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Guidance for Compounding Community

Regarding the Implementation of USP <800>

USP <800> became effective on December 1, 2019 in New Jersey pursuant to the regulations of the New Jersey Board of Pharmacy (the Board). The purpose of this document is for the Board to provide information and guidance to those pharmacists **performing hazardous sterile and non-sterile compounding activities** after December 1, 2019.

If a pharmacy is not performing any compounding, the Board's regulations requiring compliance with USP <800> do not apply to that pharmacy. For example, if a pharmacy is only taking hazardous medication that is on the NIOSH list from a manufacturer's stock bottle (ie. carbamazepine, propylthiouracil, spironolactone, fluconazole, etc.), and placing it into a prescription bottle to be dispensed to a patient, that pharmacy is not required to comply with the Board's regulations related to USP <800>.

If a pharmacy is performing compounding activities, the pharmacist must first determine if any of the ingredients that are used in compounding are present on the current NIOSH list. If they are not, the pharmacy is not required to follow the regulations requiring compliance with USP <800>.

However, if a pharmacy is performing any compounding with ingredients found on the NIOSH list, then the pharmacy must follow the Board's regulations requiring compliance with USP <800> *as they relate to compounding activities*, such as segregating those Hazardous Drug (HD) ingredients from other non-HD ingredients, supplying Personal Protective Equipment (PPE) for those performing compounding, development of a training program, etc. In this situation, this pharmacy is NOT required to follow USP <800> for any activities that are **NOT** related to compounding (e.g. segregating manufacturer bottles of medications found on the NIOSH list from other pharmacy stock).

My pharmacy is fully compliant with USP <800>. How do I address the two sections that are in conflict with the current official version of USP <797>?

Two sections that are not harmonized between the two chapters in USP are *Segregated Compounding Area* and *'Low volume' hazardous drug (HD) compounding*. Please follow this guidance on how to adopt USP <800> until the revised USP <797> is official:

Segregated Compounding Area (SCA)

- Low and medium risk level HDs may be prepared in a C-SCA provided it meets the requirements in USP chapter <800> and the CSP is assigned a BUD of 12 hours or less.
  (USP <800> allows low and medium risk level hazardous drug CSPs to be prepared in an unclassified containment segregated compounding area (C-SCA). The C-SCA is required to have fixed walls, be externally vented with 12 ACPH and have a negative pressure between 0.01 and 0.03 inches of water column relative to the adjacent areas)

"Low volume" hazardous drug compounding

- HDs must be prepared in a C-SEC meeting the requirements of USP <800>.
  (USP <800> requires facilities that prepare HDs to have a containment secondary engineering control (C-SEC) that is externally vented, physically separated, have appropriate air exchange, and have a negative pressure between 0.01 and 0.03 inches of water column relative to all adjacent areas)

What should I do if my pharmacy needs additional time to become compliant with USP <800>?

The Board understands that while many pharmacies planned well in advance to meet the implementation date of December 1, 2019, equipment shortages and other unforeseen issues may have caused delays in their implementation of USP <800>. In these situations, the permit holder should send a waiver request to the Board, containing the following information:

- Name, address and permit # of the pharmacy
- Name of RPIC
- Name and contact information for the Permit Holder
- The milestones that have been completed to date in an attempt to come into compliance with USP <800>
- A description of the outstanding issues that are delaying the pharmacy from coming into compliance with USP <800>
- A list of any remaining tasks and a timeline indicating when they are scheduled to be completed
- A realistic date on which the pharmacy expects to be compliant with USP <800>

Please email the request to rubinaccioa@dca.njoag.gov . The waiver request should be signed by the permit holder and will be reviewed by the Board. If necessary, the Board will contact the pharmacy to request additional information before making its determination.

If the waiver request is approved, licensees are reminded that they would be required to follow the current Board regulations at N.J.A.C.13:39-11B.3 and 11B.4 until they are in compliance with USP <800>.

If the pharmacy is not able to come into compliance within the timeframe granted via the waiver request, they should be prepared to enter into a Centralized Prescription Handling Agreement with a pharmacy that is compliant with USP <800>, or inform the Board of alternate containment strategies it is planning to utilize to provide continuity of care for their patients requiring hazardous compounded medications.

What do I need to do to become compliant with USP <800>?

The first thing to understand is that the amount of effort that every compounding pharmacy will need to expend will vary, as every practice setting is different. The following steps should be undertaken:

- Select a person who will be responsible for implementing the standards required by USP <800> and will act as a point of contact with the Board

- Develop and maintain of a list of hazardous drugs (HD), which must include any items on the current NIOSH list that the practice site handles

- Perform and document an *Assessment of Risk* for all HD dosage forms utilized at the pharmacy to determine alternative containment strategies and/or work practices. The *Assessment of Risk* must, at a minimum, consider the following:
  • Type of HD (e.g., antineoplastic, non-antineoplastic, reproductive risk only)
  • Dosage form
  • Risk of exposure
  • Packaging
  • Manipulation

- Develop the following documentation:
  - A Training Program for personnel involved with hazardous compounding as outlined in USP <800>
  - Standards Operating Procedures (SOPs) for Personal Protective Equipment based on the risk of exposure and activities performed
  - A Hazardous Communication Program, including SOPs to ensure effective training regarding proper labeling, transport, storage, and disposal of the HDs and use of Safety Data Sheets (SDS) as outlined in USP <800>
  - SOPs for receiving HDs
  - SOPs to prevent spills and to direct the cleanup of HD spills
  - SOPs for the safe handling of HDs for all situations in which these HDs are used throughout pharmacy

- A Medical Surveillance Program

  Note: Both USP <800> and OSHA regulations suggest that a pharmacy should establish a Medical Surveillance Program. Although it is not mandatory, the Board recommends that each pharmacy practice site evaluate the risks associated with their hazardous compounding activities and determine whether it is appropriate to develop a Medical Surveillance Program.

- Complete any required infrastructure upgrades (e.g., modification to SECs for external venting, negative pressure environment, etc.) and equipment purchases as required for USP <800>

- If you have not already done so, submit a remodeling application with the Board and indicated when the pharmacy is ready for inspection

How will inspections be performed to verify compliance with USP <800>?

The Board will continue to utilize the established process to conduct inspections of compounding pharmacies, including compliance with all applicable Board regulations. Pharmacies that sought a waiver from the Board should provide the inspector with a copy of the waiver request sent to the Board, along with any response from the Board, so that the inspector may include that information as part of the report of inspection.

Informational Links:

USP <800>:

http://go.usp.org/l/323321/2019-05-31/2dfgwl

NIOSH (National Institute for Occupational Safety and Health) Information:

https://www.cdc.gov/niosh/docs/2016-161/pdfs/2016-161.pdf?id=10.26616/NIOSHPUB2016161

New Jersey Board of Pharmacy Regulations:

https://www.njconsumeraffairs.gov/regulations/Chapter-39-State-Board-of-Pharmacy.pdf

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