General Guide to USP Proposed Chapter <800>: Hazardous Drugs – Handling in Healthcare Settings

**DISCLAIMER:** This general guide is not designed to be an all-inclusive review of USP <800>. PCCA provides this as a factual reference to the chapter. This guide is prepared with the general compounding pharmacy audience in mind and assumes a working knowledge of pharmacy compounding. We recommend fully reading the chapter and reviewing all materials provided by USP regarding the chapter. Additional information from USP can be found at:

http://www.usp.org/usp-nf/notices/compounding-notice and

http://www.usp.org/usp-nf/notices/general-chapter-hazardous-drugs

Also, comments are welcome by USP regarding the chapter. The comment period is open until July 31, 2014. Instructions on how to comment can be found at the end of this document.

USP undertook the creation of this chapter to “guide the handling of hazardous drugs (HDs) in healthcare settings.” The goal is to help “protect the patient, healthcare personnel and environment”. If adopted as-is, it would eliminate the hazardous drug low volume clause in USP <797> (sterile compounding of hazardous drugs in low volume would not require negative pressure).

**Objective of the Chapter**

“The objective of this chapter is to protect personnel and the environment when handling HDs. This includes but is not limited to receipt, storage, mixing, preparing, compounding, dispensing, administering, disposing, and otherwise altering, counting, crushing, or pouring HDs, and includes both sterile and non-sterile products and preparations. The standards in this chapter apply to all personnel who compound HD preparations and all places where HDs are prepared (e.g., pharmacies, hospitals and other healthcare institutions, patient treatment clinics, physicians’ practice facilities, veterinarians’ offices) and other locations and facilities in which HDs are stored, transported, and administered. Persons who compound HDs include but are not limited to pharmacists, nurses, pharmacy technicians, physicians, physician assistants, veterinarians, and veterinary technicians.”

From the opening paragraph, we can quickly see that this chapter affects all facets of healthcare, not just pharmacies engaged in compounding.

**Acronyms / Definitions**

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Definition</th>
</tr>
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<tbody>
<tr>
<td>ACPH</td>
<td>Air Changes Per Hour</td>
</tr>
<tr>
<td>BSC</td>
<td>Biological Safety Cabinet – a ventilated cabinet often used for preparation of HDs (Note: there are different classes of BSCs – they are defined in the chapter)</td>
</tr>
<tr>
<td>CACI</td>
<td>Compounding Aseptic Containment Isolator – e.g. a glove box ventilated outside of the building – used to compound sterile HDs</td>
</tr>
<tr>
<td>CAI</td>
<td>Compounding Aseptic Isolator – e.g. a glove box ventilated into the room that contains the CAI – cannot be used to compound sterile HDs</td>
</tr>
<tr>
<td>C-PEC</td>
<td>Containment Primary Engineering Control – the device in which the compounding will occur (e.g. CACI, BSC, CVE)</td>
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</table>
Overview

“There is no acceptable level of personnel exposure to HDs.” As such, the chapter provides recommendations on how exposure levels can be minimized. It is important to note here that the chapter states: “Where conflicts exist, the most stringent requirements prevail.” The chapter goes into a bit of detail about how an entity can provide an environment that minimizes exposure to HDs.

Types of Devices for Compounding with HDs:

<table>
<thead>
<tr>
<th>Non-sterile</th>
<th>CVE or BSC (Class I) OR CACI or BSC (Class II) may be used if dedicated for non-sterile compounding OR if they used for occasional non-sterile compounding, must be thoroughly cleaned and disinfected before being used for sterile compounding.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sterile</td>
<td>CACI or BSC (Class II)</td>
</tr>
</tbody>
</table>

List of HDs

USP designates “the entity shall include all items on the current NIOSH list and may add others not on the NIOSH list.” USP also notes here: “Uncoated tablets may present a risk of exposure from dust by skin contact and/or inhalation when the tablets are counted.” “SOPs shall identify risk mitigation strategies for items on the HD list”

The most current (2012) NIOSH list can be found here: [http://www.cdc.gov/niosh/docs/2012-150/pdfs/2012-150.pdf](http://www.cdc.gov/niosh/docs/2012-150/pdfs/2012-150.pdf)
The proposed changes for the 2014 NIOSH list can be found here:

Types of Exposure

USP presents a list of different types of exposure to HDs. The majority of them are self-evident (pouring liquids, mixing topical dosage forms, weighing components, etc.), but of note to be aware of:

- Receiving and unpacking HD orders
- Counting individual oral doses and tablets from bulk containers
- Expelling air from syringes filled with HDs
- Contacting HD residue present on drug container exteriors
- Contacting or inhaling HD residue or aerosolization from another patient’s medications

Facility Design and Engineering Controls

All requirements in Chapter <800> are in addition to requirements in Chapters <795> and <797>. The chapter details: “Separate designated areas shall be available for: Unpacking HDs, Non-sterile HD Compounding, and Sterile HD Compounding.”

Storage

- Antineoplastic HDs shall be separate from non-HDs
- Non-antineoplastic HDs shall be separate from non-HDs, unless only coated, final-manufactured dosage forms are clearly labeled as HDs and safety strategies are included in the entity’s SOPs.
- “Unless the HDs already exist in their final unit dose or unit-of-use packaging, HDs shall be stored separately from other inventory in a manner to prevent contamination and personnel exposure, which includes storage in a negative pressure room with at least 12 air changes per hour (ACPH).”
- Also, refrigerated HDs shall be stored in a dedicated refrigerator in the HD storage room, buffer room or C-SCA. HDs are to be stored at or below eye level and not stored on the floor. Storage of non-sterile and sterile HDs may be intermingled.

Engineering Controls

- HDs that require alteration shall be manipulated in a C-PEC in an area that is physically separated from other preparation areas, which is under negative pressure, and has at least 12 ACPH.
- All C-PECs shall be externally vented and placed in a restricted access segregated room which has a minimum negative pressure of 0.01 inches of water column.
- HD compounding activities must occur within a C-SEC where any C-PEC shall be vented to the outside air through high efficiency particle air (HEPA) filtration. For both sterile and non-sterile HD compounding, a sink shall be available for hand washing as well as emergency access to water for removal of hazardous substances from eyes and skin.
- For non-sterile HD compounding, any C-PEC may be used and the C-SEC must meet the following requirements:
  - Minimum of 12 ACPH
  - Maintained at a negative pressure and externally vented
- Smooth, seamless, impervious surfaces, as stated in <797> also apply to the non-sterile HD compounding area.

For sterile compounding, three configurations are acceptable for low- and medium-risk sterile compounding and only two configurations are acceptable for high-risk sterile compounding. The table from the chapter appears below:

<table>
<thead>
<tr>
<th>Configuration</th>
<th>Function</th>
<th>C-PEC</th>
<th>C-SEC</th>
<th>Airflow</th>
<th>Maximum BUD</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Compounding sterile HD in a cleanroom</td>
<td>BSC or CACI</td>
<td>ISO 7 Cleanroom</td>
<td>30 ACPH (HEPA supply)</td>
<td>As listed in &lt;797&gt;</td>
</tr>
<tr>
<td>2</td>
<td>Compounding sterile HD in a CACI that meets the requirements listed in &lt;797&gt;</td>
<td>CACI</td>
<td>C-SCA</td>
<td>12 ACPH (exhaust)</td>
<td>As listed in &lt;797&gt;</td>
</tr>
<tr>
<td>3</td>
<td>Compounding low- or medium-risk sterile HDs in a BSC. [NOTE—This configuration is not acceptable for high-risk sterile HD compounding.]</td>
<td>BSC</td>
<td>C-SCA</td>
<td>12 ACPH (exhaust)</td>
<td>12 hours</td>
</tr>
</tbody>
</table>

The chapter goes into great detail about the three different configurations for sterile HD compounding. If you currently compound sterile HDs, it is recommended to review the information located between lines 338 and 412.

The chapter does allow for non-sterile and sterile HD compounding to occur in the same C-PEC as long as the C-PEC “are sufficiently effective that the room can continuously maintain ISO 7 classification throughout the non-sterile compounding activity.”

The chapter does provide example designs of HD compounding areas in Appendix E.

Any C-PEC used in compounding HDs shall be operated continuously, for both non-sterile and sterile HD compounding.

Containment Supplemental Engineering Controls (CSTDs – defined elsewhere in the chapter as Closed System drug-Transfer Device; e.g. BD PHASEAL™) shall only be used as a supplemental control inside a C-PEC.

**Personal Protective Equipment**

The chapter provides a detailed table in Appendix F for requirements based on function, which include: receiving intact supplies, receiving suspected/broken supplies, transporting intact supplies or compounded HDs, receiving intact supplies in the compounding area, stocking and inventory control of the compounding area, non-sterile compounding, sterile compounding, collecting and disposing compounding waste, administrating, routine cleaning, collecting and disposing patient waste and managing spills.
Gloves used shall be labeled as ASTM-tested chemotherapy gloves and must be powder free. When compounding, administering, managing a spill or disposing of HDs, two pairs of ASTM-tested chemotherapy gloves must be worn. If compounding a sterile HD, the outer glove shall be sterile. Gloves must be changed every thirty minutes or when torn, punctured or contaminated.

Disposable gowns made of polyethylene-coated or other laminate materials must be used. Gowns must close in the back, have long sleeves and have closed cuffs that are elastic or knit. Gowns can only be worn in the compounding or administration area and must be removed before leaving these areas. If no permeation information is available from the manufacturer, they must be changed every two to three hours or immediately after a spill or splash.

Head, hair (beard and moustache) and shoe covers must be worn in the HD compounding areas and must be disposed of before leaving the compounding area.

Eye and face protection must be used when manipulating a HD outside of a C-PEC (e.g. surgical suite), working at or above eye level, cleaning a C-PEC or cleaning a spill.

A NIOSH-certified N95 protective respirator or surgical N95 respirator must be used when receiving suspected / broken supplies. A full list of these can be found here. Note that an appropriate, full-face piece, chemical cartridge type respirator (NOT a N95 respirator) must be used for spills when there is a known or suspected airborne exposure to vapor or gases.

All PPE must be handled and disposed of as if they were contaminated. Unless local regulations prohibit, these items shall be incinerated at a regulated medical waste incinerator. They should not be placed into red bag or red sharps containers.

**Hazard Communication Program**

“OSHA requires each workplace to have a written Hazard Communication Program. The Hazardous Communication Standard (HCS) (found here) applies to all workers. Employers are required to establish policies and procedures to ensure worker safety in all aspects of the distribution of these drugs and chemicals.

The HCS requires each employer to provide training, proper labeling, and Safety Data Sheets (SDS), based on the Globally Harmonized System of Classification of Labeling of Chemicals (GHS).

Elements of the plan shall include:

- A written plan that describes how the standard will be implemented.
- All containers of hazardous chemicals shall be labeled, tagged, or marked with the identity of the material and appropriate hazard warnings.
- Chemical manufacturers and importers are required to obtain or develop an SDS for each hazardous chemical they produce or import. Distributors are responsible for ensuring that their customers are provided a copy of these SDSs. Employers shall have an SDS for each hazardous chemical they use.
- Each employee who may be exposed to hazardous chemicals when working shall be provided information and training before initial assignment to work with a hazardous chemical, and whenever the hazard changes.
Employers shall maintain in the workplace copies of the required SDSs for each hazardous chemical and shall ensure that the SDSs are readily accessible to employees during each work shift and when they are in their work areas.”

**Training for Compounding Personnel**

All training shall be documented, and personnel competency shall be reassessed and documented every 12 months, or whenever a new HD is used or a new or significant change in process or SOP occurs. The training shall include at least the following:

- Didactic overview of types of HDs and their risks, including carcinogenic, genotoxic, teratogenic, organ toxicity, and adverse reproductive properties
- Review of the entity’s policies and procedures for personnel who handle HDs, including the process to request alternative duty
- Ordering, receiving, and stocking of HDs
- Proper hand hygiene
- Use of PPE
- Use of C-PECs and other equipment and devices
- Negative-pressure techniques when using C-PECs
- Safe aseptic practices, if applicable
- Containment, clean-up, and disposal procedures for normal use and for breakage and spills
- Treatment of personal contact and any unintended exposure

**Receiving**

HDs must be contained from the supplier in impervious plastic to segregate them from other drugs and should be immediately delivered to the C-Sec. Receiving personnel shall wear PPE, including the aforementioned chemotherapy gloves and a spill kit shall be accessible in the receiving area. The entity shall enforce a tiered approach policy for receiving:

- Visual examination for signs of damage or breaking
  - If damaged, personnel shall don the appropriate additional PPE and determine if the packaged will be returned or opened.
  - Damaged packages shall be considered spills and shall be reported to the compounding supervisor.
- If returning to supplier, the package must be placed in an impervious container and labeled “Hazardous”. The supplier shall then be contacted on how to return the package.
- If the damaged package must be opened before returning, a Class I containment device shall be used to contain the package. A plastic-backed preparation mat must be placed on the work surface. The items can then be removed, cleaned with a disposable wipe, and placed in an impervious container which is marked “Hazardous”. Once contained, clean the Class I device and discard the mat and cleaning disposables as hazardous waste.

**Transporting**

This section deals with transporting HDs not only within the facility but also to places outside the facility.
- SOPs shall be established pertaining to packaging, transport, and handling of HDs.
- HDs shall be clearly labeled at all times during their transport and use.
- HDs shall not be transported in pneumatic tubes.
- If distribution of HDs occurs to locations outside of the premises of which they are compounded, appropriate package must be selected to maintain the physical integrity, stability, and sterility (if needed) of the HDs.
- Written instructions that clearly explain how to safely open containers of packed HDs shall be provided to patients and other recipients.
- The compounding facility must ensure that each facility, patient or other recipient can store the HD properly.

Dispensing HD Dosage Form Not Requiring Alteration

HDs in unit-dose or unit-of-use packaging that are not altered may be dispensed without any further requirements unless required by the manufacturer. Non-antineoplastic HDs may be counted from the stock bottle and placed into a prescription vial without any further requirement unless required by the manufacturer. Counting of these types of HDs should be done on clean equipment dedicated for use with these drugs. Tablet and capsule forms of HDs shall not be placed in automated counting machines. Counting coated tablets and capsules does not require a C-PEC.

NOTE: The chapter does not state what should be done with antineoplastic HDs that are not in a coated tablet or capsule dosage form.

Compounding HD Dosage Forms

Given what we have already covered so far, this section is fairly straight forward. Compounding shall occur in areas as described before to ensure personnel safety. However, this section does state: “Work practices ... shall include: avoiding use of APIs if a suitable manufactured product is available and appropriate for use, e.g., using an injection rather than a bulk powder”. This statement, coupled with the word shall, disallows the use of a bulk powder for monetary reasons if a suitable manufactured product is available.

Outside of this issue, the section requires compliance with USP <795> and <797> and a handful of other items already covered previously in the chapter.

Protection When Administering HDs

This section described how HDs shall be administered, mainly in the hospital / office use setting, which we will not cover in this guide. If you are actively involved in administering HDs, it is highly recommended to read this section carefully.

Cleaning: Deactivation, Decontamination, Cleaning & Disinfection

During routine cleaning, decontamination and waste disposal, personnel shall wear two pairs of aforementioned chemotherapy gloves, eye protection and face shields (if splashing is possible). Cleaning the C-PEC, other devices and equipment, and areas used for compounding HDs involves several steps: deactivation, decontamination, cleaning & disinfecting.
Deactivation shall occur when an appropriate agent for deactivation is identified. The section specifically notes that alcohol is not a deactivation agent and using it before deactivating and decontaminating may result in the spread of contamination. The section recommends 2% sodium hypochlorite for the deactivation of appropriate HDs.

Decontamination occurs by removing HD residue from surfaces and transferring them to a low-lint wipe which is then contained and discarded as contaminated waste. Decontamination of the BSC or CACI should occur at least weekly, or any time after a spill occurs, before and after certification, voluntary interruption or if the ventilation tool is moved. The section notes that no wipe down procedure has been studied, but recommends using a lint free wipe moistened with alcohol, sterile water, peroxide or sodium hypochlorite.

Cleaning is recommend as per <797> for both non-sterile and sterile HDs.

Disinfecting C-PECs shall be done at the beginning of the workday, between batches of compounding medications, at the beginning of each subsequent shift, routinely during compounding and after anytime the C-PEC has been powered off. The section does not define “routinely during compounding”.

**Spill Control**

Spills shall be contained and cleaned immediately by trained workers. Policies and procedures shall be developed to prevent spills and to govern clean-up of HD spills. Spill kits shall be readily available. If HDs are being prepared or administered in a non-routine area (e.g., home setting, unusual patient care area), a spill kit and respirator shall be available. All circumstances and handling of spills shall be documented. The section notes in its recommendation for SOPs: “Use of an appropriate full-face piece, chemical cartridge-type respirator for spills that exceed the capacity of the spill kit, such as when an IV bag breaks or a line disconnects and leaks, or where there is known or suspected airborne exposure to vapors or gases.”

**Disposal**

Disposal shall comply with all applicable federal and state regulations.

**Environmental Quality and Control**

Environmental wipe sampling to detect uncontained HDs should be performed routinely (e.g. initially as a benchmark and at least every six months, or more often as needed, to verify containment). Sampling should include: “working area of C-PEC; countertops where finished preparations are placed; areas adjacent to BSCs and CACIs, including the floor directly under the working area; and patient administration areas.” The section details common marker HDs that can be assayed, however, it is unclear what the facility should test for if they do not handle or compound any of the items described. If contamination is found, then a thorough review of all practice shall occur (section outlines in detail).

**Documentation**

This section outlines all documentation that shall be done, including establishment of policies and procedures and documentation of activities regarding “the acquisition, preparation, and dispensing of a compounded HD, personnel training, and the use and maintenance of equipment and supplies.”
Medical Surveillance

The chapter outlines what shall be done in establishing a medical surveillance program for personnel. Employers shall ensure that healthcare workers who are exposed to HDs are routinely monitored as part of a medical surveillance program. The section goes into a fair amount of detail of what will be in this program and for the sake of brevity, we will not cover it in this document. The section also states actions that should be taken for post-exposure examinations and refers to ASHP, NIOSH, ONS and ACOEM for additional guidelines.

Instructions for Comment:

Instructions on how and where to send comments can be found on USP’s website. PCCA’s comments to the proposed chapter are attached. Please feel free to use them as template for your own comments.

Questions about this summary document can be directed to John Voliva, R.Ph., Director of Legislative Relations, at jvoliva@pccarx.com.
MEMORANDUM

To: USP Expert Committee on Compounding

From: John Voliva, R.Ph.
Director of Legislative Relations

Subject: Comments on proposed USP General Chapter <800>

PCCA provides its more than 3,600 independent community compounding pharmacy members across the United States with drug compounding ingredients, equipment, extensive education, and consulting expertise and assistance. We appreciate this opportunity to comment on the proposed USP General Chapter <800>. Keeping in mind the goal of patient access to safe and necessary compounded medications, the issues set forth in the chapter are of critical importance to our members and PCCA’s entire organization.

PCCA echoes the concerns raised in the July 10, 2014 letter sent to Dr. Piervincenzi from APhA, IACP, NACDS, NASPA, NCPA and SSPS (attached). We wholeheartedly support their recommendation of elevating the chapter to above <1000> to allow affected healthcare settings to incorporate the recommendations outlined in the chapter into the setting’s best practices. PCCA would also like to point out that by numbering this chapter below <1000>, many regulatory bodies will be able to enforce the chapter as law. The potential decrease in access to patient care if this were to occur could be devastating, as many healthcare settings could lose their licensure because of violations of <800>.

We highly recommend that USP undertake developing their own Hazardous Drugs list and to not rely on the list promulgated by the National Institute for Occupational Safety and Health (NIOSH). The list itself indicates that it is a sample list and that, “Some drugs defined as hazardous may not pose a significant risk of direct occupational exposure because of their dosage formulation (for example, intact medications such as coated tablets or capsules that are administered to patients without modifying the formulation). However, they may pose a risk if solid drug formulations are altered outside a ventilated cabinet (for example, if tablets are crushed or dissolved, or if capsules are pierced or opened)” [NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Setting 2012, p. 11]. We would strongly recommend USP considers only drugs that present a clear danger to personnel (such as antineoplastic agents, immunosuppressive agents and pregnancy category X drugs) to be considered Hazardous in terms of this chapter.

As outlined in the quote above from the NIOSH 2012 List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, no mention was made about additional handling of the Hazardous Drugs outside of the use of a ventilated cabinet. We do not disagree with the use of a ventilated cabinet for the manipulation of these drugs, however the additional containment strategies appear to be onerous,
given present decontamination strategies available. We would strongly recommend removing the storage requirements and the air quality requirements around the CVE, BSC or CACI and provide guidance on proper decontamination procedures when containers containing Hazardous Drugs are removed from one of the containment devices. In the case of sterile compounding with Hazardous Drugs, following USP <797> is paramount and would require the placement of the containment device within the proper ISO environment.

Overall, as the chapter currently stands, it would have the potential of negatively affecting patient access to medications as many facilities would not be able to comply with the standards when manipulating long-used drugs like progesterone, estrogens, testosterone, and colchicine and, if adopted, apomorphine, fluconazole, spironolactone and warfarin. At the very least, cost of health care would increase and patient access to these types of medications would be diminished.

Our specific comments regarding the chapter are as follows:

Line 50: Recommend removing the line “There is no acceptable level of personnel exposure to HDs.” Given that this chapter could carry the weight of law, having a statement like this could be problematic depending on how the applicable regulatory body interprets the language. For example, State Boards of Pharmacy could misinterpret USP’s intent for this chapter and simply say if someone is exposed to HDs, the pharmacy where the exposure occurred has violated USP <800> and therefore is in violation of the State’s Pharmacy Practice Act.

Lines 224-227 The chapter does not address here, nor anywhere else, how non-HD components used in the compounding of a medication that contains a HD should be handled. These lines are confusing at best and convey that if a non-HD is brought into the HD compounding area, it should be considered henceforth contaminated and labeled as such. Was this the intent of the authors?

Lines 272-275 Is USP requiring the sink to be within the C-SEC? If not, the section is confusing and appears that it is being required. If it is, we feel it is onerous to require the placement of the sink in the C-SEC in regards to non-sterile compounding. We feel that there should be an allowance for the sink to be located close to, but not necessarily in, the C-SEC for hand washing as well as for emergency access. In addition, if the requirement is to place a sink in the C-SEC, it appears that this would be in violation of USP <797> in regards to not placing a sink in the buffer area of the C-PEC. Further clarification is required.

Lines 303-305 Recommend further clarification for surfaces than just referring to USP <797>. For non-sterile compounding, this will be an incredible cost burden for pharmacies with negligible or no added safety benefit.
Consideration should be given for non-sterile compounding. Recommend additional guidelines for shutting off the C-PEC when not in use and allowing for a prescribed amount of time to run before compounding activities can resume.

Recommend stating that two pairs of gloves are required when the HD being handled requires them. Otherwise, one pair of gloves is appropriate for compounding, administering and disposing of HDs.

Recommend changing “every 30 minutes” to “at completion of each compounding process”.

The chapter does not address what should be done with antineoplastic HDs that are not in a coated tablet of capsule dosage form.

“Routinely during compounding” is not defined in the chapter, leaving this section open for interpretation.

The chapter recommends several “common marker HDs” to assay, but does not directly address what to do if a pharmacy does not handle the drugs mentioned in these lines. Recommend to further give guidance or clarification beyond these common marker HDs.

In closing, we appreciate the opportunity to provide comment on the proposed chapter. If we can be of assistance on the comments provided above or any other compounding issues in the future, we stand ready to assist whenever needed.
July 10, 2014

Ronald T. Piervincenzi, Ph.D.
Chief Executive Officer
U.S. Pharmacopeial Convention
12601 Twinbrook Parkway
Rockville, MD 20852-1790

Dear Dr. Piervincenzi:

The undersigned organizations are writing today to voice our concern with USP’s proposed new General Chapter <800> Hazardous Drugs—Handling in Healthcare Settings. Although each of our organizations will be submitting individual comments related to the chapter by the July 31st deadline, we wanted to take this opportunity to share our collective thoughts.

We respectfully request that the chapter be numbered above <1000> in order to be classified as a general information chapter, imparting best practices. Although there are many best practices included in the proposed chapter, the impact on our members and their patients is too great at this time and compliance would be extremely difficult if not insurmountable to the vast majority of pharmacies and pharmacists.

Our members are currently held to regulations and guidelines from the Environmental Protection Agency (EPA) and the Occupational Safety and Health Administration (OSHA) which detail the handling of hazardous material, and although we appreciate the intent of the proposed chapter <800>, anything duplicative of currently enforceable rules can lead to confusion.

By placing this chapter above <1000>, our members will be afforded the opportunity to perform the appropriate analyses, including cost impacts and the impact upon the delivery of services to patients, and integrate best practices where appropriate. Given that no assessment of the financial impacts or the potential disruption to medication access has been conducted during the development of the proposed chapter <800>, we believe placing this chapter above <1000> to be the most prudent and appropriate course of action for USP. In addition, we recommend that a re-evaluation of implementation of the standards after a period of time occur, before consideration of renumbering the chapter.

While we respect the work of your expert committee and the merits behind the proposed chapter, we appreciate your thoughtful consideration of our comments.

Sincerely,

American Pharmacists Association
International Academy of Compounding Pharmacists
National Association of Chain Drug Stores
National Alliance of State Pharmacy Associations
National Community Pharmacists Association
Specialty Sterile Pharmaceutical Society