New Jersey Office of the Attorney General
Division of Consumer Affairs
Board of Pharmacy
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New Jersey Pharmacy Practice Site Timeline for Implementation of USP <800>

While the New Jersey Board of Pharmacy (Board) currently has regulations in effect regarding hazardous compounding, the Board believes that the implementation of USP <800> will offer enhanced safeguards to improve the safety of patients and individuals working with hazardous drugs (HD) at any point in the process of preparing HD prescriptions. The Board has adopted USP <800> and the proposed effective date for pharmacies to meet the new requirements is the official date of General Chapter 800, which originally was July 1, 2018 and is now anticipated to be December 1, 2019.

The Board is reaching out to make all licensees aware of their obligations in order to be in compliance with the requirements detailed in USP <800>. The Board also understands that the extent to which each type of pharmacy practice site will be affected by complying with this new chapter will vary.

To that end, the Board has created this high-level timeline checklist to assist licensees in understanding what the requirements are for their practice site in order to prepare to be in compliance with USP <800>. **Note that the checklist is an abbreviated overview of USP <800>, and the Board encourages all licensees to review the complete text of USP <800>, which can be found using this link:**

http://www.uspnf.com/sites/default/files/usp_pdf/EN/USPNF/revisions/800-rb-notice.pdf

If a pharmacy practice site will not be in compliance with the Board's Regulations in regards to USP <800> by July 1, 2018, the Board is requiring those entities to download, complete and attach this document as part of the renewal of their annual pharmacy permit by June 30, 2018. The completed document should outline the pharmacy practice site's plans to come into compliance with the Board's Regulations related to USP <800> when this chapter becomes official; which is anticipated to be December 1, 2019.

If required, it is recommended to download and complete this document prior to renewing the pharmacy permit, to make the renewal process as efficient as possible.

Practice site name: _____

Practice site address: _____

Practice site license number: _____

Practice site classification: ☐ Retail ☐ Institutional ☐ Call Center ☐ Other - If "Other," please provide a brief description below.

Description:

Item	Description	Projected Completion Date	Actual Completion Date	Responsible Person's Name, Title, Contact info
1	The ***Permit Holder*** should determine the person who will be responsible for implementing the standards outlined in USP <800>, and will act as the point of contact for the Board of Pharmacy regarding compliance with USP <800>. This person must be qualified and trained to be responsible for developing and implementing appropriate procedures; overseeing entity compliance with this chapter and other applicable laws, regulations, and standards; ensuring competency of personnel; and ensuring environmental control of the storage and compounding areas. The designated person must thoroughly understand the rationale for risk-prevention policies, risks to themselves and others, risks of non-compliance that may compromise safety, and the responsibility to report potentially hazardous situations to the management team. The designated person must also be responsible for the oversight of monitoring the practice site and maintaining reports of testing/sampling performed, and acting on the results.	6/30/2018		
2	Incorporation of the following standards, at a minimum, into the practice site's health and safety management system to ensure with USP <800>: • A list of HDs • Facility and engineering controls • Competent personnel • Safe work practices • Proper use of appropriate Personal Protective Equipment (PPE) • Policies for HD waste segregation and disposal			
3	Development and maintenance of a list of HDs, which must include any items on the current NIOSH list that the practice site handles. The practice site's list must be reviewed at least every 12 months. Whenever a new agent or dosage form is used, it should be reviewed against the practice site's list.			
4	Completion of documenting an assessment of risk for all HD dosage forms utilized at the practice site to determine alternative containment strategies and/or work practices. *<u>From USP <800>:</u>* *• Drugs on the NIOSH list that must follow the requirements in this chapter include:* ** Any HD API* ** Any antineoplastic requiring HD manipulation*			

	• *Drugs on the NIOSH list that do not have to follow all the containment requirements of this chapter if an assessment of risk is performed and implemented include:* * *Final dosage forms of compounded HD preparations and conventionally manufactured HD products, including antineoplastic dosage forms that do not require any further manipulation other than counting or repackaging (unless required by the manufacturer).* • *For dosage forms of other HDs on the NIOSH list, the entity may perform an assessment of risk to determine alternative containment strategies and/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			
5	Development of a Training Program for personnel involved with Hazardous Compounding as outlined in USP <800>.			
6	Development of SOPs for PPE based on the risk of exposure and activities performed.			
7	Development of a Hazardous Communication Program - 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>.			
8	Development of SOPs for receiving HDs.			
9	Development of SOPs to prevent spills and to direct the cleanup of HD spills.			
10	Development of SOPs for the safe handling of HDs for all situations in which these HDs are used throughout a practice site. The SOPs must be reviewed at least every 12 months by the designated person, and the review must be documented. Revisions in forms or records must be made as needed and communicated to all personnel handling HDs.			
11	Development of a Medical Surveillance Program.			