chapter was revised again and published in the USP-NF in February 2016.

3. **Who enforces the chapter?**
   The enforcement of USP standards depends on local, state, and federal regulatory agencies. Accrediting bodies like The Joint Commission survey for compliance with USP compounding standards. The CMS State Operations Manual, which is used by surveyors to ensure that all of the Conditions of Participation are being met, includes references to USP standards. Additionally, many state pharmacy practice acts have included references to USP compounding standards. Each professional licensing board also has the ability to enforce the regulations of that state, which may include USP compounding standards.

4. **Who does the chapter apply to?**
   Chapter <800> was written to protect all workers, patients and the general public who may be accessing facilities where hazardous drugs (HDs) are prepared. This includes but is not limited to pharmacists, technicians, nurses, physicians, physician assistants, home healthcare workers, veterinarians, and veterinary technicians. If any workers come in contact with HDs, they must receive HD training, and be assessed for an understanding of the training. All personnel who handle HDs are responsible for understanding the fundamental practices and precautions and for continually evaluating these procedures and the quality of final HDs to prevent harm to patients, minimize exposure to personnel, and minimize contamination of the work and patient-care environment.

5. **What settings does the chapter apply to?**
   The chapter applies to all healthcare personnel who handle HD preparations and all entities that store, prepare, transport, or administer HDs (e.g., pharmacies, hospitals and other healthcare institutions, patient treatment clinics, physicians' practice facilities, or veterinarians'

offices).

6. **Does the chapter apply to administration of HDs?**
   Yes, the chapter applies to administration of HDs. If non-antineoplastic or reproductive risk HD dosage forms do require manipulation such as crushing tablet(s) or opening capsule(s) for a single dose, alternative containment strategies and work practices as defined in the assessment of risk must be used (e.g. appropriate personnel protective equipment (PPE), use a plastic pouch to contain any dust or particles generated). If antineoplastic HD dosage forms require manipulation, the requirements of Chapter <800> must be followed.

7. **What is the status of the General Chapter <800> and when will General Chapter <800> become official?**
   General Chapter <800> was published on February 1, 2016 in the First Supplement to USP 39–NF 34. The USP Compounding Expert Committee approved a delayed official implementation date of July 1, 2018 to allow entities additional time to implement the standard. With the delayed official date, entities have more than two years to implement this new standard.

8. **Will there be updates or changes to the chapter?**
   The final version of the chapter was published on February 1, 2016. An erratum was published on May 26, 2016 to remove the requirement that the Containment Secondary Engineering Control (C-SEC) be externally vented through high-efficiency particulate air (HEPA) filtration. This revision does not remove the requirement that the C-SEC be externally vented.

9. **How can I obtain a copy of General Chapter <800>?**
   General Chapter <800> was published on February 1, 2016 in the First Supplement to USP 39–NF 34. You may purchase the chapter through a subscription to the USP Compounding Compendium or USP-NF.

10. **Have there been any documented/published studies involving harm related to handling of HDs?**
    Yes, there are several studies demonstrating risks associated with handling HDs. Some of references are included in the References section of the chapter.

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Personnel

11. **Where does the designated person obtain training? How much training does the designated person need?**
    Any training should begin with reading the chapter in it is entirety. All of the requirements for HD handling are defined in the chapter and the chapter provides many references to other source documents. If additional training is required, many professional organizations conduct training and continuing education programs on the subject. The chapter does not specify a minimum number of training hours. The designated person must have a thorough understanding of the standards to be able to develop and implement appropriate procedures; oversee entity compliance with the chapter and other applicable laws, regulations, and standards; ensure competency of personnel; and ensure environmental control of the storage and compounding areas.

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Facilities and Engineering Controls

12. **Are there requirement for posting signs that HDs are being handled in the facility?**
    Signs are not required to be posted at the entrance of facilities. However, signs designating the hazard must be prominently displayed before the entrance to the HD handling areas. Additionally, signs must be available for restricting access to areas where HD spills occur.

13. **Can sterile and nonsterile HDs be stored together?**
    See Section 5.2 of the Chapter for guidance on storage. Sterile and nonsterile HDs may be stored together, but HDs used for nonsterile compounding should not be stored in areas designated for sterile compounding to minimize traffic into the sterile compounding area. Antineoplastic HDs requiring manipulation other than counting or repackaging of final dosage forms and any HD active pharmaceutical ingredient (API) must be stored separately from non-HDs in a manner that prevents contamination and personnel exposure. These HDs must be stored in an externally ventilated, negative-pressure room with at least 12 air changes per hour (ACPH). Non-antineoplastic, reproductive risk only, and final dosage forms of antineoplastic HDs may be stored with other inventory if permitted by entity policy. Refrigerated antineoplastic HDs must be stored in a dedicated refrigerator in a negative pressure area with at least 12 ACPH [e.g., storage room, buffer room, or containment segregated compounding area (C-SCA)].

14. **Can refrigerated non-antineoplastic HDs be stored with antineoplastic HDs?**
    Yes, a refrigerator must be dedicated to HD storage and located in a negative pressure room with at least 12 ACPH. Refrigerated antineoplastic HDs must be stored in this dedicated refrigerator. HD APIs requiring refrigeration must also be stored according to the

Chapter. Other HDs may be stored in this dedicated refrigerator or may be stored with other inventory if an assessment of risk has been performed and implemented.

15. **Where should the sink be located?**
Care must be taken to locate water sources and drains in areas where their presence will not interfere with required ISO classifications. Water sources and drains must be located at least 1 meter away from the Containment Primary Engineering Control (C-PEC). Within an ISO classified area, a hand-washing sink must be placed in the ante-room at least 1 meter from the entrance to the HD buffer room to avoid contamination migration into the negative pressure HD buffer room. Within an unclassified C-SCA, a hand-washing sink must be placed at least 1 meter from C-PEC and may be either inside the C-SCA or directly outside the C-SCA.

16. **Is the C-PEC used for sterile compounding required to be exhausted to the outside or can the C-PEC be recirculated into the negative pressure C-SEC which is exhausted to the outside of the building?**
The Chapter requires that all C-PECs used for manipulation of sterile HDs must be externally vented. Sterile HD compounding must be performed in a C-PEC that provides an ISO Class 5 or better air quality, such as a Class II or III biological safety cabinet (BSC) or compounding aseptic containment isolator (CACI). Class II BSC types A2, B1, or B2 are acceptable. C-PECs used for pre-sterilization procedures such as weighing and mixing must be either externally vented (preferred) or have redundant–HEPA filters in series and must provide personnel and environmental protection, such as a Class I BSC or Containment Ventilated Enclosure (CVE). A Class II BSC or a CACI may also be used.

17. **Can non-HDs and HDs be compounded in C-PECs located in the same C-SEC?**
Separate rooms (C-SECs) are required for sterile, nonsterile, HD and non-HD compounding with two exceptions:

(1) Per section 5.3 Compounding, for entities that compound both nonsterile and sterile HDs, the respective C- PECs must be placed in separate rooms, unless those C-PECs used for nonsterile compounding are sufficiently effective that the room can continuously maintain ISO 7 classification throughout the nonsterile compounding activity. If the C-PECs used for sterile and nonsterile compounding are placed in the same room, they must be placed at least 1 meter apart and particle-generating activity must not be performed when sterile compounding is in process; and

(2) Per section 5.3.2 Sterile Compounding, a BSC or CACI used for the preparation of HDs must not be used for the preparation of a non-HD unless the non-HD preparation is placed into a protective outer wrapper during removal from the C-PEC and is labeled to require PPE handling precautions.

18. **Can a Laminar Airflow Workbench (LAFW) or compounding aseptic isolator (CAI) be used for compounding a non-antineoplastic HD?**
Section 5.3.2 specifies that a LAFW cannot be used for compounding an antineoplastic HD. However, for handling non-antineoplastic and reproductive risk HDs, each facility may conduct an assessment of risk and implement strategies different than those required in the chapter. A LAFW does not provide any protection for the worker from the HD. A LAFW or CAI may be used for non-antineoplastic HDs, however, alternative containment strategies and/or work practices must be determined during the assessment of risk.

19. **Can a BSC or CACI used for compounding HDs be used for compounding non-HDs?**
If a non-HD is prepared in a C-PEC where HDs have been prepared, then the non-HD should be handled and labeled as an HD. The non-HD preparation should be placed into a protective outer wrapper during removal from the C-PEC and should be labeled to require PPE handling precautions. All associated materials and wrappers should be discarded as HD waste because the preparation and associated materials have potentially been contaminated by exposure to HDs.

20. **Are closed-system drug-transfer devices (CSTDs) required for compounding HDs?**
No, the Chapter does not require a CSTD for compounding HDs, although it is recommended. However, the Chapter does require that CSTDs be used when administering antineoplastic HDs when the dosage form allows.

21. **Is there an evaluation tool one can use for evaluating the performance of the different CSTDs available?**
NIOSH created a draft performance standard protocol for the containment-type CSTDs. This proposed protocol was published in the Federal Register on September 8, 2015. Five CSTDs were tested by NIOSH and two showed test substance concentration levels below the limit of detection meaning that only 2 of the 5 CSTDs evaluated prevented escape of vapors of the test substance. The protocol has not been released in final form.

22. **How can a CSTD be chemically incompatible with a HD?**
Depending on the chemical composition of the drug being compounded and the composition of the CSTD device, chemical incompatibilities may exist. In March 2015, FDA warned against the use of bendamustine with CSTDs, syringes, and adapters containing polycarbonate or acrylonitrile-butadiene-styrene (ABS). The component in bendamustine (N, N-dimethylacetamide (DMA)) dissolved the ABS or

polycarbonate on contact.

23. **What is meant by "fixed walls"?**
Fixed walls are solid hard wall modular or 'stick-build' construction. According to the Chapter, fixed walls are required to prevent the egress of HD contamination from the C-SEC (either a C-SCA or HD buffer room) as well as ingress of contamination into the ISO Class 7 HD buffer room.

24. **Are pressure gauges required to monitor the pressure differential between the C-SEC and the adjacent areas?**
The entity must be compliant with the appropriate USP standards for compounding including <795> and/or <797> and in accordance with applicable federal, state, and local regulations. Presence of a pressure gauge and at least daily monitoring is currently required for sterile compounding per USP <797>. However, pressure monitoring is not addressed in nonsterile compounding per USP <795>, so entities should follow applicable federal, state, and local regulations. Presence of a pressure gauge and at least daily monitoring of negative pressure storage areas and nonsterile compounding areas helps ensure pressure requirements are continually maintained in these areas.

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Environmental Quality And Control

25. **Is environmental wipe sampling required?**
No. The chapter recommends but does not require the performance of environmental wipe sampling. Some common marker HDs that can be assayed include cyclophosphamide, ifosfamide, methotrexate, fluorouracil, and platinum-containing drugs. If no wipe sampling kit is available for the specific HDs used by the entity, the performance of environmental wipe sampling would not be appropriate.

26. **Why is environmental wipe sampling recommended when there is currently no standard for acceptable limits on HD surface contamination?**
Environmental wipe sampling for HD surface residue should be performed to verify containment. Contamination in any amount indicates a lack of containment. Wipe sampling kits need to be evaluated to ensure they are appropriate for HDs used by the entity. If contamination is found, the chapter states that the designated person must identify, document, and contain the cause of contamination. Such action may include reevaluating work practices, re-training personnel, performing thorough deactivation, decontamination, cleaning, and improving engineering controls. Repeat the wipe sampling to validate that the deactivation/decontamination and cleaning steps have been effective.

27. **Does every area where HDs are handled require environmental sampling?**
The chapter recommends, but does not require, the performance of environmental "wipe sampling." The term "sampling" indicates that a portion, or sample, of the entire population be tested.

28. **What are the acceptable limits for HD surface contamination?**
There is currently no standard for acceptable limits for HD surface contamination. Contamination in any amount indicates a lack of containment and must be addressed.

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Personal Protective Equipment (PPE)

29. **Are compounders required to remove all PPE when leaving the compounding area?**
Yes, all PPE would need to be removed when leaving the HD compounding area. The goal is to contain all hazardous contamination within the negative pressure room.

30. **Can gowns be re-worn during the same day if a compounder leaves the HD compounding area?**
Disposable PPE must not be re-used. Consider all PPE worn when handling HDs to be contaminated with, at minimum, trace quantities of HDs. PPE must be placed in an appropriate waste container and further disposed of per local, state, and federal regulations. PPE worn during compounding should be disposed of in the proper waste container before leaving the C-SEC.

31. **What documentation is required to show that a gown will resist permeability by HDs?**
Gowns used for HD handling must be shown to resist permeability by HDs which can be determined by testing against ASTM F739-12. Manufacturers of gowns used for handling HDs should provide results of ASTM F739-12 testing. The gown manufacturer should be able to provide permeability data for commonly used HDs.

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Compounding

32. **Is an entity required to have two sets of equipment, one set for compounding HDs and another second set for compounding non-HDs?**
General Chapter <800> states that "disposable or clean equipment for compounding (such as mortars and pestles, and spatulas) must be dedicated for use with HDs." This refers to equipment (or parts of equipment) that comes in direct contact with HDs. Equipment that does not come in direct contact with HDs may be shared between HD and non-HD compounding areas provided it is deactivated, decontaminated and cleaned before it is removed from the HD area. Equipment used in HD compounding must be operated in the C-SEC unless it is operated as a closed system (e.g. certain mixers, terminal sterilization using an autoclave or convection oven).

33. **During nonsterile compounding with HD APIs, are all steps of the compounding process required to be performed in the C-PEC?**
General Chapter <800> states that "bulk containers of liquid and API HD must be handled carefully to avoid spills. If used, APIs or other powdered HDs must be handled in a C-PEC to protect against occupational exposure, especially during particle-generating activities (such as crushing tablets, opening capsules, and weighing powder)." It is recognized that under some circumstances, it is not possible to perform all steps of the compounding process in the C-PEC (e.g. due to equipment size or function). It is important for the safety of personnel that powdered HDs be weighed and mixed to the wet stage or made into capsules in the C-PEC. Once nonvolatile, non-antineoplastic, powdered HDs are wet, an assessment of risk may be performed to determine alternative containment strategies and/or work practices. The NIOSH list of antineoplastic and other HDs provides general guidance on PPE for possible scenarios that may be encountered in healthcare settings including instances where a C-PEC cannot be used.

34. **Where should HD APIs be handled prior to sterilization when compounding sterile HDs?**
In addition to <800>, sterile compounding must follow standards in <797> which states that presterilization procedures for high-risk level CSPs, such as weighing and mixing, shall be completed in no worse than an ISO Class 8 environment. Per <800>, presterilization procedures for high-risk level HD CSPs can occur in the HD ISO Class 7 negative pressure buffer room if the C-PEC used for the nonsterile presterilization procedures is sufficiently effective that the room can continuously maintain ISO 7 classification. If the C-PECs used for sterile and nonsterile compounding are placed in the same room, they must be placed at least 1 meter apart and particle-generating activity must not be performed when sterile compounding is in process. Alternatively, an ISO Class 8 or better negative pressure room could be used. An ISO Class 7 negative pressure room would be necessary if it leads directly into the HD ISO 7 negative pressure buffer room.

35. **Does the chapter apply if the HD is dissolved in a liquid dosage form and does not become an aerosol or gas?**
HDs that do not require any further manipulation, other than counting or repackaging of final dosage forms, may be prepared for dispensing without any further requirements for containment unless required by the manufacturer or if visual indicators of HD exposure hazards are present (e.g., HD dust or leakage). Consideration must be given to the aerolization of HDs in liquid formulations.

36. **If the HD is a liquid dosage form, may it be compounded in a positive pressure non-HD cleanroom?**
No, HD CSPs must be filtered in a BSC or CACI located in an ISO 7 room with negative pressure of 0.01 to 0.03 inches of water and 30 ACPH.

37. **What kind of materials may be used for the cabinets and counters in the nonsterile compounding room?**
The chapter states that cabinets in the nonsterile compounding area must be smooth, impervious, free from cracks and crevices, and non-shedding but does not limit or define the specific materials that may be used.

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Hazard Communication Program

38. **Do personnel of reproductive capability include both male and females?**
Yes, the chapter applies to anyone capable of reproduction.

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Receiving

39. **Are suppliers required to ship HDs in impervious plastic?**
No, the chapter recommends that suppliers ship HDs in impervious plastic to segregate them from other drugs and allow for safety in the receiving and internal transfer process.

40. **Does the HD return waiting area have to be separate from the regular HD storage area?**
No, a separate area is not required. HDs waiting to be returned to the supplier must be segregated in a designated negative pressure area. The regular HD storage area may be designated for this purpose.

41. **What container materials are considered impervious?**
The type of impervious packaging will vary with the situation and type of HD. Impervious packaging may be "soft" or "firm". HDs must be transported in containers that minimize the risk of breakage or leakage.

42. **What is the tiered approach for receiving HDs?**
The tiers will be defined by the entity's SOPs based on considerations such as the facility design and types of HDs being handled.

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Labeling, Packaging, Transport And Disposal

43. **What must be on the label for HDs?**
HDs identified by the entity as requiring special HD handling precautions must be clearly labeled at all times during their transport. Labeling must be compliant with the appropriate USP standards for compounding including <795> and/or <797> and in accordance with applicable federal, state, and local regulations.

44. **What kind of packaging containers can be used for packaging HDs?**
The chapter states that packaging containers and materials must be selected to maintain physical integrity, stability, and sterility (if needed) of the HDs during transport. Packaging materials must protect the HD from damage, leakage, contamination, and degradation, while protecting healthcare workers who transport HDs. The entity must have written SOPs to describe appropriate shipping containers and insulating materials, based on information from product specifications, vendors, and mode of transport. Other sources of information may include the chemical or formula and the SDS. In addition, there are multiple chapters in the USP Compounding Compendium that describes packaging.

45. **Can HDs be transported in pneumatic tubes, robots, or patient carts?**
Each facility must conduct an assessment of risk and develop SOPs accordingly. HDs must be transported in containers that minimize the risk of breakage or leakage. Pneumatic tubes must not be used to transport any liquid HDs or any antineoplastic HDs because of the potential for breakage and contamination.

46. **Are personnel involved in waste removal and cleaning required to don PPE?**
Yes, personnel must wear appropriate PPE based on their assigned tasks.

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Medical Surveillance

47. **What if the employee wants to keep their medical records private from the employer?**
Medical surveillance is recommended but not required by the chapter. The entity may choose to use a contracted employee health service to perform the medical surveillance while protecting the confidentiality of the employees' personal medical information.

48. **What "health variables" should be followed over time for individual workers?**
The chapter recommends an initial baseline assessment (pre-placement) of a worker's health status, medical history and collection of data elements including a medical (including reproductive) history and work history to assess exposure to HDs, physical examination, and laboratory testing. Methods used to assess exposure history include a review of:

- Records of HDs handled, with quantities & dosage forms
- Estimated number of HDs handled per week
- Estimates of hours spent handling HDs per week and/or per month
- Performance of a physical assessment and laboratory studies linked to target organs of commonly used HDs such as a baseline complete blood count.

49. **In a medical surveillance program, how does an employer obtain data from the unexposed workers for comparison to the exposed workers?**
The chapter recommends an initial baseline assessment (pre-placement) of a worker's health status, medical history and collection of data

elements including a medical (including reproductive) history and work history to assess exposure to HDs, physical examination, and laboratory testing. Methods used to assess exposure history include a review of:

- Records of HDs handled, with quantities & dosage forms
- Estimated number of HDs handled per week
- Estimates of hours spent handling HDs per week and/or per month
- Performance of a physical assessment and laboratory studies linked to target organs of commonly used HDs such as a baseline complete blood count.

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Add the following:

■⟨800⟩ HAZARDOUS DRUGS—HANDLING IN HEALTHCARE SETTINGS

(Chapter to become official July 1, 2018.)

1. INTRODUCTION AND SCOPE

This chapter describes practice and quality standards for handling hazardous drugs (HDs) to promote patient safety, worker safety, and environmental protection. Handling HDs includes, but is not limited to, the receipt, storage, compounding, dispensing, administration, and disposal of sterile and nonsterile products and preparations.

This chapter applies to all healthcare personnel who handle HD preparations and all entities that store, prepare, transport, or administer HDs (e.g., pharmacies, hospitals and other healthcare institutions, patient treatment clinics, physicians' practice facilities, or veterinarians' offices). Personnel who may potentially be exposed to HDs include, but are not limited to: pharmacists, pharmacy technicians, nurses, physicians, physician assistants, home healthcare workers, veterinarians, and veterinary technicians.

Entities that handle HDs must incorporate the standards in this chapter into their occupational safety plan. The entity's health and safety management system must, at a minimum, include:

- A list of HDs
- Facility and engineering controls
- Competent personnel
- Safe work practices
- Proper use of appropriate Personal Protective Equipment (PPE)
- Policies for HD waste segregation and disposal

The chapter is organized into the following main sections:

1. Introduction and Scope
2. List of Hazardous Drugs
3. Types of Exposure
4. Responsibilities of Personnel Handling Hazardous Drugs
5. Facilities and Engineering Controls
6. Environmental Quality and Control
7. Personal Protective Equipment
8. Hazard Communication Program
9. Personnel Training
10. Receiving
11. Labeling, Packaging, Transport, and Disposal
12. Dispensing Final Dosage Forms
13. Compounding
14. Administering
15. Deactivating, Decontaminating, Cleaning, and Disinfecting
16. Spill Control
17. Documentation and Standard Operating Procedures
18. Medical Surveillance

Glossary

Appendices

Appendix 1: Acronyms
Appendix 2: Examples of Designs for Hazardous Drug Compounding Areas
Appendix 3: Types of Biological Safety Cabinets

References

2. LIST OF HAZARDOUS DRUGS

The National Institute for Occupational Safety and Health (NIOSH) maintains a list of antineoplastic and other HDs used in healthcare. An entity must maintain a list of HDs, which must include any items on the current NIOSH list that the entity handles. The entity's list must be reviewed at least every 12 months. Whenever a new agent or dosage form is used, it should be reviewed against the entity's list.

The NIOSH list of antineoplastic and other HDs provides the criteria used to identify HDs. These criteria must be used to identify HDs that enter the market after the most recent version of the NIOSH list, or that the entity handles as an investigational drug. If the information available on a drug is deemed insufficient to make an informed decision, consider the drug hazardous until more information is available.

Box 1: Containment Requirements

- Drugs on the NIOSH list that must follow the requirements in this chapter include:
  - Any HD API
  - Any antineoplastic requiring HD manipulation
- Drugs on the NIOSH list that do not have to follow all the containment requirements of this chapter if an assessment of risk is performed and implemented include:
  - Final dosage forms of compounded HD preparations and conventionally manufactured HD products, including antineoplastic dosage forms that do not require any further manipulation other than counting or repackaging (unless required by the manufacturer)
- For dosage forms of other HDs on the NIOSH list, the entity may perform an assessment of risk to determine alternative containment strategies and/work practices

Some dosage forms of drugs defined as hazardous may not pose a significant risk of direct occupational exposure because of their dosage formulation (e.g., tablets or capsules—solid, intact medications that are administered to patients without modifying the formulation). However, dust from tablets and capsules may present a risk of exposure by skin contact and/or inhalation. An assessment of risk may be performed for these dosage forms to determine alternative containment strategies and/or work practices. If an assessment of risk is not performed, all HDs must be handled with all containment strategies defined in this chapter.

The assessment of risk must, at a minimum, consider the following:

- Type of HD (e.g., antineoplastic, non-antineoplastic, reproductive risk only)
- Dosage form
- Risk of exposure
- Packaging
- Manipulation

If an assessment of risk approach is taken, the entity must document what alternative

containment strategies and/or work practices are being employed for specific dosage forms to minimize occupational exposure. If used, the assessment of risk must be reviewed at least every 12 months and the review documented.

3. TYPES OF EXPOSURE

Routes of unintentional entry of HDs into the body include dermal and mucosal absorption, inhalation, injection, and ingestion (e.g., contaminated foodstuffs, spills, or mouth contact with contaminated hands). Containers of HDs have been shown to be contaminated upon receipt. Both clinical and nonclinical personnel may be exposed to HDs when they handle HDs or touch contaminated surfaces. *Table 1* lists examples of potential routes of exposure based on activity.

Table 1. Examples of Potential Opportunities of Exposure Based on Activity

Activity	Potential Opportunity of Exposure
Receipt	• Contacting HD residues present on drug containers, individual dosage units, outer containers, work surfaces, or floors
Dispensing	• Counting or repackaging tablets and capsules
Compounding and other manipulations	• Crushing or splitting tablets or opening capsules • Pouring oral or topical liquids from one container to another • Weighing or mixing components • Constituting or reconstituting powdered or lyophilized HDs • Withdrawing or diluting injectable HDs from parenteral containers • Expelling air or HDs from syringes • Contacting HD residue present on PPE or other garments • Deactivating, decontaminating, cleaning, and disinfecting areas contaminated with or suspected to be contaminated with HDs • Maintenance activities for potentially contaminated equipment and devices
Administration	• Generating aerosols during administration of HDs by various routes (e.g., injection, irrigation, oral, inhalation, or topical application) • Performing certain specialized procedures (e.g., intraoperative intraperitoneal injection or bladder instillation) • Priming an IV administration set
Patient-care activities	• Handling body fluids (e.g., urine, feces, sweat, or vomit) or body-fluid-contaminated clothing, dressings, linens, and other materials
Spills	• Spill generation, management, and disposal
Transport	• Moving HDs within a healthcare setting
Waste	• Collection and disposal of hazardous waste and trace contaminated waste

4. RESPONSIBILITIES OF PERSONNEL HANDLING HAZARDOUS DRUGS

Each entity must have a designated person who is qualified and trained to be responsible for developing and implementing appropriate procedures; overseeing entity compliance with this chapter and other applicable laws, regulations, and standards; ensuring competency of personnel; and ensuring environmental control of the storage and compounding areas. The designated person must thoroughly understand the rationale for risk-prevention policies, risks to themselves and others, risks of non-compliance that may compromise safety, and the responsibility to report potentially hazardous situations to the management team. The designated person must also be responsible for the oversight of monitoring the facility and maintaining reports of testing/sampling performed in facilities, and acting on the results.

All personnel who handle HDs are responsible for understanding the fundamental practices and precautions and for continually evaluating these procedures and the quality of final HDs to prevent harm to patients, minimize exposure to personnel, and minimize contamination of the work and patient-care environment.

5. FACILITIES AND ENGINEERING CONTROLS

HDs must be handled under conditions that promote patient safety, worker safety, and environmental protection. Signs designating the hazard must be prominently displayed before the entrance to the HD handling areas. Access to areas where HDs are handled must be restricted to authorized personnel to protect persons not involved in HD handling. HD handling areas must be located away from breakrooms and refreshment areas for personnel, patients, or visitors to reduce risk of exposure.

Designated areas must be available for:

- Receipt and unpacking
- Storage of HDs
- Nonsterile HD compounding (if performed by the entity)
- Sterile HD compounding (if performed by the entity)

Certain areas are required to have negative pressure from surrounding areas to contain HDs and minimize risk of exposure. Consideration should be given to uninterrupted power sources (UPS) for the ventilation systems to maintain negative pressure in the event of power loss.

5.1 Receipt

Antineoplastic HDs and all HD APIs must be unpacked (i.e., removal from external shipping containers) in an area that is neutral/normal or negative pressure relative to the surrounding areas. HDs must not be unpacked from their external shipping containers in sterile compounding areas or in positive pressure areas.

5.2 Storage

HDs must be stored in a manner that prevents spillage or breakage if the container falls. Do not store HDs on the floor. In areas prone to specific types of natural disasters (e.g., earthquakes) the manner of storage must meet applicable safety precautions, such as secure shelves with raised front lips.

Antineoplastic HDs requiring manipulation other than counting or repackaging of final dosage forms and any HD API must be stored separately from non-HDs in a manner that prevents contamination and personnel exposure. These HDs must be stored in an externally ventilated, negative-pressure room with at least 12 air changes per hour (ACPH). Non-antineoplastic, reproductive risk only, and final dosage forms of antineoplastic HDs may be stored with other

inventory if permitted by entity policy.

Sterile and nonsterile HDs may be stored together, but HDs used for nonsterile compounding should not be stored in areas designated for sterile compounding to minimize traffic into the sterile compounding area.

Refrigerated antineoplastic HDs must be stored in a dedicated refrigerator in a negative pressure area with at least 12 ACPH [e.g., storage room, buffer room, or containment segregated compounding area (C-SCA)]. If a refrigerator is placed in a negative pressure buffer room, an exhaust located adjacent to the refrigerator's compressor and behind the refrigerator should be considered.

5.3 Compounding

Engineering controls are required to protect the preparation from cross-contamination and microbial contamination (if preparation is intended to be sterile) during all phases of the compounding process. Engineering controls for containment are divided into three categories representing primary, secondary, and supplementary levels of control. A containment primary engineering control (C-PEC) is a ventilated device designed to minimize worker and environmental HD exposure when directly handling HDs. The containment secondary engineering control (C-SEC) is the room in which the C-PEC is placed. Supplemental engineering controls [e.g., closed-system drug-transfer device (CSTD)] are adjunct controls to offer additional levels of protection. *Appendix 2* provides examples for designs of HD compounding areas.

Sterile and nonsterile HDs must be compounded within a C-PEC located in a C-SEC. The C-SEC used for sterile and nonsterile compounding must:

- Be externally vented through high-efficiency particulate air (HEPA) filtration
- Be physically separated (i.e., a different room from other preparation areas)
- Have an appropriate air exchange (e.g., ACPH)
- Have a negative pressure between 0.01 and 0.03 inches of water column relative to all adjacent areas

The C-PEC must operate continuously if it supplies some or all of the negative pressure in the C-SEC or if it is used for sterile compounding. If there is any loss of power to the C-PEC, or if repair or moving occurs, all activities occurring in the C-PEC must be suspended immediately. If necessary, protect the unit by covering it appropriately per the manufacturer's recommendations. Once the C-PEC can be powered on, decontaminate, clean, and disinfect (if used for sterile compounding) all surfaces and wait the manufacturer-specified recovery time before resuming compounding.

A sink must be available for hand washing. An eyewash station and/or other emergency or safety precautions that meet applicable laws and regulations must be readily available. Care must be taken to locate water sources and drains in areas where their presence will not interfere with required ISO classifications. Water sources and drains must be located at least 1 meter away from the C-PEC.

For entities that compound both nonsterile and sterile HDs, the respective C-PECs must be placed in separate rooms, unless those C-PECs used for nonsterile compounding are sufficiently effective that the room can continuously maintain ISO 7 classification throughout the nonsterile compounding activity. If the C-PECs used for sterile and nonsterile compounding are placed in the same room, they must be placed at least 1 meter apart and particle-generating activity must not be performed when sterile compounding is in process.

5.3.1 NONSTERILE COMPOUNDING

In addition to this chapter, nonsterile compounding must follow standards in *Pharmaceutical Compounding—Nonsterile Preparations* ⟨795⟩. A C-PEC is not required if manipulations are limited to handling of final dosage forms (e.g., counting or repackaging of tablets and capsules) that do not produce particles, aerosols, or gasses.

The C-PECs used for manipulation of nonsterile HDs must be either externally vented (preferred) or have redundant-HEPA filters in series. Nonsterile HD compounding must be performed in a C-PEC that provides personnel and environmental protection, such as a Class I Biological Safety Cabinet (BSC) or Containment Ventilated Enclosure (CVE). A Class II BSC or a compounding aseptic containment isolator (CACI) may also be used. For occasional nonsterile HD compounding, a C-PEC used for sterile compounding (e.g., Class II BSC or CACI) may be used but must be decontaminated, cleaned, and disinfected before resuming sterile compounding in that C-PEC. A C-PEC used only for nonsterile compounding does not require unidirectional airflow because the critical environment does not need to be ISO classified.

The C-PEC must be placed in a C-SEC that has at least 12 ACPH. *Table 2* summarizes the engineering controls required for nonsterile HD compounding.

Due to the difficulty of cleaning HD contamination, surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in the nonsterile compounding area must be smooth, impervious, free from cracks and crevices, and non-shedding.

Table 2. Engineering Controls for Nonsterile HD Compounding

C-PEC	C-SEC Requirements
• Externally vented (preferred) or redundant-HEPA filtered in series • Examples: CVE, Class I or II BSC, CACI	• Externally vented • 12 ACPH • Negative pressure between 0.01 and 0.03 inches of water column relative to adjacent areas

5.3.2 STERILE COMPOUNDING

In addition to this chapter, sterile compounding must follow standards in ⟨797⟩.

All C-PECs used for manipulation of sterile HDs must be externally vented. Sterile HD compounding must be performed in a C-PEC that provides an ISO Class 5 or better air quality, such as a Class II or III BSC or CACI. Class II BSC types A2, B1, or B2 are acceptable. For most known HDs, type A2 cabinets offer a simple and reliable integration with the ventilation and pressurization requirements of the C-SEC. Class II type B2 BSCs are typically reserved for use with volatile components. *Appendix 3* describes the different types of BSCs.

A laminar airflow workbench (LAFW) or compounding aseptic isolator (CAI) must not be used for the compounding of an antineoplastic HD. A BSC or CACI used for the preparation of HDs must not be used for the preparation of a non-HD unless the non-HD preparation is placed into a protective outer wrapper during removal from the C-PEC and is labeled to require PPE handling precautions.

The C-PEC must be located in a C-SEC, which may either be an ISO Class 7 buffer room with an ISO Class 7 ante-room (preferred) or an unclassified containment segregated compounding area (C-SCA). If the C-PEC is placed in a C-SCA, the beyond-use date (BUD) of all compounded sterile preparations (CSPs) prepared must be limited as described in ⟨797⟩ for CSPs prepared in a segregated compounding area. *Table 3* summarizes the engineering

controls required for sterile HD compounding.

Table 3. Engineering Controls for Sterile HD Compounding

Configuration	C-PEC	C-SEC	Maximum BUD
ISO Class 7 buffer room with an ISO Class 7 ante-room	• Externally vented • Examples: Class II BSC or CACI	• Externally vented • 30 ACPH • Negative pressure between 0.01 and 0.03 inches of water column relative to adjacent areas	As described in ⟨797⟩
Unclassified C-SCA	• Externally vented • Examples: Class II BSC or CACI	• Externally vented • 12 ACPH • Negative pressure between 0.01 and 0.03 inches of water column relative to adjacent areas	As described in ⟨797⟩ for CSPs prepared in a segregated compounding area

ISO Class 7 buffer room with an ISO class 7 ante-room: The C-PEC is placed in an ISO Class 7 buffer room that has fixed walls, HEPA-filtered supply air, a negative pressure between 0.01 and 0.03 inches of water column relative to all adjacent areas and a minimum of 30 ACPH.

The buffer room must be externally vented. Because the room through which entry into the HD buffer room (e.g., ante-room or non-HD buffer room) plays an important role in terms of total contamination control, the following is required:

- Minimum of 30 ACPH of HEPA-filtered supply air
- Maintain a positive pressure of at least 0.02 inches of water column relative to all adjacent unclassified areas
- Maintain an air quality of ISO Class 7 or better

An ISO Class 7 ante-room with fixed walls is necessary to provide inward air migration of equal cleanliness classified air into the negative pressure buffer room to contain any airborne HD. A hand-washing sink must be placed in the ante-room at least 1 meter from the entrance to the HD buffer room to avoid contamination migration into the negative pressure HD buffer room.

Although not a recommended facility design, if the negative-pressure HD buffer room is

entered though the positive-pressure non-HD buffer room, the following is also required:

- A line of demarcation must be defined within the negative-pressure buffer room for donning and doffing PPE
- A method to transport HDs, HD CSPs, and HD waste into and out of the negative pressure buffer room to minimize the spread of HD contamination. This may be accomplished by use of a pass-through chamber between the negative-pressure buffer area and adjacent space. The pass-through chamber must be included in the facility's certification to ensure that particles are not compromising the air quality of the negative-pressure buffer room. A refrigerator pass-through must not be used. Other methods of containment (such as sealed containers) may be used.

HD CSPs prepared in an ISO Class 7 buffer room with an ISO Class 7 ante-room may use the BUDs described in ⟨797⟩, based on the categories of CSP, sterility testing, and storage temperature.

Containment segregated compounding area (C-SCA): The C-PEC is placed in an unclassified C-SCA that has fixed walls, a negative pressure between 0.01 and 0.03 inches of water column relative to all adjacent areas, and a minimum of 12 ACPH. The C-SCA must be externally vented. A hand-washing sink must be placed at least 1 meter from C-PEC and may be either inside the C-SCA or directly outside the C-SCA.

Only low- and medium-risk HD CSPs may be prepared in a C-SCA. HD CSPs prepared in the C-SCA must not exceed the BUDs described in ⟨797⟩ for CSPs prepared in a segregated compounding area.

5.4 Containment Supplemental Engineering Controls

Containment supplemental engineering controls, such as CSTDs, provide adjunct controls to offer an additional level of protection during compounding or administration. Some CSTDs have been shown to limit the potential of generating aerosols during compounding. However, there is no certainty that all CSTDs will perform adequately. Until a published universal performance standard for evaluation of CSTD containment is available, users should carefully evaluate the performance claims associated with available CSTDs based on independent, peer-reviewed studies and demonstrated containment reduction.

A CSTD must not be used as a substitute for a C-PEC when compounding. CSTDs should be used when compounding HDs when the dosage form allows. CSTDs must be used when administering antineoplastic HDs when the dosage form allows. CSTDs known to be physically or chemically incompatible with a specific HD must not be used for that HD.

6. ENVIRONMENTAL QUALITY AND CONTROL

Environmental wipe sampling for HD surface residue should be performed routinely (e.g., initially as a benchmark and at least every 6 months, or more often as needed, to verify containment). Surface wipe sampling should include:

- Interior of the C-PEC and equipment contained in it
- Pass-through chambers
- Surfaces in staging or work areas near the C-PEC
- Areas adjacent to C-PECs (e.g., floors directly under C-PEC, staging, and dispensing area)
- Areas immediately outside the HD buffer room or the C-SCA
- Patient administration areas

There are currently no studies demonstrating the effectiveness of a specific number or size of

wipe samples in determining levels of HD contamination. Wipe sampling kits should be verified before use to ensure the method and reagent used have been tested to recover a specific percentage of known marker drugs from various surface types found in the sampled area. There are currently no certifying agencies for vendors of wipe sample kits.

There is currently no standard for acceptable limits for HD surface contamination. Common marker HDs that can be assayed include cyclophosphamide, ifosfamide, methotrexate, fluorouracil, and platinum-containing drugs. An example of measurable contamination would be cyclophosphamide levels >1.00 ng/cm^2, which were shown in some studies to result in uptake of the drug in exposed workers. If any measurable contamination is found, the designated person must identify, document, and contain the cause of contamination. Such action may include reevaluating work practices, re-training personnel, performing thorough deactivation, decontamination, cleaning, and improving engineering controls. Repeat the wipe sampling to validate that the deactivation/decontamination and cleaning steps have been effective.

7. PERSONAL PROTECTIVE EQUIPMENT

Personal Protective Equipment (PPE) provides worker protection to reduce exposure to HD aerosols and residues. Additional PPE may be required to handle the HDs outside of a C-PEC, such as treating a patient or cleaning a spill. The NIOSH list of antineoplastic and other HDs provides general guidance on PPE for possible scenarios that may be encountered in healthcare settings. Disposable PPE must not be re-used. Reusable PPE must be decontaminated and cleaned after use.

Gowns, head, hair, shoe covers, and two pairs of chemotherapy gloves are required for compounding sterile and nonsterile HDs. Two pairs of chemotherapy gloves are required for administering antineoplastic HDs. Gowns shown to resist permeability by HDs are required when administering injectable antineoplastic HDs. For all other activities, the entity's SOP must describe the appropriate PPE to be worn based on its occupational safety plan and assessment of risk (if used). The entity must develop SOPs for PPE based on the risk of exposure (see *Types of Exposure*) and activities performed.

Appropriate PPE must be worn when handling HDs including during:

- Receipt
- Storage
- Transport
- Compounding (sterile and nonsterile)
- Administration
- Deactivation/decontamination, cleaning, and disinfecting
- Spill control
- Waste disposal

7.1 Gloves

When chemotherapy gloves are required, they must meet American Society for Testing and Materials (ASTM) standard D6978 (or its successor). Chemotherapy gloves should be worn for handling all HDs including non-antineoplastics and for reproductive risk only HDs. Chemotherapy gloves must be powder-free because powder can contaminate the work area and can adsorb and retain HDs. Gloves must be inspected for physical defects before use. Do not use gloves with pin holes or weak spots.

When used for sterile compounding, the outer chemotherapy gloves must be sterile.

Chemotherapy gloves should be changed every 30 minutes unless otherwise recommended by the manufacturer's documentation and must be changed when torn, punctured, or contaminated. Hands must be washed with soap and water after removing gloves.

7.2 Gowns

When gowns are required, they must be disposable and shown to resist permeability by HDs. Gowns must be selected based on the HDs handled. Disposable gowns made of polyethylene-coated polypropylene or other laminate materials offer better protection than those made of uncoated materials. Gowns must close in the back (i.e., no open front), be long sleeved, and have closed cuffs that are elastic or knit. Gowns must not have seams or closures that could allow HDs to pass through.

Cloth laboratory coats, surgical scrubs, isolation gowns, or other absorbent materials are not appropriate protective outerwear when handling HDs because they permit the permeation of HDs and can hold spilled drugs against the skin, thereby increasing exposure. Clothing may also retain HD residue from contact, and may transfer to other healthcare workers or various surfaces. Washing of non-disposable clothing contaminated with HD residue should only be done according to facility policy as drug residue may be transferred to other clothing. Potentially contaminated clothing must not be taken home under any circumstances.

Gowns must be changed per the manufacturer's information for permeation of the gown. If no permeation information is available for the gowns used, change them every 2–3 hours or immediately after a spill or splash. Gowns worn in HD handling areas must not be worn to other areas in order to avoid spreading HD contamination and exposing other healthcare workers.

7.3 Head, Hair, Shoe, and Sleeve Covers

Head and hair covers (including beard and moustache, if applicable), shoe covers, and sleeve covers provide protection from contact with HD residue. When compounding HDs, a second pair of shoe covers must be donned before entering the C-SEC and doffed when exiting the C-SEC. Shoe covers worn in HD handling areas must not be worn to other areas to avoid spreading HD contamination and exposing other healthcare workers.

Disposable sleeve covers may be used to protect areas of the arm that may come in contact with HDs. Disposable sleeve covers made of polyethylene-coated polypropylene or other laminate materials offer better protection than those made of uncoated materials.

7.4 Eye and Face Protection

Many HDs are irritating to the eyes and mucous membranes. Appropriate eye and face protection must be worn when there is a risk for spills or splashes of HDs or HD waste materials when working outside of a C-PEC (e.g., administration in the surgical suite, working at or above eye level, or cleaning a spill). A full-facepiece respirator provides eye and face protection. Goggles must be used when eye protection is needed. Eye glasses alone or safety glasses with side shields do not protect the eyes adequately from splashes. Face shields in combination with goggles provide a full range of protection against splashes to the face and eyes. Face shields alone do not provide full eye and face protection.

7.5 Respiratory Protection

Personnel who are unpacking HDs that are not contained in plastic should wear an elastomeric half-mask with a multi-gas cartridge and P100-filter until assessment of the packaging integrity can be made to ensure no breakage or spillage occurred during transport. If the type of drug can be better defined, a more targeted cartridge can be used.

Surgical masks do not provide respiratory protection from drug exposure and must not be used when respiratory protection from HD exposure is required. A surgical N95 respirator provides the respiratory protection of an N95 respirator, and like a surgical mask, provides a barrier to splashes, droplets, and sprays around the nose and mouth.

For most activities requiring respiratory protection, a fit-tested NIOSH-certified N95 or more protective respirator is sufficient to protect against airborne particles. However, N95 respirators offer no protection against gases and vapors and little protection against direct liquid splashes (see the Centers for Disease Control and Prevention's (CDC's) Respirator Trusted-Source Information).

Fit test the respirator and train workers to use respiratory protection. Follow all requirements in the Occupational Safety and Health Administration (OSHA) respiratory protection standard (29 CFR 1910.134). An appropriate full-facepiece, chemical cartridge-type respirator or powered air-purifying respirator (PAPR) should be worn when there is a risk of respiratory exposure to HDs, including when:

- Attending to HD spills larger than what can be contained with a spill kit
- Deactivating, decontaminating, and cleaning underneath the work surface of a C-PEC
- There is a known or suspected airborne exposure to powders or vapors

7.6 Disposal of Used Personal Protective Equipment

Consider all PPE worn when handling HDs to be contaminated with, at minimum, trace quantities of HDs. PPE must be placed in an appropriate waste container and further disposed of per local, state, and federal regulations. PPE worn during compounding should be disposed of in the proper waste container before leaving the C-SEC. Chemotherapy gloves and sleeve covers (if used) worn during compounding must be carefully removed and discarded immediately into a waste container approved for trace contaminated waste inside the C-PEC or contained in a sealable bag for discarding outside the C-PEC.

8. HAZARD COMMUNICATION PROGRAM

Entities are required to establish policies and procedures that ensure worker safety during all aspects of HD handling. The entity must develop SOPs to ensure effective training regarding proper labeling, transport, storage, and disposal of the HDs and use of Safety Data Sheets (SDS), based on the Globally Harmonized System of Classification and Labeling of Chemicals (GHS).

Elements of the hazard communication program plan must include:

- A written plan that describes how the standard will be implemented
- All containers of hazardous chemicals must be labeled, tagged, or marked with the identity of the material and appropriate hazard warnings
- Entities must have an SDS for each hazardous chemical they use (29 CFR 1910.1200)
- Entities must ensure that the SDSs for each hazardous chemical used are readily accessible to personnel during each work shift and when they are in their work areas
- Personnel who may be exposed to hazardous chemicals when working must be provided information and training before the initial assignment to work with a hazardous chemical, and also whenever the hazard changes
- Personnel of reproductive capability must confirm in writing that they understand the risks of handling HDs

9. PERSONNEL TRAINING

All personnel who handle HDs must be trained based on their job functions (e.g., in the receipt, storage, compounding, repackaging, dispensing, administrating, and disposing of HDs). Training must occur before the employee independently handles HDs. The effectiveness of training for HD handling competencies must be demonstrated by each employee. Personnel competency must be reassessed at least every 12 months. Personnel must be trained prior to the introduction of a new HD or new equipment and prior to a new or significant change in process or SOP. All training and competency assessment must be documented.

The training must include at least the following:

- Overview of entity's list of HDs and their risks
- Review of the entity's SOPs related to handling of HDs
- Proper use of PPE
- Proper use of equipment and devices (e.g., engineering controls)
- Response to known or suspected HD exposure
- Spill management
- Proper disposal of HDs and trace-contaminated materials

10. RECEIVING

The entity must establish SOPs for receiving HDs. HDs should be received from the supplier in impervious plastic to segregate them from other drugs and to allow for safety in the receiving and internal transfer process. HDs must be delivered to the HD storage area immediately after unpacking.

PPE, including chemotherapy gloves, must be worn when unpacking HDs (see *Personal Protective Equipment*). A spill kit must be accessible in the receiving area.

The entity must enforce policies that include a tiered approach, starting with visual examination of the shipping container for signs of damage or breakage (e.g., visible stains from leakage, sounds of broken glass). *Table 4* summarizes the steps for receiving and handling of damaged shipping containers.

Table 4. Summary of Requirements for Receiving and Handling Damaged HD Shipping Containers

If the shipping container appears damaged	• Seal container without opening and contact the supplier • If the unopened package is to be returned to the supplier, enclose the package in an impervious container and label the outer container "Hazardous" • If the supplier declines return, dispose of as hazardous waste
If a damaged shipping container must be opened	• Seal the container in plastic or an impervious container • Transport it to a C-PEC and place on a plastic-backed preparation mat • Open the package and remove undamaged items • Wipe the outside of the undamaged items with a disposable wipe • Enclose the damaged item(s) in an impervious container and label the outer container "Hazardous" • If the supplier declines return, dispose of as hazardous waste • Deactivate, decontaminate, and clean the C-PEC (see *Deactivating, Decontaminating, Cleaning, and Disinfecting*) and discard the mat and cleaning disposables as hazardous waste

When opening damaged shipping containers, they should preferably be transported to a C-PEC designated for nonsterile compounding. If a C-PEC designated for sterile compounding is the only one available, it must be disinfected after the decontamination, deactivation, and cleaning step before returning to any sterile compounding activity.

Damaged packages or shipping cartons must be considered spills that must be reported to the designated person and managed according to the entity's SOPs. Segregate HDs waiting to be returned to the supplier in a designated negative pressure area. Clean-up must comply with established SOPs.

11. LABELING, PACKAGING, TRANSPORT AND DISPOSAL

The entity must establish SOPs for the labeling, packaging, transport, and disposal of HDs. The SOPs must address prevention of accidental exposures or spills, personnel training on response to exposure, and use of a spill kit. Examples of special exposure-reducing strategies include small-bore connectors (such as Luer Lock) and syringes, syringe caps, CSTDs, the capping of container ports, sealed impervious plastic bags, impact-resistant and/or water-tight containers, and cautionary labeling.

11.1 Labeling

HDs identified by the entity as requiring special HD handling precautions must be clearly labeled at all times during their transport. Personnel must ensure that the labeling processes for compounded preparations do not introduce contamination into the non-HD handling areas.

11.2 Packaging

Personnel must select and use packaging containers and materials that will maintain physical integrity, stability, and sterility (if needed) of the HDs during transport. Packaging materials must protect the HD from damage, leakage, contamination, and degradation, while protecting healthcare workers who transport HDs. The entity must have written SOPs to describe appropriate shipping containers and insulating materials, based on information from product specifications, vendors, and mode of transport.

11.3 Transport

HDs that need to be transported must be labeled, stored, and handled in accordance with applicable federal, state, and local regulations. HDs must be transported in containers that minimize the risk of breakage or leakage. Pneumatic tubes must not be used to transport any liquid HDs or any antineoplastic HDs because of the potential for breakage and contamination.

When shipping HDs to locations outside the entity, the entity must consult the Transport Information on the SDS. The entity must ensure that labels and accessory labeling for the HDs include storage instructions, disposal instructions, and HD category information in a format that is consistent with the carrier's policies.

11.4 Disposal

All personnel who perform routine custodial waste removal and cleaning activities in HD handling areas must be trained in appropriate procedures to protect themselves and the environment to prevent HD contamination. Disposal of all HD waste, including, but not limited to, unused HDs and trace-contaminated PPE and other materials, must comply with all applicable federal, state, and local regulations.

12. DISPENSING FINAL DOSAGE FORMS

HDs that do not require any further manipulation, other than counting or repackaging of final dosage forms, may be prepared for dispensing without any further requirements for containment unless required by the manufacturer or if visual indicators of HD exposure hazards are present (e.g., HD dust or leakage).

Counting or repackaging of HDs must be done carefully. Clean equipment should be dedicated for use with HDs and should be decontaminated after every use. Tablet and capsule forms of antineoplastic HDs must not be placed in automated counting or packaging machines, which subject them to stress and may create powdered contaminants.

13. COMPOUNDING

Entities and personnel involved in compounding HDs must be compliant with the appropriate USP standards for compounding including ⟨795⟩ and ⟨797⟩. Compounding must be done in proper engineering controls as described in *Compounding*. When compounding HD preparations in a C-PEC, a plastic-backed preparation mat should be placed on the work surface of the C-PEC. The mat should be changed immediately if a spill occurs and regularly during use, and should be discarded at the end of the daily compounding activity. Disposable or clean equipment for compounding (such as mortars and pestles, and spatulas) must be dedicated for use with HDs.

Bulk containers of liquid and API HD must be handled carefully to avoid spills. If used, APIs or other powdered HDs must be handled in a C-PEC to protect against occupational exposure, especially during particle-generating activities (such as crushing tablets, opening capsules, and weighing powder).

14. ADMINISTERING

HDs must be administered safely using protective medical devices and techniques. Examples of protective medical devices include needleless and closed systems. Examples of protective techniques include spiking or priming of IV tubing with a non-HD solution in a C-PEC and crushing tablets in a plastic pouch.

Appropriate PPE must be worn when administering HDs. After use, PPE must be removed and disposed of in a waste container approved for trace-contaminated HD waste at the site of drug administration. Equipment (such as tubing and needles) and packaging materials must be disposed of properly, such as in HD waste containers, after administration.

CSTDs must be used for administration of antineoplastic HDs when the dosage form allows. Techniques and ancillary devices that minimize the risk posed by open systems must be used when administering HDs through certain routes. Administration into certain organs or body cavities (e.g., the bladder, eye, peritoneal cavity, or chest cavity) often requires equipment for which locking connections may not be readily available or possible.

Healthcare personnel should avoid manipulating HDs such as crushing tablets or opening capsules if possible. Liquid formulations are preferred if solid oral dosage forms are not appropriate for the patient. If HD dosage forms do require manipulation such as crushing tablet(s) or opening capsule(s) for a single dose, personnel must don appropriate PPE and use a plastic pouch to contain any dust or particles generated.

15. DEACTIVATING, DECONTAMINATING, CLEANING, AND DISINFECTING

All areas where HDs are handled and all reusable equipment and devices must be

deactivated, decontaminated, and cleaned. Additionally, sterile compounding areas and devices must be subsequently disinfected.

The entity must establish written procedures for decontamination, deactivation, and cleaning, and for sterile compounding areas disinfection. Additionally, cleaning of nonsterile compounding areas must comply with ⟨795⟩ and cleaning of sterile compounding areas must comply with ⟨797⟩. Written procedures for cleaning must include procedures, agents used, dilutions (if used), frequency, and documentation requirements.

All personnel who perform deactivation, decontamination, cleaning, and disinfection activities in HD handling areas must be trained in appropriate procedures to protect themselves and the environment from contamination. All personnel performing these activities must wear appropriate PPE resistant to the cleaning agents used, including two pairs of chemotherapy gloves and impermeable disposable gowns (see *Personal Protective Equipment*). Additionally, eye protection and face shields must be used if splashing is likely. If warranted by the activity, respiratory protection must be used.

The deactivating, decontaminating, cleaning, and disinfecting agents selected must be appropriate for the type of HD contaminant(s), location, and surface materials. The products used must be compatible with the surface material. Consult manufacturer or supplier information for compatibility with cleaning agents used. Agents used for deactivation, decontamination, and cleaning should be applied through the use of wipes wetted with appropriate solution and not delivered by a spray bottle to avoid spreading HD residue. All disposable materials must be discarded to meet EPA regulations and the entity's policies. Perform cleaning in areas that are sufficiently ventilated. *Table 5* summarizes the purpose and example agents for each step.

Table 5. Cleaning Steps

Cleaning Step	Purpose	Example Agents
Deactivation	Render compound inert or inactive	As listed in the HD labeling or other agents which may incorporate Environmental Protection Agency (EPA)-registered oxidizers (e.g., peroxide formulations, sodium hypochlorite, etc.)
Decontamination	Remove HD residue	Materials that have been validated to be effective for HD decontamination, or through other materials proven to be effective through testing, which may include alcohol, water, peroxide, or sodium hypochlorite
Cleaning	Remove organic and inorganic material	Germicidal detergent
Disinfection (for sterile manipulations)	Destroy microorganisms	EPA-registered disinfectant and/or sterile alcohol as appropriate for use

15.1 Deactivation

Deactivation renders a compound inert or inactive. Residue from deactivation must be removed by decontaminating the surface.

There is no one proven method for deactivating all compounds. The ultimate goal should be

complete surface decontamination. Products that have known deactivation properties (EPA-registered oxidizing agents that are appropriate for the intended use) should be used when possible. Care should be taken when selecting materials for deactivation due to potential adverse effects (hazardous byproducts, respiratory effects, and caustic damage to surfaces). Damage to surfaces is exhibited by corrosion to stainless steel surfaces caused by sodium hypochlorite if left untreated. To prevent corrosion, sodium hypochlorite must be neutralized with sodium thiosulfate or by following with an agent to remove the sodium hypochlorite (e.g., sterile alcohol, sterile water, germicidal detergent, or sporicidal agent).

15.2 Decontamination

Decontamination occurs by inactivating, neutralizing, or physically removing HD residue from non-disposable surfaces and transferring it to absorbent, disposable materials (e.g., wipes, pads, or towels) appropriate to the area being cleaned. When choosing among various products available for decontaminating HDs, consideration should be given to surface compatibility and facility requirements. It is imperative to adhere to manufacturer's use instructions. Because of the growing number of assays available for HDs, additional surface wipe sampling is now possible and should be done to document the effectiveness of any agent used for decontamination of HD residue from work surfaces (see *Environmental Quality and Control*).

The amount of HD contamination introduced into the C-PEC may be reduced by wiping down HD containers. The solution used for wiping HD packaging must not alter the product label. The work surface of the C-PEC must be decontaminated between compounding of different HDs. The C-PEC must be decontaminated at least daily (when used), any time a spill occurs, before and after certification, any time voluntary interruption occurs, and if the ventilation tool is moved.

C-PECs may have areas under the work tray where contamination can build up. These areas must be deactivated, decontaminated, and cleaned at least monthly to reduce the contamination level in the C-PEC. Accessing this area may be difficult. Deactivate, decontaminate, and clean as much as possible of the C-PEC surfaces before accessing the area under the work tray. When deactivating, decontaminating, and cleaning the area under the work tray of a C-PEC, the containment airflows are compromised by opening the cabinets. To provide protection to the worker performing this task, respiratory protection may be required.

15.3 Cleaning

Cleaning is a process that results in the removal of contaminants (e.g., soil, microbial contamination, HD residue) from objects and surfaces using water, detergents, surfactants, solvents, and/or other chemicals. Cleaning agents used on compounding equipment should not introduce microbial contamination. No cleaning step may be performed when compounding activities are occurring.

15.4 Disinfection

Disinfection is a process of inhibiting or destroying microorganisms. Before disinfection can be adequately performed, surfaces must be cleaned. Disinfection must be done for areas intended to be sterile, including the sterile compounding areas.

16. SPILL CONTROL

All personnel who may be required to clean up a spill of HDs must receive proper training in spill management and the use of PPE and NIOSH-certified respirators (see *Personal Protective Equipment*). Spills must be contained and cleaned immediately only by qualified personnel with

appropriate PPE. Qualified personnel must be available at all times while HDs are being handled. Signs must be available for restricting access to the spill area. Spill kits containing all of the materials needed to clean HD spills must be readily available in all areas where HDs are routinely handled. If HDs are being prepared or administered in a non-routine healthcare area, a spill kit and respirator must be available. All spill materials must be disposed of as hazardous waste.

The circumstances and management of spills must be documented. Personnel who are potentially exposed during the spill or spill clean up or who have direct skin or eye contact with HDs require immediate evaluation. Non-employees exposed to an HD spill should follow entity policy, which may include reporting to the designated emergency service for initial evaluation and completion of an incident report or exposure form.

SOPs must be developed to prevent spills and to direct the clean up of HD spills. SOPs must address the size and scope of the spill and specify who is responsible for spill management and the type of PPE required. The management of the spill (e.g., decontamination, deactivation, and cleaning) may be dependent on the size and type of spill. The SOP must address the location of spill kits and clean-up materials as well as the capacity of the spill kit. Written procedures should address use of appropriate full-facepiece, chemical cartridge-type respirators if the capacity of the spill kit is exceeded or if there is known or suspected airborne exposure to vapors or gases.

17. DOCUMENTATION AND STANDARD OPERATING PROCEDURES

The entity must maintain SOPs for the safe handling of HDs for all situations in which these HDs are used throughout a facility. The SOPs must be reviewed at least every 12 months by the designated person, and the review must be documented. Revisions in forms or records must be made as needed and communicated to all personnel handling HDs.

The SOPs for handling of HDs should include:

- Hazard communication program
- Occupational safety program
- Designation of HD areas
- Receipt
- Storage
- Compounding
- Use and maintenance of proper engineering controls (e.g., C-PECs, C-SECs, and CSTDs)
- Hand hygiene and use of PPE based on activity (e.g., receipt, transport, compounding, administration, spill, and disposal)
- Deactivation, decontamination, cleaning, and disinfection
- Dispensing
- Transport
- Administering
- Environmental monitoring (e.g., wipe sampling)
- Disposal
- Spill control
- Medical surveillance

Personnel who transport, compound, or administer HDs must document their training according to OSHA standards (see OSHA Standard 1910.120 Hazardous Waste Operations and Emergency Response) and other applicable laws and regulations.

18. MEDICAL SURVEILLANCE

Medical surveillance is part of a comprehensive exposure control program complementing engineering controls, safe work processes, and use of PPE. Healthcare workers who handle HDs as a regular part of their job assignment should be enrolled in a medical surveillance program. The general purpose of surveillance is to minimize adverse health effects in personnel potentially exposed to HDs. Medical surveillance programs involve assessment and documentation of symptom complaints, physical findings, and laboratory values (such as a blood count) to determine whether there is a deviation from the expected norms.

Medical surveillance can also be viewed as a secondary prevention tool that may provide a means of early detection if a health problem develops. Tracking personnel through medical surveillance allows the comparison of health variables over time in individual workers, which may facilitate early detection of a change in a laboratory value or health condition. Medical surveillance programs also look for trends in populations of workers. Examining grouped data compared with data from unexposed workers may reveal a small alteration or increase in the frequency of a health effect that would be obscured if individual workers' results alone were considered.

Medical surveillance evaluates the protection afforded by engineering controls, other administrative controls, safe work processes, PPE, and worker education about the hazards of the materials they work with in the course of their duties. The data-gathering elements of a medical surveillance program are used to establish a baseline of workers' health and then to monitor their future health for any changes that may result from exposure to HDs.

Elements of a medical surveillance program should be consistent with the entity's Human Resource policies and should include:

- Development of an organized approach to identify workers who are potentially exposed to HDs on the basis of their job duties
- Use of an entity-based or contracted employee health service to perform the medical surveillance while protecting the confidentiality of the employees' personal medical information
- Initial baseline assessment (pre-placement) of a worker's health status and medical history. Data elements collected include a medical (including reproductive) history and work history to assess exposure to HDs, physical examination, and laboratory testing. Methods used to assess exposure history include a review of:
    - — Records of HDs handled, with quantities and dosage forms
    - — Estimated number of HDs handled per week
    - — Estimates of hours spent handling HDs per week and/or per month
    - — Performance of a physical assessment and laboratory studies linked to target organs of commonly used HDs, such as a baseline complete blood count. Biological monitoring to determine blood or urine levels of specific HDs is not currently recommended in surveillance protocols, but may have a role in the follow-up of acute spills with a specific agent.
- Medical records of surveillance should be maintained according to OSHA regulation concerning access to employee exposure and medical records
- Monitoring workers' health prospectively through periodic surveillance using the elements of data gathering described above (updated health and exposure history, physical assessment, and laboratory measures, if appropriate)
- Monitoring of the data to identify prevention failure leading to health effects; this

monitoring may occur in collaboration with the employee health service

- Development of a follow-up plan for workers who have shown health changes suggesting toxicity or who have experienced an acute exposure. This follow-up should include evaluation of current engineering and administrative controls and equipment to ensure that all systems are appropriately and accurately implemented (see *Follow-Up Plan*)
- Completion of an exit examination when a worker's employment at the entity ends, to document the information on the employee's medical, reproductive, and exposure histories. Examination and laboratory evaluation should be guided by the individual's history of exposures and follow the outline of the periodic evaluation

18.1 Follow-Up Plan

The occurrence of exposure-related health changes should prompt immediate re-evaluation of primary preventive measures (e.g., administrative and engineering controls, PPE, and others). In this manner, medical surveillance acts as a check on the effectiveness of controls already in use.

The entity should take the following actions:

- Perform a post-exposure examination tailored to the type of exposure (e.g., spills or needle sticks from syringes containing HDs). An assessment of the extent of exposure should be conducted and included in a confidential database and in an incident report. The physical examination should focus on the involved area as well as other organ systems commonly affected (i.e., the skin and mucous membranes for direct contact or inhalation; the pulmonary system for aerosolized HDs). Treatment and laboratory studies will follow as indicated and be guided by emergency protocols
- Compare performance of controls with recommended standards; conduct environmental sampling when analytical methods are available
- Verify and document that all engineering controls are in proper operating condition
- Verify and document that the worker complied with existing policies. Review policies for the use of PPE and employee compliance with PPE use and policies. Review availability of appropriate PPE (see *Personal Protective Equipment*)
- Develop and document a plan of action that will prevent additional exposure of workers
- Ensure confidential, two-way communication between the worker and the employee health unit(s) regarding notification, discussions about a change in health condition, or detection of an adverse health effect
- Provide and document a follow-up medical survey to demonstrate that the plan implemented is effective
- Ensure that any exposed worker receives confidential notification of any adverse health effect. Offer alternative duty or temporary reassignment
- Provide ongoing medical surveillance of all workers at risk for exposure to HDs to determine whether the plan implemented is effective

GLOSSARY

Active pharmaceutical ingredient (API): Any substance or mixture of substances intended to be used in the compounding of a drug preparation, thereby becoming the active ingredient in that preparation and furnishing pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans and animals or affecting the structure and function of the body.

Alternative duty: Performance of other tasks that do not include the direct handling of HDs.
Ante-room: An ISO Class 7 or cleaner room where personnel hand hygiene, garbing procedures, and other activities that generate high particulate levels are performed. The ante-room is the transition room between the unclassified area of the facility and the buffer room.
Assessment of risk: Evaluation of risk to determine alternative containment strategies and/or work practices.
Beyond-use date (BUD): The date or time beyond which a compounded preparation cannot not be used and must be discarded (see ⟨795⟩ and ⟨797⟩). The date or time is determined from the date or time when the preparation was compounded.
Biological safety cabinet (BSC): A ventilated cabinet often used for preparation of hazardous drugs. These cabinets are divided into three general classes (Class I, Class II, and Class III). Class II BSCs are further divided into types (Type A1, Type A2, Type B1, and Type B2). See *Appendix 3* for details.
Buffer room: A type of C-SEC under negative pressure that meets ISO Class 7 or better air quality where the C-PEC that generates and maintains an ISO Class 5 environment is physically located. Activities that occur in this area are limited to the preparation and staging of components and supplies used when compounding HDs.
Chemotherapy glove: A medical glove that meets the ASTM Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs (D6978) or its successor.
Classified space: An area that maintains an air cleanliness classification based on the International Organization for Standardization (ISO).
Cleaning: The process of removing soil (e.g., organic and inorganic material) from objects and surfaces, normally accomplished by manually or mechanically using water with detergents or enzymatic products.
Closed-system drug-transfer device (CSTD): A drug-transfer device that mechanically prohibits the transfer of environmental contaminants into the system and the escape of HD or vapor concentrations outside the system.
Compounded preparation: A nonsterile or sterile drug or nutrient preparation that is compounded in a licensed pharmacy or other healthcare-related facility in response to or anticipation of a prescription or a medication order from a licensed prescriber.
Compounding aseptic containment isolator (CACI): A specific type of CAI that is designed for the compounding of sterile HDs. The CACI is designed to provide worker protection from exposure to undesirable levels of airborne drugs throughout the compounding and material transfer processes and to provide an aseptic environment with unidirectional airflow for compounding sterile preparations.
Compounding aseptic isolator (CAI): An isolator specifically designed for compounding sterile, non-hazardous pharmaceutical ingredients or preparations. The CAI is designed to maintain an aseptic compounding environment throughout the compounding and material transfer processes.
Compounding personnel: Individuals who participate in the compounding process.
Compounding supervisor: Individual(s) responsible for developing and implementing appropriate procedures; overseeing facility compliance with this chapter and other applicable laws, regulations, and standards; ensuring the competency of personnel; and maintaining environmental control of the compounding areas.
Containment primary engineering control (C-PEC): A ventilated device designed and operated to minimize worker and environmental exposures to HDs by controlling emissions of airborne contaminants through the following:

- The full or partial enclosure of a potential contaminant source
- The use of airflow capture velocities to trap and remove airborne contaminants near their point of generation
- The use of air pressure relationships that define the direction of airflow into the cabinet
- The use of HEPA filtration on all potentially contaminated exhaust streams

Containment secondary engineering control (C-SEC): The room with fixed walls in which the C-PEC is placed. It incorporates specific design and operational parameters required to contain the potential hazard within the compounding room.
Containment segregated compounding area (C-SCA): A type of C-SEC with nominal requirements for airflow and room pressurization as they pertain to HD compounding.
Containment ventilated enclosure (CVE): A full or partial enclosure that uses ventilation principles to capture, contain, and remove airborne contaminants through HEPA filtration and prevent their release into the work environment.
Deactivation: Treatment of an HD contaminant on surfaces with a chemical, heat, ultraviolet light, or another agent to transform the HD into a less hazardous agent.
Decontamination: Inactivation, neutralization, or removal of HD contaminants on surfaces, usually by chemical means.
Doff: To remove PPE.
Don: To put on PPE.
Disinfection: The process of inhibiting or destroying microorganisms.
Engineering control: Primary, secondary, and supplemental devices designed to eliminate or reduce worker exposure to HDs.
EPA-registered disinfectant: Antimicrobial products registered with the Environmental Protection Agency (EPA) for healthcare use against pathogens specified in the product labeling.
Externally vented: Exhausted to the outside
Final dosage form: Any form of a medication that requires no further manipulation before administration.
Globally Harmonized System of Classification and Labeling of Chemicals (GHS): A system for standardizing and harmonizing the classification and labeling of chemicals.
Goggles: Tight-fitting eye protection that completely covers the eyes, eye sockets, and facial area that immediately surrounds the eyes. Goggles provide protection from impact, dust, and splashes. Some goggles fit over corrective lenses.
Hazardous drug (HD): Any drug identified by at least one of the following criteria:

- Carcinogenicity, teratogenicity, or developmental toxicity
- Reproductive toxicity in humans
- Organ toxicity at low dose in humans or animals
- Genotoxicity or new drugs that mimic existing HDs in structure or toxicity

High-efficiency particulate air (HEPA) filtration: An extended-medium, dry-type filter in a rigid frame, having a minimum particle collection efficiency of 99.97% for particles with a mass median diameter of 0.3 μm when tested at a rated airflow in accordance with MIL STD 282 using IEST Recommended Standard RP-CC001.5.
Negative-pressure room: A room that is maintained at a lower pressure than the adjacent areas; therefore the net flow of air is into the room.
Pass-through: An enclosure with interlocking doors that is positioned between two spaces for the purpose of reducing particulate transfer while moving materials from one space to another. A pass-through serving negative-pressure rooms needs to be equipped with sealed doors.

Personal protective equipment (PPE): Items such as gloves, gowns, respirators, goggles, faceshields, and others that protect individual workers from hazardous physical or chemical exposures.

Positive-pressure room: A room that is maintained at a higher pressure than the adjacent areas; therefore, the net flow of air is out of the room.

Repackaging: The act of removing a product from its original primary container and placing it into another primary container, usually of smaller size.

Safety data sheet (SDS): An informational document that provides written or printed material concerning a hazardous chemical. The SDS is prepared in accordance with the HCS [previously known as a Material Safety Data Sheet (MSDS)].

Spill kit: A container of supplies, warning signage, and related materials used to contain the spill of an HD.

Standard operating procedure (SOP): Written procedures describing operations, testing, sampling, interpretation of results, and corrective actions that relate to the operations that are taking place.

Supplemental engineering control: An adjunct control (e.g., CSTD) that may be used concurrently with primary and secondary engineering controls. Supplemental engineering controls offer additional levels of protection and may facilitate enhanced occupational protection, especially when handling HDs outside of primary and secondary engineering controls (e.g., during administering).

Unclassified space: A space not required to meet any air cleanliness classification based on the International Organization for Standardization (ISO).

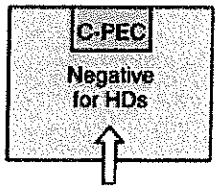
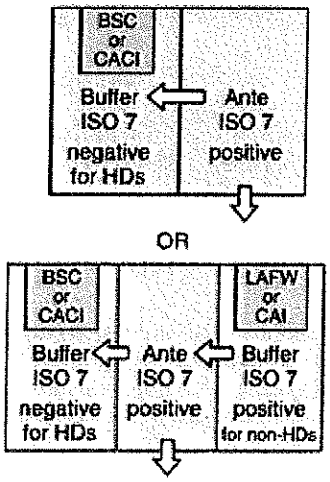
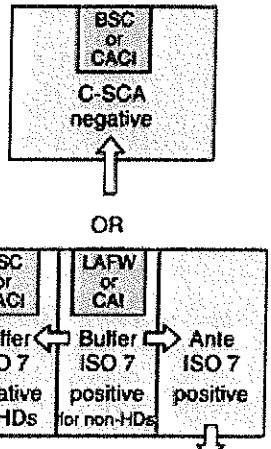
APPENDICES

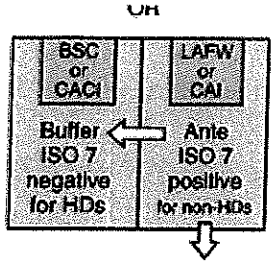
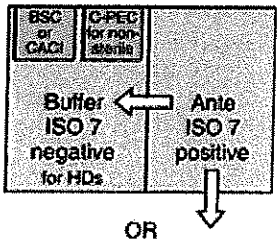
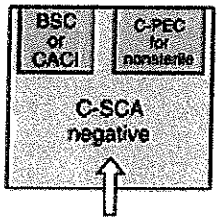
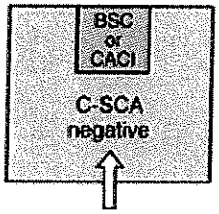
Appendix 1: Acronyms

ACPH	Air changes per hour
API	Active pharmaceutical ingredient
ASTM	American Society for Testing and Materials
BSC	Biological safety cabinet
BUD	Beyond-use date
CACI	Compounding aseptic containment isolator
CAI	Compounding aseptic isolator
CDC	Centers for Disease Control and Prevention
C-PEC	Containment primary engineering control
C-SCA	Containment segregated compounding area
C-SEC	Containment secondary engineering control
CSP	Compounded sterile preparation
CSTD	Closed-system drug-transfer device
CVE	Containment ventilated enclosure

EPA	Environmental Protection Agency
GHS	Globally Harmonized System of Classification and Labeling of Chemicals
HCS	Hazard Communication Standard
HD	Hazardous drug
HEPA	High-efficiency particulate air
IV	Intravenous
LAFW	Laminar airflow workbench
NIOSH	National Institute for Occupational Safety and Health
ONS	Oncology Nursing Society
OSHA	Occupational Safety and Health Administration
PAPR	Powered air-purified respirator
PPE	Personal protective equipment
SDS	Safety Data Sheet
SOP	Standard operating procedure
ULPA	Ultra-low particulate air
UPS	Uninterrupted power source

Appendix 2: Examples of Designs for Hazardous Drug Compounding Areas[a]

Use	Optimal Primary and Secondary Control	Minimum ACPH	Limitations Primary and Secondary Control	Minimum ACPH	Notes for limitations
Nonsterile HD compounding		12			
Sterile HD compounding		30		12 30	Maximum BUD as described in <797> for segregated compounding area. If this design is in place, measures must be taken to avoid contamination of the positive-pressure buffer room.

			 Typically used in oncology clinic settings.	30	Maximum BUD as described in <797>.
Both sterile HD and nonsterile HD compounding	A separate room for sterile and nonsterile compounding is recommended		 OR  OR 	30 12 12	For rooms used for both sterile and nonsterile compounding, particle-generating activity must not be performed when sterile compounding is in process. C-PECs must be at least 1 meter apart. Maximum BUD as described in <797> for segregated compounding area. Maximum BUD as described in <797> for segregated compounding area.

[a] The arrows indicate direction of airflow.

Appendix 3: Types of Biological Safety Cabinets

Class I: A BSC that protects personnel and the environment but does not protect the product/preparation. A minimum velocity of 75 linear feet/minute of unfiltered room air is drawn through the front opening and across the work surface, providing personnel protection. The air is then passed through a HEPA/ULPA (ultra-low particulate air) filter, either into the room or to the outside in the exhaust plenum, providing environmental protection.
Class II: Class II (Types A1, A2, B1, and B2) BSCs are partial barrier systems that rely on the movement of air to provide personnel, environmental, and product/preparation protection. Personnel and product/preparation protection are provided by the combination of inward and downward airflow captured by the front grille of the cabinet. Side-to-side cross-contamination of products/preparations is minimized by the internal downward flow of HEPA/ULPA filtered air moving toward the work surface and then drawn into the front and rear intake grilles. Environmental protection is provided when the cabinet exhaust air is passed through a HEPA/ULPA filter.

Type A1 (formerly, Type A): These Class II BSCs maintain a minimum inflow velocity of 75 feet/minute; have HEPA-filtered, down-flow air that is a portion of the mixed down-flow and

inflow air from a common plenum; may exhaust HEPA-filtered air back into the laboratory or to the environment through an exhaust canopy; and may have positive-pressure contaminated ducts and plenums that are not surrounded by negative-pressure plenums. Type A1 BSCs are not suitable for use with volatile toxic chemicals and volatile radionucleotides.

Type A2 (formerly, Type B3): These Class II BSCs maintain a minimum inflow velocity of 100 feet/minute; have HEPA-filtered, down-flow air that is a portion of the mixed down-flow and inflow air from a common exhaust plenum; may exhaust HEPA-filtered air back into the laboratory or to the environment through an exhaust canopy; and have all contaminated ducts and plenums under negative pressure or surrounded by negative-pressure ducts and plenums. If these cabinets are used for minute quantities of volatile toxic chemicals and trace amounts of radionucleotides, they must be exhausted through properly functioning exhaust canopies.

Type B1: These Class II BSCs maintain a minimum inflow velocity of 100 feet/minute; have HEPA-filtered, down-flow air composed largely of uncontaminated, recirculated inflow air; exhaust most of the contaminated down-flow air through a dedicated duct exhausted to the atmosphere after passing it through a HEPA filter; and have all contaminated ducts and plenums under negative pressure or surrounded by negative-pressure ducts and plenums. If these cabinets are used for work involving minute quantities of volatile toxic chemicals and trace amounts of radionucleotides, the work must be done in the directly exhausted portion of the cabinet.

Type B2 (total exhaust): These Class II BSCs maintain a minimum inflow velocity of 100 feet/minute; have HEPA-filtered, down-flow air drawn from the laboratory or the outside; exhaust all inflow and down-flow air to the atmosphere after filtration through a HEPA filter without recirculation inside the cabinet or return to the laboratory; and have all contaminated ducts and plenums under negative pressure or surrounded by directly exhausted negative-pressure ducts and plenums. These cabinets may be used with volatile toxic chemicals and radionucleotides.

Class III: The Class III BSC is designed for work with highly infectious microbiological agents and other hazardous operations. It provides maximum protection for the environment and the worker. It is a gas-tight enclosure with a viewing window that is secured with locks and/or requires the use of tools to open. Both supply and exhaust air are HEPA/ULPA filtered. Exhaust air must pass through two HEPA/ULPA filters in series before discharge to the outdoors.

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■1S (*USP39*)

Auxiliary Information— Please see FAQs for this GC before contacting USP.

Topic/Question	Contact	Expert Committee
General Chapter	Jeanne H. Sun, Pharm.D. Associate Scientific Liaison (301) 230-3361	(CMP2015) Compounding 2015

USP39–NF34 Supplement : No. 1 Page 7721
Pharmacopeial Forum: Volume No. 41(2)

Healthcare Quality & Safety

December 7, 2016
Shawn Becker, MS, BSN

About USP

USP's Mission: To improve global health through public standards and related programs that help ensure the quality, safety, and benefit of medicines & foods.

- Founded in 1820
- Non-profit, non-governmental international organization
- Global organization >1000 employees worldwide

Mission: to improve global health through public standards and related programs that help ensure the quality, safety, and benefit of medicines and foods.

- Works with more than 900 scientists, practitioners and regulators to revise standards that help protect public health

About USP

- **What We Do Today**
  - Establish and disseminate public written standards for the quality, purity, identity, strength, and labeling of medicines
  - Provide recommendations to practitioners on the safe use of medicines
  - Work with national and international health agencies to improve the quality of medicines worldwide
  - Educate practitioners and others seeking information and implementation of quality standards

USP Healthcare Quality and Safety (HQS) supports the development and implementation of science-based standards and services to ensure accessibility and the informed, safe use of quality medicines for patients and healthcare providers.

Healthcare Quality & Safety Public Health Focus Areas

- **↑ Safe Use of Medication & ↓Medication Errors**
  - Errors caused by **Drug Names / Pronunciation**
  - Unsafe sterile and nonsterile **Compounding Practices**
- **↓ Hazardous Drug Exposure** to healthcare providers and patients
- **↑ Patient Health Literacy** related to prescription drugs

Impact
Across distribution channel and across the continuum of care

Manufacturers
>200 Manufacturers
>40 new drugs approved/year

Institutions
5,627 Hospitals
15,600 SNF
67,000 Pharmacies

Healthcare Providers
300K Pharmacists
380K Pharmacy techs
2.7M Nurses
1M MDs

Patients
33M hospital admissions
1.7M patients in SNF
4B prescriptions

USP Process

- **Standard Setting Organization**
  - Create quality standards that help promote healthcare worker and patient safety
  - Unique process that leverages
    - Science
    - Expertise
    - Stakeholder / Public Comment
- **Committed to collaboration and diverse partnerships**
- **Committed to education and implementation of current and emerging standards**

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- Compounding
- Handling Hazardous Drugs

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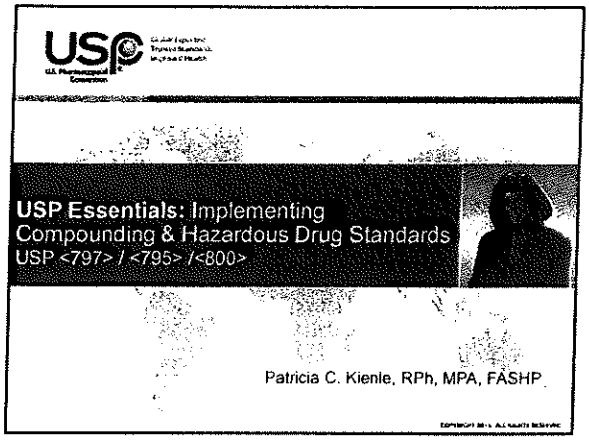

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2. Upon **receipt of the course completion email**, go to the **NABP Learner Community** site (https://nabp.learnercommunity.com) and log in. If you do not have an account, you will need to create one.
3. Once logged in, you will need to **select the USP Essentials**: Implementing Compounding and Hazardous Drug Standards – USP <797>/<795>/<800> course and enter the completion code found in the course completion email.
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Disclosures

- Patricia Kienle is an employee of Cardinal Health
- She is a member of the USP Compounding Expert Committee
- She authored the upcoming ASHP publication, *The 800 Answer Book*

Objectives

- Describe the process and impact of USP standards for safe compounding preparations and handling drugs in healthcare settings
- Identify requirements for training, documentation, component selection, equipment and establishing beyond-use dates for nonsterile compounding
- Identify facility and equipment requirements for compounding nonsterile hazardous drugs
- Describe the conditions for low-, medium-, and high-risk levels categories of compounded sterile preparations
- Identify requirements for training, documentation, equipment, and establishing beyond-use dates for sterile compounding
- Distinguish the facility requirements for compounding sterile hazardous drugs and sterile non-hazardous drugs

Agenda

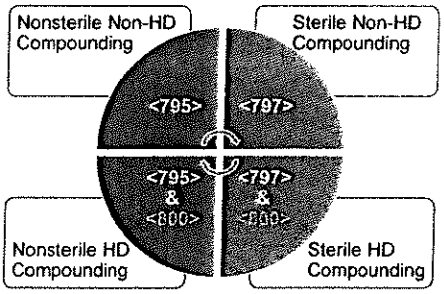
Nonsterile Compounding

- Compounding Nonsterile Non-Hazardous Drugs
  <795> Pharmaceutical Compounding – Nonsterile Preparations
- Compounding Nonsterile Hazardous Drugs
  <800> Hazardous Drugs – Handling in Healthcare Settings

Sterile Compounding

- Compounding Sterile Non-Hazardous Drugs
  <797> Pharmaceutical Compounding – Sterile Preparations
- Compounding Sterile Hazardous Drugs
  <800> Hazardous Drugs – Handling in Healthcare Settings

USP Compounding Chapters



Overview of USP Compounding Standards Meaning and Impact

Legal Considerations	Compliance Implications
• USP Standards in Federal Law – 1997 FDA Modernization Act: Compliance to USP Monographs – 2013 Drug Quality and Security Act: Congress reaffirmed USP * The guidance specifically references <795> & <797> • USP Standards in State Law – ≥ 87% of the U.S. State Boards of Pharmacy require full or partial compliance with <797> in their state regulation	• <797> & <795> are published & enforceable Standards • <800> published Standard, enforcement beginning July 1, 2018 • CMS Conditions of Participation • Accrediting Bodies (e.g. TJC) reviewing alignment with USP standards

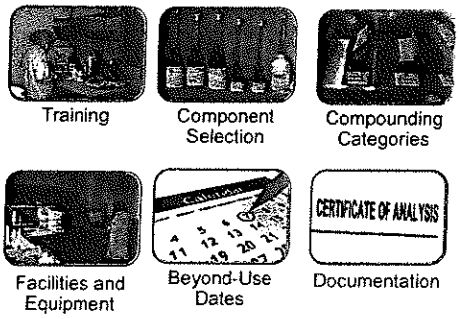
USP General Chapters Overview

- General Chapters can be:
  - **Enforceable**
    - Numbered below <1000>
  - **Informational**
    - Numbered above <1000>
- Terminology
  - "**Shall**" OR "**Must**" requirements
  - "**Should**" recommendations

Nonsterile Compounding

Non Hazardous Drugs

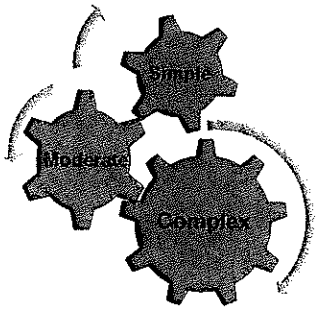
<795> Nonsterile Compounding Key Elements



<795> Nonsterile Compounding Training

- Orientation
- Training
- Inservicing
- Annual review of skills
- Remediation
- Documentation of all aspects

<795> Nonsterile Compounding Levels of Compounding



<795> Nonsterile Compounding Simple Compounding

- **Reconstituting or manipulating** a commercial product that may require the addition of one or more ingredients as directed by the manufacturer
- A preparation that has a **USP compounding monograph** or appears in a peer-reviewed article that contains
  - Specific quantities for all components
  - Compounding procedures and equipment
  - Stability data for that formulation with beyond-use date (BUD)

www.usp.org/usp-healthcare-professionals/compounding/compounding-monographs/usp-nf-monographs-compounded-preparations

<795> Nonsterile Compounding Moderate Compounding

- Making a preparation that requires **special calculations** or procedures to determine quantities of components per preparation or per individualized dosage units
- Making a preparation for which **stability data** for that specific formulation is **not available**
  - Example: mixing two or more manufactured creams when the stability of the mixture is not known

<795> Nonsterile Compounding Complex Compounding

- Making a preparation that requires special training, environment, facilities, equipment, and procedures
- Examples
  - Transdermal dosage forms
  - Modified-release preparations

<795> Nonsterile Compounding
Compounded Preparation Monograph

- Title
- Definition
  - Lists the range of labeled amount of active ingredient
- Formula
  - Ingredients and quantities
- Compounding Procedures
- Stability-indicating Assay
- pH
- Packaging and Storage
- Labeling
- Beyond-use dates
  - Stability studies
  - General Chapters <795> or <797>

ASSAY

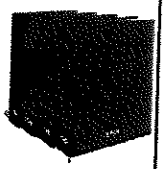
SPECIFIC TESTS
- **pH** ⟨791⟩: 3.6–4.6

ADDITIONAL REQUIREMENTS
- **PACKAGING AND STORAGE:** Package in tight, light-resistant containers. Store at 2°–8° or at controlled room temperature.
- **BEYOND-USE DATE:** NMT 90 days after the date on which it was compounded when stored at 2°–8° or controlled room temperature.
- **LABELING:** Label it to indicate that it is to be well-shaken before use, and to state the *Beyond-Use Date*.
- **USP REFERENCE STANDARDS** ⟨11⟩
  USP Metronidazole Benzoate RS

Injection volume: 5 µL
System suitability
Sample: Standard solution
[NOTE—The retention time for metronidazole is about 7.7 min.]
Shake to mix well.

<795> Nonsterile Compounding
Component Selection

- **API and Other Bulk Substances**
  - Preferred:
    - USP, NF or FCC (Food Chemical Codex) substances
    - Manufactured in an FDA registered facility
  - Ingredients from a non-FDA registered facility:
    - Use professional judgment
    - Obtain a Certificate of Analysis
  - Caution with components not of "compendial quality"
    - Standards of American Chemical Society (ACS) grade materials are not tested for impurities that may raise patient safety concerns



<795> Nonsterile Compounding
Component Selection

- **Bulk Components without Expirations Dates**
  - Manufacturer's expiration date can be used when stored in the original container under conditions designed to avoid decomposition
    - See USP <1191> *Stability Considerations in Dispensing Practice*
    - Minimal exposure of remaining material
    - Removal performed by those trained in proper handling
  - If transferred to another container
    - Identified with component name, original supplier, lot or control number, expiration date
    - Provided the integrity is equal to or better than the original container

<795> Nonsterile Compounding
Component Selection

- **Expiration Date of Bulk Components**
  - If there is no expiration date
    - Label with the date of receipt
    - Assign a conservative expiration date
    - Cannot exceed three years from date of receipt

<795> Nonsterile Compounding
Facilities

- Adequate space specifically designed for compounding
  - Separate and distinct from sterile preparation area
- Clean, orderly, sanitary and in good state of repair
- Orderly placement of equipment and materials
- Designed, arranged, and used to prevent cross-contamination
- Appropriate heating, ventilation, air conditioning
- Well-lighted

<795> Nonsterile Compounding
Equipment

- Appropriately designed
- Adequate capacity
- Surfaces that contact components are not reactive, additive, nor sorptive
- Are maintained as directed by the manufacturer
- Refer to USP <1176> *Prescription Balances and Volumetric Apparatus*
- Routinely inspected
- Calibrated, if necessary

<795> Nonsterile Compounding Beyond-Use Dates

- Stability of Compounded Nonsterile Preparations
  - Manufacturer's information
    - Package insert
  - USP
    - Compounding monographs
    - Applicable USP General Chapters
    - Peer-reviewed literature

<795> Nonsterile Compounding Beyond-Use Dates

The BUD cannot exceed the expiration date of the API or any other component

Type of Formulation	Maximum BUD
Non-aqueous formulation	6 months
Water-containing oral formulations	14 days under refrigeration
Water-containing topical/dermal and mucosal liquid and semisolid formulations	30 days

<795> Nonsterile Compounding Documentation

Personnel Competency
- Orientation
- Training
- Inservicing
- Annual review of skills
- Remediation

Compounding Records
- Master Formulation Record
- Compounding Record
- Certificate of Analysis

Facility Records
- Standard Operating Procedures
- Safety Data Sheets

Nonsterile Compounding

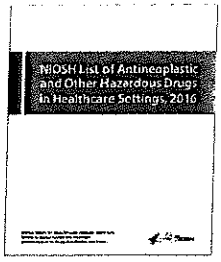
Hazardous Drugs

<800> Hazardous Drugs

- Published as an official standard on **Feb 1, 2016**
- Delayed Implementation Date of **July 1, 2018**
- Applies to both nonsterile and sterile compounding
  - Supplements <795> and <797>
- Extends beyond compounding (storage, spill management, etc.)
- Promote patient safety, worker safety, and environmental protection when handling hazardous drugs (HDs)

<800> Hazardous Drugs

- List of Hazardous Drugs
  - NIOSH publishes a **List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings**
- Facilities may add other HDs to their list but there is no requirement to do so



www.cdc.gov/niosh/docs/2016-161/pdfs/2016-161.pdf

<800> Hazardous Drugs

- Two options for handling HDs

Treat all dosage forms of all HDs the same

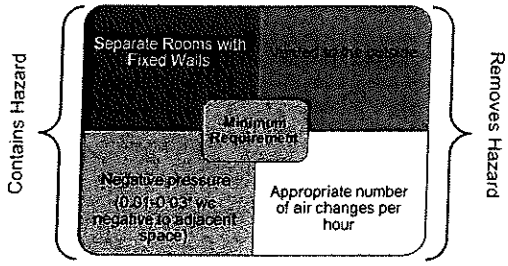
- Follow all the containment requirements in <800>

Perform an Assessment of Risk

- Identify and use alternative containment strategies and/or work practices for specific dosage forms of HDs that are not antineoplastic agents or are not API

<800> Hazardous Drugs

- Facility Requirements



<800> Hazardous Drugs

- **Engineering Controls:** Protect the preparation from cross-contamination

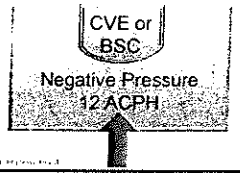
Primary
- the ventilated device ("hood") designed to minimize worker and environmental HD exposure when directly handling HDs

Secondary
- the room in which the C-PEC is placed

<800> Hazardous Drugs

- Facility Requirements

C-PEC	C-SEC Requirements
• Externally vented (preferred) OR redundant HEPA-filtered in series • Examples: CVE, Class I or II BSC, CACI	• 12 ACPH • Externally vented • Negative pressure between 0.01 and 0.03" w.c. • Fixed walls



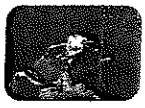
<800> Hazardous Drugs

- **C-PECs for Nonsterile Compounding**
  - CVE ("powder hood")
    - Protects the worker
    - Used for nonsterile compounding only
  - **BSC or CACI**
    - Protect the worker and the preparation
    - If used only for nonsterile, airflow not required to be unidirectional
    - May use C-PEC designed for sterile compounding
      - If a C-PEC designated for sterile compounding will be used for occasional nonsterile compounding, it **must** be decontaminated, cleaned, and disinfected

Sterile Compounding

Non Hazardous Drugs

<797> Sterile Compounding Key Elements

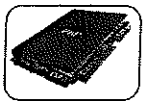

Training


Microbial Contamination Risk Levels


Equipment

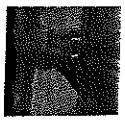

Beyond-Use Dates


Environmental monitoring


Documentation

<797> Sterile Compounding Personnel Training

- **Didactic**
- **Hands-on Competency Evaluation**
  - Gloved Fingertip
  - Media Fill Testing
- **Core Competencies**
  - Hand hygiene
  - Aseptic technique
  - Personal protective equipment
  - Assigning BUDs
  - Labeling
  - Monitoring



<797> Sterile Compounding Personnel Monitoring

Aseptic Media Fill Testing

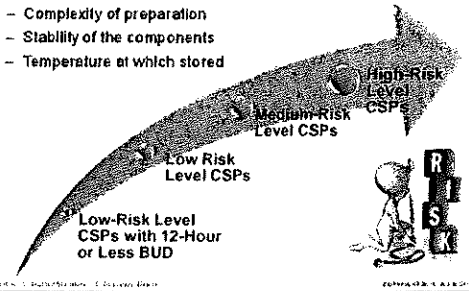
- Demonstrates ability to aseptically prepare CSPs
- Must mimic the most complex CSPs made

Gloved Fingertip Testing

- Confirms ability to aseptically garb
  - 3 times Initially
  - On-going

<797> Sterile Compounding CSP Risk Level

- Assigned based on
  - Maintenance of sterility vs. achievement of sterility
  - **Complexity of preparation**
  - **Stability of the components**
  - **Temperature at which stored**



<797> Sterile Compounding CSP Risk Level

High-Risk

Medium-Risk

Low-Risk

Low-Risk with 12 Hour BUD

Low-Risk Level CSPs with 12-Hour or Less BUD

- Segregated Compounding Area
  - LAFW or BSC outside of ISO Class 7
  - CAI or CACI that does not meet specific requirements
- Limited to nonhazardous and radiopharmaceuticals
- Expectations still include:
  - Hand hygiene and garbing
  - Cleaning and disinfecting
  - Environmental Sampling

<797> Sterile Compounding CSP Risk Level

High-Risk

Medium-Risk

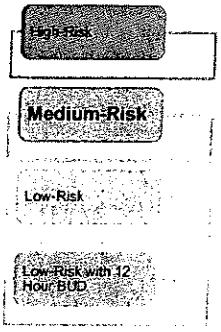
Low-Risk

Low-Risk with 12 Hour BUD

Low-Risk Level CSPs

- Compounded within ISO Class 5 PEC within an ISO 7 environment
- Only uses sterile ingredients and equipment
- Limited to transfer, measuring, and mixing manipulations
- No more than 3 packages
- No more than 2 entries per container

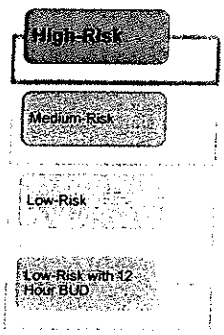
<797> Sterile Compounding
CSP Risk Level



Medium-Risk Level CSPs

- Multiple individual or small doses of sterile products combiner or pooled
- CSP administered to multiple patients or one patient on multiple occasions
- Complex aseptic manipulations
- Compounding requires usually long duration

<797> Sterile Compounding
CSP Risk Level



High-Risk Level CSPs

- Nonsterile ingredients and/or non-sterile devices and equipment
- Sterile ingredients exposed to worse than ISO class 5
- Storage of nonsterile preparation more than 6 hours prior to sterilization
- Chemical purity and content strength assumed and not verified by documentation

<797> Sterile Compounding
CSP Risk Level

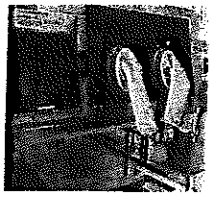
	Low-Risk with 12 hour	Low-Risk Level CSPs	Medium-Risk Level CSPs	High-Risk Level CSPs
Controlled Room Temperature (20° to 25° C)	• 12 hours	• 48 hours	• 30 hours	• 24 hours
Cold Temperature (2° to 8° C)	• 12 hours	• 14 days	• 9 days	• 3 days
Solid Frozen State (-25° to -10° C)	• N/A	• 45 days	• 45 days	• 45 days

<797> Sterile Compounding
Immediate-CSPs

- Intended only for emergency or immediate administration
- Must meet the following criteria:
  - Not more than 3 sterile products
  - Not more than 2 punctures into any container
  - Only nonhazardous or diagnostic radiopharmaceutical products
  - Administration begins within **1 hour** of compounding
  - Labeled

<797> Sterile Compounding
Equipment

- Primary engineering controls (PECs)
- Secondary engineering controls (SECs)
- Compounding devices
  - Automated compounders
  - Repeater pumps
- Other technology



<797> Sterile Compounding
Environmental Monitoring

Monitoring	Function	Frequency
Certification	Monitors primary and secondary engineering controls	Every six months
Viable monitoring	Monitors for environmental microbial growth	Every six months
Surface sampling	Demonstrates ability to clean surfaces and correct cleaning solutions and dilutions are in use	Periodically

Results must be documented

<797> Sterile Compounding Environmental Monitoring

Recommended Action Levels for Microbial Contamination

Area	Air Sample (per 1000 L of air per plate)	Surface (per plate)
ISO 5	> 1	>3
ISO 7	> 10	>5
ISO 8 or worse	> 100	>100

<797> Sterile Compounding Documentation

Personnel
- Competency Evaluation
  - Gloved Fingertip Sampling
  - Media-Fill Testing

PECs and SECs
- Certification
- Environmental monitoring
  - Viable monitoring
  - Surface sampling

CSPs
- Physical Inspection
- Accuracy Checks
- Sterility and Endotoxin Testing

Equipment
- Preventive maintenance
- Calibration

Sterile Compounding

Hazardous Drugs

<800> Hazardous Drugs

- **Engineering Controls:** Protect the preparation from cross-contamination and microbial contamination

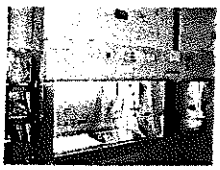
C-PEC
- the ventilated device ("hood") designed to minimize worker and environmental HD exposure when directly handling HDs

C-SEC
- the room in which the C-PEC is placed
  - ISO Class 7 Buffer Room or Segregated Compounding Area

Supplemental Engineering Controls
- adjunct control that offer additional levels of protection (i.e. closed system drug-transfer devices)

<800> Hazardous Drugs

- **C-PECs for Sterile Compounding**
  - Class II Biological safety cabinet (BSC)
    - **Type A2 (recirculating)**
    - **Type B2 (total exhaust)**
  - Compounding aseptic containment isolator (CACI)



<800> Hazardous Drugs

- **C-SECs**
  - Separate room
  - Negative pressure between 0.01 – 0.03" wc
  - Externally vented
  - 12 ACPH
- Options
  - Positive pressure ante-room with negative pressure buffer room
  - C-SCA

USP <800> Hazardous Drugs

- **Supplemental Engineering Controls**
- CSTD is not a substitute for a C-PEC
  - **Should** be used in compounding when the dosage form allows
  - **Must** be used in administering when the dosage form allows
- CSTDs known to be physically or chemically incompatible with a specific HD must not be used for that HD

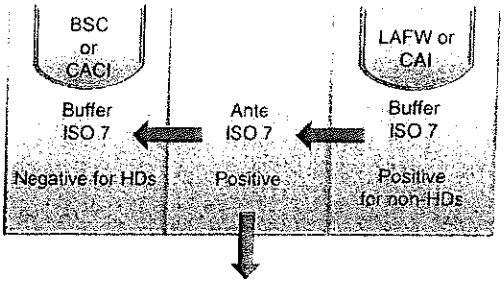
USP <800> Hazardous Drugs

Elimination of "low use" exemption in <797>

Configuration	C-PEC	C-SEC	Maximum BUD
ISO Class 7 Buffer Room	• Externally Vented • Examples: Class II BSC or CACI	• 30 ACPH • Externally vented • Negative pressure between 0.01 and 0.03" w.c.	As described for CSP Risk Levels
C-SCA	• Externally Vented • Examples: Class II BSC or CACI	• 12 ACPH • Externally vented • Negative pressure between 0.01 and 0.03" w.c.	12 hours

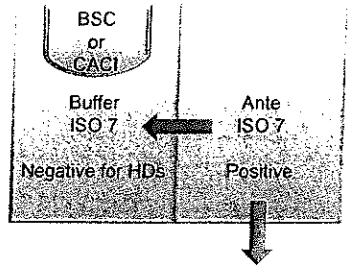
USP <800> Hazardous Drugs

- **Example Configuration**



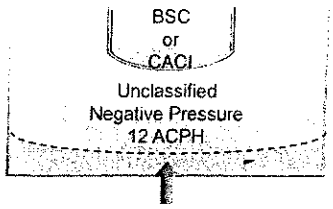
USP <800> Hazardous Drugs

- **Example Configuration**



USP <800> Hazardous Drugs

- **Example Configuration (C-SCA)**
  - Not currently allowed in <797>
  - Not acceptable for high-risk



USP <800> Hazardous Drugs

- **Personal Protective Equipment**
  - **Gloves**
    - Must meet ATSM standard D6978
  - **Gowns**
    - Must be impervious and intended for use with HDs
  - **Shoe Covers**
    - Two pairs required in a negative room

<800> Hazardous Drugs

- **Environmental Monitoring**
  - Detection of HD residue which may contaminate surfaces
  - Environmental wipe samples for HD surface residue should be performed routinely to verify containment
    - E.g., initially as a baseline and ≤ every 6 months
- Common HD Markers
  - Cyclophosphamide
  - Ifosfamide
  - Methotrexate
  - Fluorouracil
  - Platinum-containing drugs

<800> Hazardous Drugs

- **Medical Surveillance**
  - Assessment and documentation
    - Symptom complaints
    - Physical findings
    - Laboratory values
  - Monitors for health changes
    - Acute exposure
    - Long-term exposure

Questions

Revised: ~~June 4, 2014~~ December 12, 2016

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 <u>for a newly opened pharmacy or a new location for an existing pharmacy</u> indicating compliance with the requirements of statute, including compliance with USP-NF standards for pharmacies performing ~~sterile and~~ 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. <u>An "opening" inspection report for</u>

a newly opened pharmacy or a new location for an existing pharmacy ~~pharmacies~~ 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.

Revised: ~~June 4, 2014~~ December 12, 2016

Virginia Board of Pharmacy

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requirements for obtaining initial registration 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 as a nonresident pharmacy.

Virginia Board of Pharmacy

Protocol for the Prescribing and Dispensing of Naloxone

Pharmacists shall follow this protocol when dispensing naloxone pursuant to an oral, written or standing order to a person to administer to another person believed to be experiencing or about to experience a life-threatening opiate overdose as authorized in §54.1-3408.

1) **Procedure:** When someone requests naloxone, or when a pharmacist in his or her professional judgment decides to advise of the availability and appropriateness of naloxone, the pharmacist shall:
   a) Provide counseling in opioid overdose prevention, recognition, response, administration of naloxone, to include dosing, effectiveness, adverse effects, storage conditions, shelf-life, and safety. Recipient cannot waive receipt of this counseling, unless the pharmacist is able to verify successful completion of the REVIVE! training program.
   b) The pharmacist shall provide the recipient with the current REVIVE! brochure available on the Department of Behavioral Health and Developmental Services website at http://www.dhp.virginia.gov/Pharmacy/docs/osas-revive-pharmacy-dispensing-brochure.pdf If the recipient indicates interest in addiction treatment, recovery services, or medication disposal resources at this time, the pharmacist may provide information or referrals to appropriate resources.

2) **Product Selection:** The pharmacist who dispenses naloxone pursuant to an oral, written or standing order shall dispense the drug and other items for the kit, if applicable, as prescribed and in accordance with this protocol.

3) **Standing Order:** In addition to dispensing naloxone pursuant to an oral or written order issued to a specific individual, a pharmacist may dispense naloxone pursuant to a standing order. The standing order may be issued by an individual prescriber to a specific pharmacy or pharmacies, or the standing order may be issued by the Health Commissioner to all pharmacies located and permitted in Virginia. The standing order authorizes a pharmacist to dispense one or more of the specified naloxone formulations to any person seeking to obtain naloxone. A standing order shall be valid for no more than two years from the date of issuance and shall contain the following information at a minimum:
   a) Name of pharmacy authorized to dispense naloxone pursuant to standing order if the standing order is issued by a prescriber for a particular pharmacy or pharmacies;
   b) Contents of kit to be dispensed for dispensing naloxone 2mg/2ml prefilled syringes for intranasal administration, to include quantity of drug and directions for administration;
   c) Prescriber's signature; and
   d) Date of issuance.

4) Kit Contents for Intranasal or Auto-Injector Administration:

Intranasal	Auto-Injector	Intranasal
Naloxone 2mg/2ml prefilled syringe, # 2 syringes SIG: Spray one-half of the syringe into each nostril upon signs of opioid overdose. Call 911. May repeat x 1. Mucosal Atomization Device (MAD) # 2 SIG: Use as directed for naloxone administration. Kit must contain 2 prefilled syringes and 2 atomizers and instructions for administration.	Naloxone 0.4 mg/0.4 ml #1 twin pack SIG: Use one auto-injector upon signs of opioid overdose. Call 911. May repeat x 1. No kit is required. Product is commercially available.	Narcan Nasal Spray 4mg, #2<u>1 twin pack</u> SIG: Administer a single spray intranasally into one nostril. Administer additional doses using a new nasal spray with each dose, if patient does not respond or responds and then relapses into respiratory depression. <u>Call 911.</u> Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives. No kit is required. Product is commercially available.

Optional items for the kits include rescue breathing masks, and latex-free gloves.

Pharmacies may obtain kits to have on-hand for dispensing naloxone 2mg/2ml prefilled syringes for intranasal administration from the REVIVE! program at the Department of Behavioral Health and Developmental Services. To request kits, contact <u>REVIVE@dbhds.virginia.gov</u>

5) Labeling and Records:

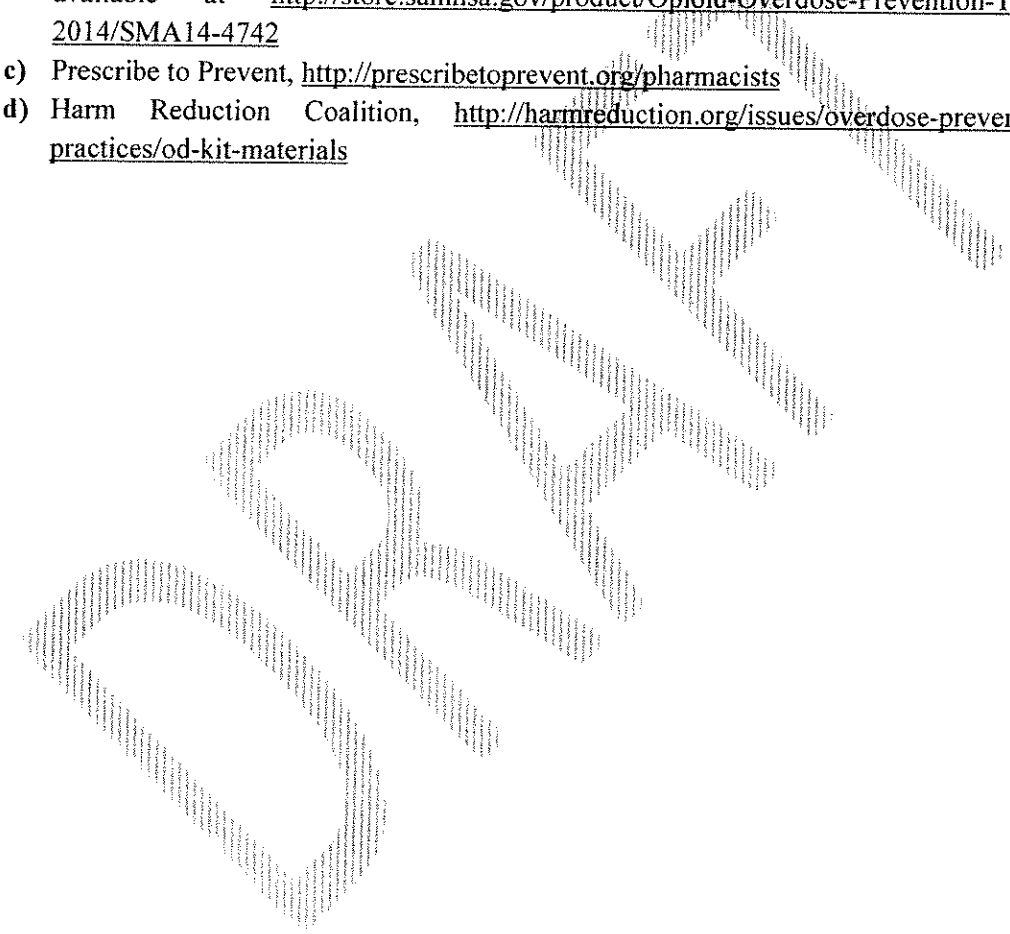
Each vial or syringe of naloxone shall be dispensed and labeled in accordance with §54.1-3410 with the exception that the name of the patient does not have to appear on the label. The pharmacist shall maintain a record of dispensing in accordance with recordkeeping requirements of law and regulation. <u>A standing order issued by an individual prescriber or the Health Commissioner shall be maintained by the pharmacist for two years from the date of the last dispensing prior to expiration or discontinuation of the standing order.</u>

Protocol for Dispensing to Law-Enforcement Officers and Firefighters

Alternatively, a pharmacy, wholesale distributor, third party logistics provider, or manufacturer may distribute naloxone via invoice to designated law enforcement officers or firefighters who have successfully completed a training program developed by the Department of Behavioral Health and Developmental

Services in consultation with the Department of Criminal Justice Services or Department of Fire Programs, respectively, at the address of the law enforcement agency or fire department. Training shall be conducted in accordance with policies and procedures of the law enforcement agency or fire department.

6) **Resources:**
   a) REVIVE! Opioid Overdose Reversal for Virginia Training Curriculum "Understanding and Responding to Opioid Overdose Emergencies Using Naloxone", available at http://www.dhp.virginia.gov/pharmacy/docs/osas-revive-training-curriculum.pdf
   b) Substance Abuse Mental Health Services Administration's "Opioid Prevention Toolkit" (2014), available at http://store.samhsa.gov/product/Opioid-Overdose-Prevention-Toolkit-Updated-2014/SMA14-4742
   c) Prescribe to Prevent, http://prescribetoprevent.org/pharmacists
   d) Harm Reduction Coalition, http://harmreduction.org/issues/overdose-prevention/tools-best-practices/od-kit-materials



National Association of Boards of Pharmacy

e-Profile Connect

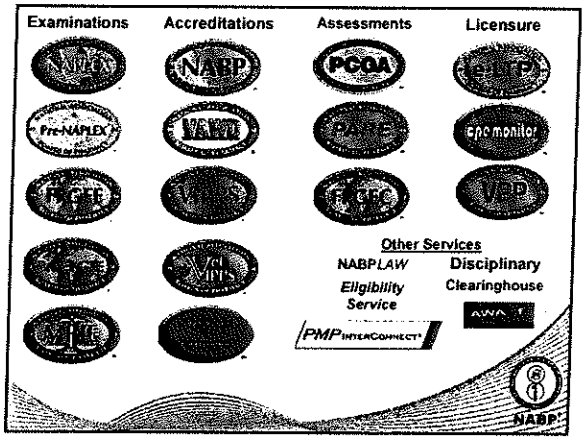
Presented by Neal Watson
Member Relations and Government Liaison

NABP

National Association of Boards of Pharmacy®

- **501(c)(3) charitable and educational organization**
  - **Founded in 1904**
- **Members are the state boards of pharmacy** for 50 states, District of Columbia, and United States territories.
- **NABP's mission is to assist member boards in public protection.**
  - License transfer program
  - Examinations
  - Accreditations

NABP



NABP e-Profile Connect

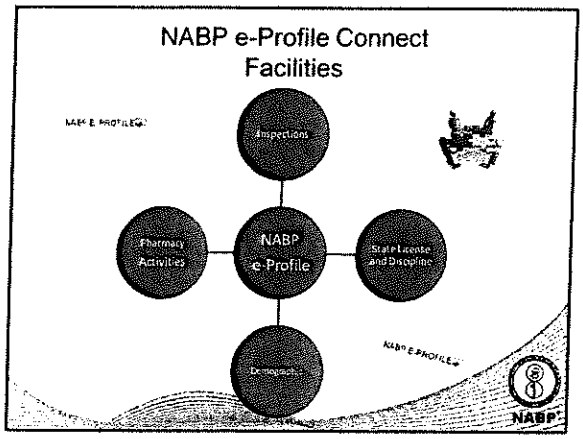
What is it?

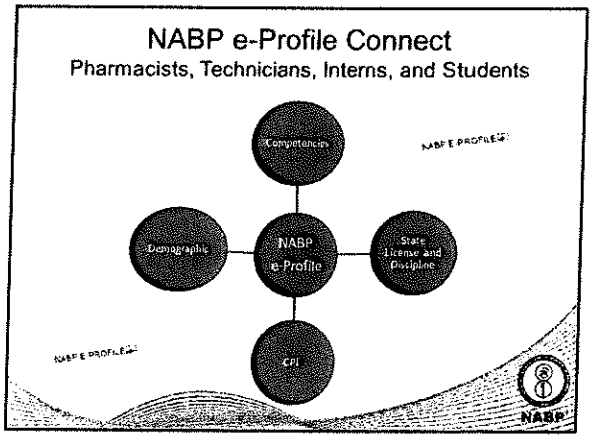
NABP E-PROFILE

- A Unique Identifier assigned to licensed or registered individuals and Facilities
- Links licensees to all NABP Programs and state pharmacy board's shared data.
- e-Profile Hub
  - Securely stores valuable licensure information which is readily available to boards of pharmacy when rendering licensing decisions

"I thought that was only for CPE Monitor??" .....

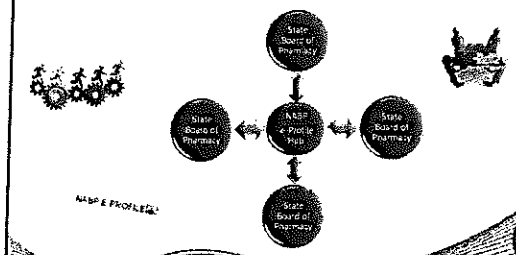
NABP

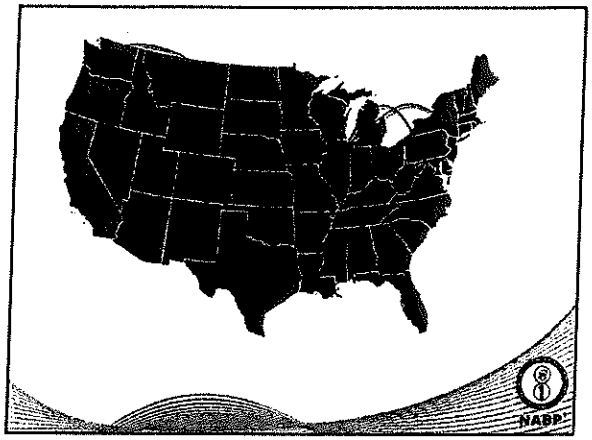




State to State

- **State to state data sharing**





NABP e-Profile Connect

Why do we need it?

- Streamlines licensure processes
  - Disciplinary reporting
- Reduces administrative burden for board staff
  - Reduce the necessity to identify through sensitive data
- Decreases turn around time on application
- Enhances board members and staff ability to make informed licensing decisions

Implementing the NABP e-Profile ID

- Require the NABP e-profile on initial and renewal licensure applications for pharmacist and technicians
  - No cost to board or licensee
  - Facilities coming in 2017
- Sync board data to NABP data utilizing the e-Profile Identifier
- Future
  - Real-time data exchange

Questions?

- Contact Information:
  - nwatson@nabp.pharmacy
  - 847/391-4481

§ 54.1-3314.1. Continuing education requirements; exemptions; extensions; procedures; out-of-state licensees; nonpractice licenses.

A. Each pharmacist shall have obtained a minimum of 15 continuing education hours of pharmaceutical education through an approved continuing pharmaceutical education program during the year immediately preceding his license renewal date.

B. An approved continuing pharmaceutical education program shall be any program approved by the Board.

C. Pharmacists who have been initially licensed by the Board during the one year preceding the license renewal date shall not be required to comply with the requirement on the first license renewal date that would immediately follow.

D. The Board may grant an exemption from the continuing education requirement if the pharmacist presents evidence that failure to comply was due to circumstances beyond the control of the pharmacist.

E. Upon the written request of a pharmacist, the Board may grant an extension of one year in order for a pharmacist to fulfill the continuing education requirements for the period of time in question. Such extension shall not relieve the pharmacist of complying with the continuing education requirement for the current period.

F. The pharmacist shall attest to the fact that he has completed the continuing education requirements as specified by the Board.

G. The following shall apply to the requirements for continuing pharmaceutical education:

1. The provider of an approved continuing education program shall issue to each pharmacist who has successfully completed a program certification that the pharmacist has completed a specified number of hours.

2. The certificates so issued to the pharmacist shall be maintained by the pharmacist for a period of two years following the renewal of his license.

3. The pharmacist shall provide the Board, upon request, with certification of completion of continuing education programs in a manner to be determined by the Board.

H. Pharmacists who are also licensed in other states and who have obtained a minimum of fifteen hours of approved continuing education requirements of such other states need not obtain additional hours.

I. The Board shall provide for an inactive status for those pharmacists who do not wish to practice in Virginia. The Board shall require upon request for change from inactive to active status proof of continuing education hours as specified in regulations. No person shall practice in Virginia unless he holds a current active license.

J. As part of the annual 15-hour requirement, the Board may require up to two hours of continuing education in a specific subject area. If the Board designates a subject area for continuing education, it shall publish such requirement no later than January 1 of the calendar year for which the specific continuing education is required.