COMMONWEALTH OF VIRGINIA
Meeting of the Board of Pharmacy

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Tentative Agenda of Regulation Committee Meeting

November 2, 2017

9AM

TOPIC	PAGES
Call to Order: Michael Elliott, Committee Chairman	
• Welcome & Introductions	
• Approval of Agenda	
Call for Public Comment	
Agenda Items	
• Amend Guidance Document 110-36 to address Compliance with USP Chapter <800>	1-18
• Discuss Piloting Changes to Physician Selling Inspection Program	19-27
• Adopt Regulation to Address White Bagging/Brown Bagging	28-34
• Amend Regulation 18VAC110-20-390 to Strengthen Prohibition Against Kickbacks	35
• Consider Possible Disciplinary Action for Repeat Deficiencies	Handout
Adjourn	

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

*****A panel of the board will convene at 1PM or following adjournment of the Committee meeting, whichever is later. *****

(DRAFT)

Virginia Board of Pharmacy

COMPLIANCE WITH USP STANDARDS FOR COMPOUNDING

§54.1-3410.2 of the Code of Virginia and Regulation 18VAC110-20-321 requires pharmacies performing sterile or non-sterile compounding to comply with USP Standards. USP standards for sterile and non-sterile compounding may be found in the current editions of the USP-NF. In accordance with 18VAC110-20-170, the Board requires a pharmacy to maintain references consistent with the pharmacy's scope of practice and with public safety.

USP Chapter 795 lists the requirements for non-sterile compounding including information about the compounding environment, equipment, stability criteria and beyond-use dating and records. USP Chapter 797 lists requirements for policies and procedures, training and evaluation of personnel performing sterile compounding, determining risk levels and the physical standards for the sterile compounding area. The Board expects that the requirements of Chapters 795 and 797 will be found in compliance at time of inspection. USP Chapter 800 describes practice and quality standards for handling hazardous drugs to promote patient safety, worker safety, and environmental protection. USP first published Chapter 800 in 2014. It was first published as an official standard in February 2016 with a delayed implementation date of July 1, 2018. On September 27, 2017, USP published a notification of intent to revise the effective date of chapter <800> to December 1, 2019. ~~The Board expects that the requirements of 800 related to non-physical standards of chapter <800>, e.g., list of hazardous drugs received, stored, or dispensed, performance of assessment of risk if not complying will all containment requirements for all drugs, will be found in compliance at time of inspection beginning January 1, 2019. The Board also expects that the requirements of 800 related to physical and engineering standards will be found in compliance at time of inspection beginning July 1, 2019. Prior to these dates, inspectors will note non-compliance as a "comment" on the inspection report and no monetary sanction will be imposed. As of these dates, the Board will begin imposing monetary sanctions for non-compliance with the applicable requirements.~~

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

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

   A subscription to the current version of "USP on Compounding: A Guide for the Compounding Practitioner" may be purchased at http://www.usp.org/store/products-services/usp-

compounding This guide provides access to all compounding-related General Chapters from the USP-NF and is updated with the release of each new USP-NF edition and supplement. ~~The latest edition, USP 36- NF 31, published on November 1, 2012 becomes official May 1, 2013.~~

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

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

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

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

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

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

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

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

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

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

5. ***Is it appropriate to assign a BUD of 90 days in the absence of sterility testing if there is literature indicating the stability of the drug is assured for 90 days?***
   No, it is inappropriate and a violation of law to assign a BUD which exceeds the USP default BUDs in the absence of sterility testing. Drug stability should not be confused with drug sterility.

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

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

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

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

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

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

   Skip lot testing is a process that only tests a fraction of the drugs compounded. It is NOT appropriate for sterility testing. It may only be used for ensuring consistency and drug strength (potency). Because skip lot testing is complex and requires a robust program, it may not be

possible for a pharmacy to properly implement. Information regarding skip lot testing may be accessed at http://www.itl.nist.gov/div898/handbook/pmc/section2/pmc27.htm

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

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

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

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

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

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

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

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

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

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

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

the twelfth month from the date the previous media-fill test was initiated. Semiannual media-fill testing must be performed no later than the last day of the sixth month from the date the previous media-fill test was initiated.

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

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

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

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

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

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

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

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

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

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

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

- Maintain a written policy and procedure manual clearly identifying sterility testing procedures used by the pharmacy and processes for assigning BUDs.
- Prior to using an outside testing company to perform sterility testing, evaluate the company to determine if it performs testing in full compliance with USP Chapter <71>. This may be done by reviewing 483 reports issued by the FDA to the testing company and which may be available on the FDA website. Alternatively, request copies of the 483 reports directly from the testing company. The observed deficiencies noted on the 483 reports will assist the pharmacist in evaluating the testing company's level of compliance. Also, request written documentation from the testing company which explains the sterility testing processes used and how it complies with USP Chapter <71> in its totality. This documentation should contain, at a minimum, specific details regarding the method of testing, method suitability associated with each sterility testing process to ensure the drug being tested will not interfere with the test, identification of testing method (membrane filtration is the preferred method of testing), two growth media, and number of days of incubation. Have this documentation readily available for inspector review.
- When performing sterility testing in-house, document in the written policy and procedure manual, at a minimum, specific details regarding the method of testing, method suitability associated with each sterility testing process to ensure the drug being tested will not interfere with the test, identification of two growth media, and number of days of incubation.
- Vendors providing products for in-house testing must describe all conditions and limitations to their testing products. Ensure the appropriate filtration volume and sample size is being tested.
- When determining an appropriate sterility testing process, note that the preferred method per USP is membrane filtration. The Board strongly recommends that written documentation justifying the use of direct inoculation be available for inspection
- Ensure the sterility testing incorporates two media for growth.
- The sample size used for testing must comply with USP Chapter <71>, tables 2 and 3.
- Maintain robust recordkeeping, e.g., chart the dates, temperatures, growth associated with the two media incubations, and employee signatures. Do not simply indicate "no growth" without indicating which growth media was used and the number of days incubated.

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

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

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

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

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

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

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

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

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

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

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

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

fingertip sampling by donning sterile gloves within the ISO Class 5 main chamber and testing those gloves.

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

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

26. What minimally should be taken into consideration when having primary and secondary engineering controls certified?

Certification and testing of primary (LAFWs, BSCs, CAIs and CACIs) and secondary engineering controls (buffer and ante areas) shall be performed by a qualified individual no less than every six months and whenever the device or room is relocated, altered, or major service to the facility is performed. Certification procedures such as those outlined in the CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006) shall be used. Pharmacists shall request written documentation from the certifying company explaining how the company's certifying processes fully comply with these standards. This shall include written acknowledgement that certification testing will be performed under dynamic conditions. Certifications issued shall specifically indicate the ISO standard for each primary and secondary engineering control and not simply indicate "passed".

27. What minimally should be taken into consideration when compounding multidose vials?

Currently USP Chapter <797> does not contain specific requirements for compounding multiple-dose containers, such as the need for a preservative, nor requirements for testing, labeling, and container closures for compounded multiple-dose containers. Chapter <797> references Chapter <51> for informational purposes as the source of the 28-day BUD after initially entering or opening a multiple-dose container, unless otherwise specified by the manufacturer.

28. What BUDs are recommended for non-sterile compounded products?

USP Chapter <795> makes the following recommendations for assigned BUDs of non-sterile compounded products:

Nonaqueous formulations - The BUD is not later than the time remaining until the earliest expiration date of any API or 6 months, whichever is earlier.
Water-Containing Oral Formulations - The BUD is not later than 14 days when stored at controlled cold temperatures.

Water-Containing Topical/Dermal and Mucosal Liquid and Semisolid Formulations – The BUD is not later than 30 days.

These maximum BUDs are recommended for nonsterile compounded drug preparations in the absence of stability information that is applicable to a specific drug or preparation. The BUD shall not be later than the expiration date on the container of any component.

29. May a non-sterile compounded product be assigned an extended BUD beyond the recommendations in USP Chapter <795>?

The Board advises that non-sterile compounded products should not be assigned an extended BUD unless the pharmacist maintains full documentation to justify the appropriateness of the extended BUD.

30. Under what conditions may a glove box be used to perform sterile compounding?

The glove box, referred to as an isolator (CAI/CACI) in Chapter <797>, must be placed in an ISO 7 buffer area UNLESS it meets all of the following conditions listed in USP Chapter 797:

- The isolator shall provide isolation from the room and maintain ISO Class 5 during dynamic operating conditions, including transferring ingredients, components, and devices into and out of the isolator and during preparation of CSPs.
- Particle counts sampled approximately 6 to 12 inches upstream of the critical exposure site shall maintain ISO Class 5 levels during compounding operations.
- Not more than 3520 particles (0.5 µm and larger) per m^3 shall be counted during material transfer, with the particle counter probe located as near to the transfer door as possible without obstructing the transfer.[8]

It is incumbent upon the compounding personnel to obtain documentation from the manufacturer that the CAI/CACI will meet this standard when located in environments where the background particle counts exceed ISO Class 8 for 0.5-µm and larger particles. When isolators are used for sterile compounding, the recovery time to achieve ISO Class 5 air quality shall be documented and internal procedures developed to ensure that adequate recovery time is allowed after material transfer before and during compounding operations.

If the primary engineering control (PEC) is a CAI or CACI that does not meet the requirements above or is a LAFW or BSC that cannot be located within an ISO Class 7 buffer area, then only low-risk level nonhazardous and radiopharmaceutical CSPs pursuant to a physician order for a specific patient may be prepared, and administration of the CSP shall commence within 12 hours of preparation or as recommended in the manufacturer's package insert, whichever is less.

The weighing of chemicals must occur in at least ISO Class 8 conditions. An isolator used to compound hazardous drugs (with exception of "low volume") must be located in a separate negative pressure room and exhausted outside.

31. May hazardous sterile products be compounded in the same hood as non-hazardous sterile drugs?

No. Hazardous sterile products may not be compounded in the same hood as non-hazardous CSPs.

32. Under what conditions may hazardous drugs be compounded in a cleanroom with positive air pressure?

USP allows a "low volume" of hazardous CSPs to be compounded in a cleanroom with positive air pressure, however, USP does not currently define the term "low volume". The "low volume" hazardous CSPs must be compounded under two tiers of containment, the isolator or biologic safety cabinet and closed system transfer device.

33. Must a compounding pharmacy using Schedule II powders comply with the perpetual inventory requirements of Regulation 18VAC110-20-240?

Yes.

34. Must bladder irrigation fluids and irrigations for wounds be prepared in a sterile manner in compliance with USP-NF requirements?

Yes.

35. In addition to bladder irrigation and irrigations for wounds, what other types of drugs must be prepared in a sterile manner in compliance with USP-NF requirements?

USP Chapter <797> states that for the purposes of the chapter, a compounded sterile product includes any of the following: compounded biologics, diagnostics, drugs, nutrients, and radiopharmaceuticals, including but not limited to the following dosage forms that must be sterile when they are administered to patients: aqueous bronchial and nasal inhalations for the lungs, baths and soaks for live organs and tissues, injections (e.g., colloidal dispersions, emulsions, solutions, suspensions), irrigations for wounds and body cavities, ophthalmic drops and ointments, and tissue implants. Note: Nasal sprays and irrigations for the nasal passages may be prepared as non-sterile compounds.

36. May a pharmacist provide a compounded drug to another pharmacy or veterinarian who will then dispense the drug to his client?

No. Va Code §54.1-3410.2 indicates pharmacists shall not distribute compounded drug products for subsequent distribution or sale to other persons or to commercial entities, including distribution to pharmacies or other entities under common ownership or control with the facility in which such compounding takes place.

VA Code §54.1-3410.2 does authorize pharmacists to provide compounded drug to practitioners of medicine, osteopathy, podiatry, dentistry, or veterinary medicine to administer to their patients in the course of their professional practice, either personally or under their direct and immediate supervision. The compounded drug must be labeled with (i) the statement "For Administering in Prescriber Practice Location Only"; (ii) the name and strength of the compounded medication or list of the active ingredients and strengths; (iii) the facility's control number; (iv) an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding; and (v) quantity.

37. May a prescriber or patient obtain a compounded sterile product from an out-of-state pharmacy that is not registered by the Virginia Board of Pharmacy as a nonresident pharmacy?

No, only nonresident pharmacies registered by the Virginia Board of Pharmacy may ship compounded sterile products into Virginia. Verification of registration may be determined at https://secure01.virginiainteractive.org/dhp/cgi-bin/search_publicdb.cgi by searching the business name and choosing the occupation of "non-resident pharmacy".

38. What risk-level is associated with repackaging an undiluted multi-dose vial?

The repackaging of an undiluted multi-dose vial, e.g., insulin, into multiple syringes is a medium-risk level manipulation when puncturing the vial more than 3 times. Note: this guidance addresses repackaging, not administration.

39. May a microbiological method alternative to compendial methods be used?

Regarding sterility testing, USP Chapter <797> states, "The *Membrane Filtration* method is the method of choice where feasible (e.g., components are compatible with the membrane). A method not described in the *USP* may be used if verification results demonstrate that the alternative is at least as effective and reliable as the *USP Membrane Filtration* method or the *USP Direct Inoculation of the Culture Medium* method where the *Membrane Filtration* method is not feasible." Additionally, USP General Chapter <1223> "provides guidance on the selection, evaluation, and use of microbiological methods as alternatives to compendial methods. To properly implement alternative methods, one must consider a number of important issues before selecting the analytical technology and qualifying that method with the actual product. These issues include, but are not limited to, identification of suitable alternative methodology, development of user specifications for equipment selection, demonstration of the applicability of the method as a replacement for a standard compendial method, and qualification of the method in the laboratory.....*General Notices and Requirements* in the *USP* states, "Alternative methods and/or procedures may be used if they provide advantages in terms of accuracy, sensitivity, precision, selectivity, or adaptability to automation or computerized data reduction, or in other special circumstances." General Chapter <1223> also makes reference to 21 CFR Part 211.194 stating, "This subsection of the regulations also recognizes the legal basis of *USP* and the *National Formulary (NF)* standards and makes it clear that it is the responsibility of the user to validate methods or procedures that differ from those standardized in the compendia." Refer to *USP* for additional guidance.

40. What are the hazardous drugs (HD) that USP Chapter <800> oversees?

Refer to the most current National Institute for Occupational Safety and Health (NIOSH) list at www.cdc.gov. Note: Chapter <800> defines HDs are those on the NIOSH list, not the EPA hazardous materials list. Some drugs on the Environmental Protection Agency (EPA) list may not be on the NIOSH list, e.g., epinephrine.

41. In general, how are drugs grouped within the NIOSH list?

Hazardous drugs are categorized into three tables:

- Antineoplastic drugs, e.g., cisplatin, methotrexate
- Non-antineoplastic drugs, e.g., carbamazepine, estrogen/progesterone combinations
- Non-antineoplastic drugs that have adverse reproductive effects, e.g., temazepam, warfarin

42. What drugs MUST comply with all USP Chapter <800> containment requirements?

Drugs on the NIOSH list that must follow the requirements in this chapter include:

- Any HD active pharmaceutical ingredient (API) on any of the three tables, and
- Any antineoplastic requiring manipulation other than counting or repackaging.

43. What drugs do NOT have to comply with all the USP Chapter <800> containment requirements?

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)

44. How should a pharmacist determine how to comply with 800?

Pharmacists should ask themselves the following questions, at a minimum:

- What drugs do I receive, store, dispense that are deemed hazardous pursuant to the NIOSH list?
- Must those drugs comply with all containment requirements or do some qualify for performing an assessment of risk?
- What changes will I need to make to my facility in order to comply with Chapter <800>?
- What personnel training is needed to meet compliance?
- What cleaning processes must be implemented or changed to meet compliance?
- What activities do I perform with these hazardous drugs, e.g., compounding, administration, etc.?

45. If it is determined that the pharmacy stocks HDs, what options exist for the pharmacy?

The pharmacy may treat all dosage forms of all HDs the same and follow all containment requirements in Chapter <800> or it may perform an assessment of risk to identify and use alternative containment strategies and/or work practices for specific dosage forms of HDs that are not antineoplastic agents or not API.

46. What hazardous drugs may be considered during an assessment of risk?

- Antineoplastics that only need to be counted or packaged
- Non-antineoplastics
- Reproductive-only hazards

47. What should be considered, at a minimum, during an assessment of risk?

- Type of HD, dosage form, risk of exposure, packaging, manipulation to be performed
- Alternative containment strategies and/or work practices should be documented
- The assessment of risk shall be reviewed every 12 months and documented.

48. What minimal questions and/or information will an inspector for the Board of Pharmacy be asking during an inspection? Note: Refer to page 1 regarding enforcement of Chapter <800>.

- Does the pharmacy perform sterile or non-sterile compounding?
- Does the pharmacy stock HDs? The list of HDs the pharmacy stocks must be provided for inspector review.
- Are all HDs contained in a manner consistent with USP Chapter <800> or was an assessment of risk performed to identify and use alternative containment strategies and/or work practices for specific dosage forms of HDs that are not antineoplastic agents or not API. The assessment of risk must be provided for inspector review.
- Who is the 'designated person' for the pharmacy who is responsible for the continuing to evaluate the fundamental practices and precautions for handling HDs?
- Documentation of required training.
- Appropriate personnel equipment.
- Appropriate engineering controls.
- Standard operating procedures for safe handling of HDs for all situations in which the HDs are used throughout the facility.

49. What does USP Chapter <800> list as the general engineering control requirements for performing non-sterile HD compounding?

Table 2. Engineering Controls for Nonsterile HD Compounding

Containment Primary Engineering Control (C-PEC)	Containment Secondary Engineering Control (C-SEC)
• Externally vented (preferred) or redundant-HEPA filtered in series • Examples: CVE, Class I or II BSC, CACI	• Externally vented • 12 air changes per hour (ACPH) • Negative pressure between 0.01 and 0.03 inches of water column relative to adjacent areas • Fixed walls

50. What does USP Chapter <800> list as the general engineering control requirements for performing 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 air changes per hour-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

51. Where may a list of recommended personal protective equipment by type of drug formulation and engineering controls for working with HDs in a healthcare setting be found?

Table 5 of the NIOSH list.

52. Regarding the Segregated Compounding Area (SCA) definition, Chapter <797> states an SCA may be a designated space, room or demarcated area. Chapter <800> states SCA requires fixed walls and removes the "space or demarcated area". Please clarify the Board's expectations on this issue.

Per USP, please note the differences in terminology in <797> and <800>. General Chapter <800> specifies that this is a containment segregated compounding area (C-SCA). For hazardous drug compounding, the C-SCA must have fixed walls. For nonhazardous drug sterile compounding, the SCA may be in an unclassified area (and not necessarily have fixed walls). For the C-SCA, fixed are also necessary to maintain negative pressure.

53. ***Regarding low-risk level compounding with 12 hour or less beyond use dating (hood within a non-ISO Class 7 area), Chapter <797> states that this configuration does not allow hazardous compounding. Chapter <800> states that it is allowed, but only low and medium risk HDs may be prepared and beyond use dating (BUD) that cannot exceed <797> for being prepared in a SCA. Please clarify the Board's understanding on this issue.***

Per USP, the intent of <800> is to apply a 12-hour or less BUD to low- and medium- risk level compounded sterile products prepared in a containment segregated compounding area (C-SCA). USP is aware of the conflict and is in the process of revising <797> to align with the requirements in <800>.

54. ***Chapter <797> also allows for placement of an isolator outside of an ISO Class 7 buffer room with meeting of specification requirements and allowance of full BUD. Chapter <800> states if the containment primary engineering control (C-PEC) is placed in a containment segregated compounding area (C-SCA), then the BUD of all compounded sterile products must be limited as described in <797>. Again, Chapter <797> states that this configuration does not allow hazardous compounding. Please clarify the Board's understanding on this issue.***

Per USP, the intent of <800> is to apply a 12-hour or less BUD to low- and medium- risk level compounded sterile products prepared in a C-SCA. USP is aware of the conflict and is in the process of revising <797> to align with the requirements in <800>.

55. ***With the implementation of Chapter <800>, will USP continue to allow compounding aseptic isolators (CAI) placed outside of a classified area to be used to compound sterile products and assigned a full BUD as authorized in <797>?***

Yes, Chapter <797> still allows for a compounding aseptic isolator (CAI) placed outside of a classified area to be used to compound sterile products and assigned the full storage period BUD provided the conditions specified in the chapter are met. Note, for compounding sterile hazardous drugs, the compounding aseptic containment isolator (CACI) must be placed in a negative pressure containment secondary engineering control (C-SEC) with adequate air changes per hour (ACPH).

56. ***Does Chapter <800> recommend wipe sampling and medical surveillance?***

Yes, Chapter <800> states that "environmental wipe sampling for HD surface residue should be performed routinely." Medical surveillance is also a recommendation of the chapter. The

chapter states that "healthcare workers who handle HDs as a regular part of their job assignment should be enrolled in a medical surveillance program." Note, both of these issues are recommendations of Chapter <800> and not a requirement.

57. ***USP Chapter <800> states that antineoplastic hazardous drugs (HD) that require manipulation other than counting or repackaging should be stored separately. Does this include any dosage formulation, or is that left to the risk assessment?***

    Per USP, this is intended to include any dosage form that does NOT require any further manipulation (i.e. counting tablets, pouring liquids).

58. ***USP <797> and USP <800> recommend the use of closed-system drug-transfer devices (CSTD). Is there guidance on the proper evaluation of the available technologies?***

    USP currently recommends the use of CSTDs for compounding HDs. Per USP, it is not a requirement as there is no published universal performance standard for evaluation of CSTD containment. NIOSH is currently working on developing such a protocol.

59. ***Is a line of demarcation for doffing personal protective equipment (PPE) required for all hazardous containment secondary engineering controls?***

    USP <800> *requires* a doffing area if the negative-pressure hazardous drug (HD) buffer room is entered through the positive-pressure non-hazardous drug buffer room. Additionally, it states a designated doffing area *should* be indicated within all containment secondary engineering controls (C-SEC). Other than the line of demarcation mentioned in section 5.3.2, General Chapter <800> does not specify where doffing should occur. However, this is entity dependent and should additionally follow garbing requirements in <797>.

60. ***USP <800>, within Section 5.3, indicates that an eyewash station and/or other emergency or safety precautions that meet applicable laws and regulations must be readily available. Are there applicable laws and regulations in Virginia regarding eyewash stations and/or other emergency or safety precautions?***

    The Board is not currently aware of laws and regulations in Virginia related to use of eyewash stations or other safety precautions related to this issue.

61. ***May a laminar airflow workbench (LAFW) or a compounding aseptic isolator (CAI) be used for compounding with an antineoplastic hazardous drug (HD)?***

    No.

62. ***Is it required to compound all sterile hazardous drugs within an externally vented containment primary engineering control (biological safety cabinet (BSC) or compounding aseptic containment isolator (CACI))?***

No, dosage forms of non-antineoplastic and reproductive risk hazardous drugs may be handled and compounded under an assessment of risk. If, however, bulk active pharmaceutical ingredients (API) of these drugs are used as starting ingredients, all of the containment requirements in <800> would apply. Refer to Box 1 within USP Chapter <800>.

63. ***What are the specifications required of a pass through chamber? Is it required be interlocking and HEPA filtered purged? Between what areas may these chambers be utilized?***

General Chapter <800> defines a pass-through as "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. The chapter does not require the pass-through to be HEPA filter purged and does not limit where these pass-throughs may be placed. General Chapter <800> additionally states that refrigerator pass-throughs must not be used.

64. ***Chapter <800> states 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. What is the intent of this statement?***

The intent of prohibiting the storage of nonsterile compounding materials in sterile compounding areas is to minimize traffic flow into the sterile classified areas.

65. ***May bulk active pharmaceutical ingredients (API) used for sterile compounding be stored in the negative pressure C-SEC?***

Yes. Refer also to USP's frequently asked question #16 found at http://www.usp.org/frequently-asked-questions/hazardous-drugs-handling-healthcare-settings

66. ***Where must manipulation of non-sterile, non-antineoplastic and reproductive risk hazardous drugs (that are not bulk active pharmaceutical ingredients (API)) occur?***

The location where manipulation occurs should follow an assessment of risk for non-antineoplastic and reproductive risk hazardous drugs (that are not bulk APIs). Facilities should determine their own strategies based on its assessment of risk.

67. ***Does Chapter <800> address whether scrubs that are worn within the hazardous compounding/storage area may be allowed to be taken home?***

No. General Chapter <800> does not specify best practices for clothing under the gown. However, section 7.2 does require gowns to be disposable and shown to resist permeability by HDs.

68. ***What is the best practice for receiving hazardous drugs (HD)?***

USP <800>, within Section 5.1, states antineoplastic HDs and all HD active pharmaceutical ingredients (API) 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. Best practice is to unpack the hazardous drugs from the delivery tote, and leave packaged in a zip-locked plastic bag. From there, the unopened plastic bags should be moved to HD storage room, where the HDs can be removed from the bags and received into inventory. HDs should never be withdrawn from the plastic transport bags in any room other than the HD storage room.

69. ***If the C-PEC vents externally and the room is able to maintain appropriate negative pressure and air exchanges, does the C-SEC need to be vented?***

No.

For more information regarding USP Chapter <800>, an extensive list of frequently asked questions published by USP may be accessed at http://www.usp.org/frequently-asked-questions/hazardous-drugs-handling-healthcare-settings.

Virginia Board of Pharmacy
Practitioner of the Healing Arts Selling Controlled Substances
Inspection Deficiency Monetary Penalty Guide

Major Deficiency	Law/Reg Cite	Conditions	$ Penalty
1. Practitioner selling on an expired license.	18VAC110-30-30	Per individual	100
2. Selling by unauthorized individuals.	§ 54.1-3302 & 18VAC110-30-20	Per individual	500
3. Change of location, remodel, or addition of a selling location without application or Board approval.	18VAC110-30-80	must submit an application and fee	250
4. More than one person present in the storage and selling area to assist in performance of pharmacy technician tasks.	18VAC110-30-40 & 18VAC110-30-130	per each person First Offense – Minor 3 deficiency Second Offense – Major 4 deficiency	100
5. Persons assisting in the performance of pharmacy technicians duties other than a registered pharmacy technician or licensed nurse or physician assistant who has received training in technician tasks.	18VAC110-30-40	Per individual	250
6. Refrigerator/freezer temperature out of range greater than +/- 4 degrees.	18VAC110-30-110	determined using inspector'calibrated thermometer	100 Drugs may be embargoed
7. Insufficient enclosures or locking devices.	18VAC110-30-120	Major 7 if there is evidence that non-compliance contributed to a drug loss. Minor 6 if no drug loss.	500

Major Deficiency	Law/Reg Cite	Conditions	$ Penalty
8. Storage of drugs for sale not in the storage and selling area.	18VAC110-30-90		500
9. Alarm not operational or not being set. Enclosure not locked and alarmed when licensee not on duty.	18VAC110-30-120		1000
10. Unauthorized access to alarm or locking device to the drug storage and selling area.	18VAC110-30-120 & 18VAC110-30-130		1000
11. No biennial inventory, or over 30 days late, or substantially incomplete, i.e., did not include all drugs in Schedules II-V.	54.1-3404 & 18VAC110-30-180	Minor 23 if only expired drugs not included in inventory.	500
12. Theft/unusual loss of drugs not reported to the Board as required or report not maintained.	54.1-3404	per report/theft-loss	250
13. Hard copy prescription or record of sale not maintained or retrievable as required.	18VAC110-30-190		250
14. Automated data processing records of sale not maintained as required.	18VAC110-30-200		250
15. Practitioner not verifying or failing to document verification of prescriptions sold.	18VAC110-30-40	10% threshold for documentation	500
16. Practitioner not checking and documenting repackaging.	18VAC110-30-210	Review all entries for 5 drugs for six consecutive months. Deficiency if 10% or more are not compliant	250
17. Practitioner not documenting final verification of non-sterile compounding.	54.1-3410.2, 18VAC110-30-40		500
18. Practitioner not documenting final verification of sterile compounding.	54.1-3410.2 18VAC110-30-40		5000

Major Deficiency	Law/Reg Cite	Conditions	$ Penalty
19. Schedule II through VI drugs are being purchased from a wholesale distributor, warehouse, or other entity not licensed or registered by the Board or from a pharmacy not in compliance.	110-30-255		250
20. No clean room.	54.1-3410.2		10000
21. Have clean room, but not all physical standards in compliance, e.g., flooring, ceiling.	54.1-3410.2		2000
22. Performing sterile compounding outside of a clean room.	54.1-3410.2	Compliant clean room present but not utilized for preparation of compounded sterile drug products.	3000
23. Sterile compounding of hazardous drugs performed in an area not physically separated from other preparation areas.	54.1-3410.2		2000
24. High-risk drugs intended for use are improperly stored.	54.1-3410.2		5000
25. Certification of the direct compounding area (DCA) for compounded sterile preparations indicating ISO Class 5 not performed by a qualified individual no less than every 6 months and whenever the device or room is relocated, altered, or major service to the facility is performed.	54.1-3410.2	Review 2 most recent reports; certification must be performed no later than the last day of the sixth month from the previous certification	3000

Major Deficiency	Law/Reg Cite	Conditions	$ Penalty
26. Certification of the buffer or clean room and ante room indicating ISO Class 7 / ISO Class 8 or better not performed by a qualified individual no less than every six months and whenever the device or room is relocated, altered, or major service to the facility is performed.	54.1-3410.2	Review 2 most recent reports; certification must be performed no later than the last day of the sixth month from the previous certification	
27. Low or medium-risk compounded sterile preparations assigned inappropriate beyond use date (BUD).	54.1-3410.2		1000
28. No documentation of sterilization methods or endotoxin pyrogen testing for high-risk level compounded sterile preparations or high risk compounded sterile preparations assigned inappropriate beyond use date (BUD).	54.1-3410.2		5000
29. No documentation of initial and annual (12 months) media-fill testing for persons performing low and medium-risk level compounded sterile preparations.	54.1-3410.2	Review 2 most recent reports. Media-fill testing must be performed no later than the last day of the twelth month from the date the previous media-fill test was initiated.	500

Major Deficiency	Law/Reg Cite	Conditions	$ Penalty
30. No documentation of initial and semi-annual (6 months) media-fill testing for persons performing high-risk level compounded sterile preparations.	54.1-3410.2	Review 2 most recent reports. Media-fill testing must be performed no later than the last day of the sixth month from the date the previous media-fill test was initiated	5000
31. Documentation that a person who failed a media-fill test has performed low or medium risk level compounded sterile preparations after receipt of the failed test result and prior to retraining and receipt of passing media-fill test.	54.1-3410.2		500
32. Documentation that a person who failed a media-fill test has performed high-risk level compounded sterile preparations after receipt of the failed test result and prior to retraining and receipt of passing media-fill test.	54.1-3410.2		5000
33. Compounding using ingredients in violation of §54.1-3410.2.	54.1-3410.2		1000
34. Compounding copies of commercially available products.	54.1-3410.2	per Rx dispensed up to maximum of 100 RX or $5000	50
35. Unlawful compounding for further distribution by other entities.	54.1-3410.2		500

Minor Deficiencies

If five (5) or more minor deficiencies are cited, a $250 monetary penalty shall be imposed. Another $100 monetary penalty will be added for each additional minor deficiency over the initial five.

Minor Deficiency	Law/Regulation Cite	Conditions
1. Selling drugs from a location prior to approval by the Board.	18VAC110-30-80	
2. Special/limited-use scope being exceeded without approval.	18VAC110-30-20	
3. More than one person present in the storage and selling area to assist in performance of pharmacy technician tasks.	18VAC110-30-40 & 18VAC110-30-130	per each person First Offense – Minor 3 deficiency Second Offense – Major 4 deficiency
4. No site-specific training program and manual.	18VAC110-30-40	
5. No documentation of successful completion of site-specific training program.	18VAC110-30-40	
6. Insufficient enclosures or locking devices.	18VAC110-30-120	Major 7 if there is evidence that non-compliance contributed to a drug loss. Minor 6 if no drug loss.
7. Emergency access alarm code/key not maintained in compliance.	18VAC110-30-120	
8. Selling and storage area, work counter space and equipment not maintained in a clean and orderly manner.	18VAC110-30-90	must have picture documentation
9. Controlled substances for ultimate sale not clearly separated from other drugs (i.e. samples, drugs for administration).	18VAC110-30-90	

10. Storage of prescriptions prepared for delivery not in compliance.	18VAC110-30-140	
11. Expired drugs in the working stock.	18VAC110-30-150	10% threshold
Minor Deficiency	**Law/Regulation Cite**	**Conditions**
12. No prescription balance sensitive to 15mg and weights or electronic scale if engaged in dispensing activities that require the weighing of components.	18VAC110-30-110	
13. Sink with hot and cold running water not available within the immediate vicinity of the selling and storage area.	18VAC110-30-90	
14. Failure to conspicuously display sign in a public area advising patients of their right to choose where to have their prescriptions filled.	18VAC110-30-170	
15. Documentation of patient's choice to have prescription filled by practitioner not in compliance..	18VAC110-30-170	
16. No thermometer or non-functioning thermometer in refrigerator/freezer, but temperature within range, +/-4 degrees Fahrenheit.	18VAC110-30-110	determined using inspector's calibrated thermometer
17. No current dispensing information reference source.	18VAC110-30-110	
18. Labels do not include all required information	18VAC110-30-220	10% Threshold Review 25 prescriptions
19. Special packaging not used, no documentation of request for non-special packaging, sign not posted near the compounding and selling area advising patients nonspecial packaging may be requested.	18VAC110-30-240	

20. Repackaging records and labeling not kept as required or in compliance.	18VAC110-30-210	10% threshold
21. Packaging not compliant with USP-NF standards.	18VAC110-30-230	

Minor Deficiency	Law/Regulation Cite	Conditions
22. Biennial inventory taken late but within 30 days.	54.1-3404 & 18VAC110-30-180	
23. Inventories taken on time, but not in compliance, i.e., no signature, date, opening or close, Schedule II drugs not separate, failure to include expired drugs.	54.1-3404 & 18VAC110-30-180	
24. Records of receipt (e.g.invoices) of controlled substances not maintained as required.	§ 54.1-3404 & 18VAC110-30-180	
25. Offer to counsel not made as required.	18VAC110-30-40	
26. Prospective drug review not performed as required.	18VAC110-30-40	
27. Improper disposal of unwanted drugs.	18VAC110-30-160	
28. Particle counts, environmental sampling, and smoke pattern testing not performed under dynamic conditions.	§54.1-3410.2	
29. Equipment for sterile compounding does not comply with USP-NF standards.	18VAC110-30-110 & § 54.1-3410.2	
30. Equipment for non-sterile compounding does not comply with USP-NF standards.	54.1-3410.2	

White bagging/brown bagging

Possible regulatory concepts to address patient-safety concerns:

- Define white bagging and brown bagging;
- Prohibit brown bagging since this potentially introduces liability and safety concerns for administering the drug;
- Require the specialty pharmacy participating in white bagging to:
    - notify the receiving pharmacy of the shipment
    - provide estimated arrival date
    - provide the name of the patient to whom the drug has been dispensed
    - provide the exact address where the product has been shipped
    - require the specialty pharmacy to label the drug patient-specifically
    - require the specialty pharmacy to use ship the drug in a manner that ensures appropriate temperature range, to include use of a temperature monitoring device, if necessary.

Background
From June 14, 2016 Full Board Meeting Agenda:

Agenda Item: Recommend Gathering of Additional Information from NABP Discussions regarding White Bagging and Brown Bagging

Background: Pharmacy Benefit Manager (PBM) Workgroup agreed that the Board of Pharmacy should address any identified issues of concern, including the promulgation of regulations to reduce the potential for patient harm and promote consistency within the process. Full board in March agreed that the Regulation Committee should discuss issues of white bagging and brown bagging. Staff is only aware of Oregon having addressed white bagging in regulation, however, it appears to address reconstitution, but not other forms of compounding, and does not address brown bagging.

Included in your agenda package is:

Excerpts from the PBM Workgroup Report, March 4, 2016

Oregon's Final Rule 3.00.27

NABP Resolution – passed 5\2016

Regulation Committee Recommendation:

Committee recommends gathering additional information from upcoming NABP discussions on white bagging and brown bagging based on adoption of NABP resolution on this matter.

"White bagging and brown bagging"

These are relatively new patient delivery models used by specialty pharmacies that may or may not be owned or associated with a PBM. Brown bagging involves specialty pharmacies mailing specialty drugs to the patient's residence, and white bagging involves specialty drugs being mailed to the prescriber or another pharmacy, e.g., hospital pharmacy, for subsequent administration to a specific individual in the clinical setting. A hospital pharmacist whose health system participates in white bagging indicated to the Workgroup: the specialty pharmacy dispenses the drug(s) pursuant to a patient-specific prescription; the receiving pharmacy may not be aware that drugs are being shipped to it prior to the package arriving; the receiving pharmacy may be required to further compound or reconstitute the already dispensed drug prior to administration and without reviewing the prescription, a process which may not comply with the law; the patient may be delayed in receiving the drug from the specialty pharmacy as it must be mailed from the specialty pharmacy even though the receiving pharmacy may have the prescribed drugs in stock; and the drugs appear to be delivered by the specialty pharmacy in a manner that does not comply with Board of Pharmacy Regulation 18VAC110-20-275. Mr. Gray stated there is a general lack of consistency for how these processes occur. There was consensus among the Workgroup that the Board of Pharmacy should review the practices of white bagging and brown bagging to address any issues of concern.

Parity regarding access to and requirements of plans

Comment was received from several independent pharmacy owners that there is a disparity between chain pharmacies and independent pharmacies regarding access to plans. These individuals stated patients have a right to choose their supplier of drugs, and forcing patients to use mail order pharmacies is violating that right. It was noted that Virginia law does have a freedom of choice requirement in §38.2-3407.7 regarding fully-insured health plans; and therefore, these plans cannot require a patient to use a mail order pharmacy. However, self-insured health plans may require patients to use mail order pharmacies, and both self-insured and fully-insured health plans may require drugs to be obtained from a specialty pharmacy.

Prior authorizations

Several issues related to prior authorizations were discussed. There was general consensus among the pharmacists offering comment and the pharmacy associations that the prior authorization process is overly burdensome; can delay patient access to drugs up to 7-10 days; can increase cost to the patient when the branded drug is covered and the generic drug is not, thereby pushing the patient into the Medicare "donut hole" faster; and can result in the pharmacist not being reimbursed if he or she chooses to provide the patient with the drug prior to receiving approval of the prior authorization or over a weekend when the mail order supply did not arrive in time. Those representing the health plans and PBMs indicated §38.2-3407.15:2 requires fully-insured health plans to process prior authorizations, once the required information is received, within 24 hours for emergencies and 2 business days for non-emergencies. It was also noted that the state does not have oversight of Medicare Part D. There was acknowledgement that the process is time-consuming for prescribers as well, often requiring dedicated administrative staff in the office for processing prior authorization requests. There appeared to be consensus that prior authorizations should not be eliminated, as many acknowledged there are benefits to both patients and payers for drug utilization management,

Specialty drugs

There were some comments by Workgroup members and the public regarding the increasing number of drugs being classified by health plans as specialty drugs which often must be dispensed by specialty pharmacies. There is no uniform definition for a specialty drug or specialty pharmacy. At one time, the practice was reserved for expensive or complex drug therapy, but presently it appears specialty drugs are no longer limited to these types of drugs. Commenters in support believe the use of specialty pharmacies increases patient safety and helps decrease overall healthcare costs. Commenters in opposition stated it appears to impact patient safety by unnecessarily delaying patients' receipt of the drug and drive business toward specialty pharmacies that are often owned by PBMs.

Potential Policy Options:

Below are potential policy options that may be taken. There was general consensus for options #1 and 2.

1. The Medical Society of Virginia along with the Virginia Pharmacists Association will meet with the Virginia Health Plans and other key stakeholders with technical expertise to address current concerns with the prior authorization process and develop a strategy for implementing electronic prior authorizations in the near future and encourage the use of e-prescribing by prescribers.
2. The Board of Pharmacy will review the practices of white bagging and brown bagging to address any identified issues of concern, including the promulgation of regulations to reduce the potential for patient harm and promote consistency within the processes.

Other Possible Policy Options/Considerations:

Those representing pharmacists, pharmacies, and the Medical Society of Virginia generally supported options #3-5. VDH OLC found option #5 feasible with sufficient resources. Those representing health plans and PBMs did not support options #3-5.

3. The Board of Pharmacy will consider the issue involving specialty drugs and whether it should and has the legal authority to define the criteria for a specialty drug.
4. Future policy discussions should include the impact that the closing of pharmacies in a rural setting would have on patient care in that environment.
5. Increase oversight of the administration of pharmacy benefits by reviewing relevant statutes. Such oversight could provide VDH OLC with ability to:
    a. license PBMs;
    b. describe in regulation information which may be collected and/or prohibited from being collected by a PBM during the credentialing process of providers/pharmacies;
    c. define "specialty drug" to describe the criteria to be used in determining drug eligibility; and
    d. receive complaints against PBMs and take enforcement action when warranted.

Oregon's Final Rule

3.00.27 Outlet to Outlet Drug Reconstitution. A pharmacist at a prescription drug outlet may reconstitute a prescription originally dispensed in an unreconstituted form pursuant to a patient-specific order at another prescription drug outlet or nonresident prescription drug outlet provided the following conditions are met:

a. The prescription is delivered directly from the originating outlet to the receiving outlet;

b. The prescription is at no time in the physical possession of the patient until after the prescription has been reconstituted;

c. The prescription is reconstituted according to the corresponding manufacturer's directions;

d. The prescription is not a controlled substance;

e. The pharmacist at the receiving outlet does not alter the prescription or its original labeling in any way other than to reconstitute, re-label for re-dispensing for administration, and properly store the prescription; and

f. The originating outlet is ultimately accountable to the Board for the accurate dispensing of the original prescription, and the receiving outlet is ultimately accountable for the accurate reconstitution and re-dispensing of the prescription.

RESOLUTION NO: 112-1-16

TITLE: **Study to Review the Practices of "White Bagging" and "Brown Bagging"**

MEMBERSHIP VOTE: **PASS**

WHEREAS, "white bagging" generally refers to a patient-specific medication that is distributed by a pharmacy to a hospital, clinic, physician's office, or pharmacy for later preparation and administration to a patient where allowed by law and "brown bagging" generally refers to a patient-specific medication that is dispensed by a pharmacy to the patient and then brought by the patient to the hospital, clinic, or physician's office for administration;

WHEREAS, the practices of "white bagging" and "brown bagging" are becoming more prevalent and often defined and mandated by third-party payers outside of the authority of the state boards of pharmacy; and

WHEREAS, the need exists for the boards of pharmacy to define such practices and ensure appropriate regulatory oversight in order to protect patients;

THEREFORE BE IT RESOLVED that NABP conduct a study, which may include, if appropriate, other key health care stakeholders to review and define the practices of "white bagging" and "brown bagging" and recommend regulatory language, if necessary, to the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy* to assist boards of pharmacy in overseeing and addressing the accountability and safety of medications dispensed and administered via these methods.

of "covered substance" in §54.1-2519 and its reference in §54.1-2520 to include Schedule V controlled substances.

- RECOMMEND GATHERING OF ADDITIONAL INFORMATION FROM NABP DISCUSSIONS REGARDING WHITE BAGGING AND BROWN BAGGING:

Ms. Shinaberry stated that the Pharmacy Benefits Manager Workgroup (PBM Workgroup) agreed that the Board of Pharmacy should address any identified issues of concern with white bagging and brown bagging, including the promulgation of regulations to reduce the potential for patient harm and promote consistency within the process. At the March 25, 2016 Board meeting, it was agreed that the Regulation Committee discuss the issues of white bagging and brown bagging. Oregon is the only state that staff is aware of that addresses white bagging in regulation and it appears to only address reconstitution, but not any other forms of compounding. There is no mention of brown bagging in Oregon's regulations. The Regulation Committee recommends gathering additional information from upcoming NABP discussions on white bagging and brown bagging based on a recently adopted NABP resolution on this matter.

MOTION:

The Board voted unanimously to accept the Regulation Committee recommendation to gather additional information from upcoming NABP discussions on white bagging and brown bagging based on a recently adopted NABP resolution on the matter.

- RECOMMENDED MEETING OF PBM TASK FORCE SUBGROUP TO ADDRESS CONCERNS WITH DESIGNATION OF SPECIALTY DRUGS:

The Regulation Committee recommends forming a subgroup with representation from those PBM Workgroup members who supported the policy option of the board considering the issue of specialty drugs to identify possible actions that would effectively address the concerns involving specialty drugs as identified in the PBM Workgroup report. Dr. Brown recommended that the board not limit itself to a subgroup of the PBM Workgroup, but to rather form an ad hoc committee and ensure that the committee's charge is aligned with the board's mission to protect the public. It was discussed that the main focus of the committee would be to address patient access to drugs. Those members expressing interest in participating on the committee included Freeda Cathcart, Michael Elliott, and Jody Allen.

MOTION:

The Board voted unanimously for the chairman to appoint members to an ad hoc committee to address concerns with specialty drugs as identified by the Pharmacy Benefit Manager Workgroup and that representation from the following groups, at a minimum, would be invited to participate on the ad hoc committee: board members, health plans, health system pharmacists, the Medical Society of Virginia, and the Virginia Pharmacists Association.
(motion by Shinaberry, second by S. Elliott)

RECOMMENDED ADOPTION OF 2017 LEGISLATIVE

DRAFT

18VAC110-20-390. 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.