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Board of Registration in Pharmacy

Advisory: USP <800> in Community Pharmacies

Although most community pharmacies typically only handle and dispense hazardous drugs ("HD") in their final dosage form, they are also required to follow USP <800> *Hazardous Drugs – Handling in Healthcare Settings*. This advisory is intended to provide practical guidance for community pharmacies in order to comply with the requirements of USP <800> and is not intended to be all-inclusive; refer to USP <800> for all requirements.

There are 4 scenarios when all the containment strategies of USP <800> must be followed:

1. when storing antineoplastic HDs requiring any future manipulation (other than counting or repackaging of final dosage forms);
2. when manipulating antineoplastic HDs;
3. when compounding with any NIOSH hazardous drug active pharmaceutical ingredient ("API"), including crushing tablets or opening capsules of an HD; or
4. if an assessment of risk has not been performed.

As an example, if clonazepam is crushed to compound a suspension**,** this would be considered non-sterile HD compounding and subject to the containment requirements of USP <800>. Containment would include a containment primary engineering control (e.g., powder hood) located in a negative pressure room.

Each entity must designate a person who is qualified and trained to be responsible for developing and implementing procedures, overseeing compliance, as well as other requirements of USP <800>. This person does not necessarily have to be a licensed pharmacy individual nor be on the premises.

It is important for each pharmacy to have a documented formal hazardous drug program that encompasses all applicable requirements of USP <800> including, but not limited to the following:

Identify Hazardous Drugs ("HD"):

- Review the most recent National Institute for Occupational Safety and Health ("NIOSH") list
- Identify all stocked HDs:
    - Develop a list of HDs including any items on the current NIOSH list
    - Identify other HDs that may not be on the NIOSH list
    - Review the list at least every 12 months
    - Develop a procedure to assess any new drugs
- Identify the risk category of each drug:
    - Antineoplastic
    - Non-antineoplastic
    - Reproductive risk only

Assess Risk:

Manipulation of antineoplastic drugs or compounding with any NIOSH hazardous drug API must follow the containment requirements outlined in USP <800>.

For other identified HD drugs, an assessment of risk approach may be utilized.

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 (e.g., splitting tablets, reconstituting commercially manufactured products)
- Documentation of the alternate containment strategies and/or work practices
- Documentation of the review
- Assessment is reviewed at least every 12 months

Examples of alternate containment strategies and/or work practices include purchasing unit dose HDs, wearing gloves to count HDs, and using a dedicated counting tray and spatula.

Personal Protective Equipment ("PPE"):

Refer to the NIOSH list for general guidance on PPE for possible scenarios that may be encountered in healthcare settings.

- Consider use of PPE and other containment strategies and/or work practices for each HD risk category in all areas of the pharmacy:
    - Receiving
    - Storage
    - Handling / Dispensing
    - Transportation
    - Disposal / Waste Management

Storage and Handling:

Non-antineoplastic, reproductive risk only, and final dosage forms of antineoplastic HDs may be stored with other medications in accordance with the pharmacy's policies and procedures.

Tablet or capsule forms of antineoplastic HDs must not be placed in automated counting or packaging machines. Placement of other HDs in these machines is not recommended.

Consider using shelf labels or other methods to identify HDs and handling requirements (e.g., "PPE Precautions", "Use Gloves", "Use Dedicated Tray", etc.).

Training:

Before independently handling HDs, all employees must be trained based on their job functions (e.g., receipt, storage, dispensing, etc.).

Competency assessments must be conducted initially and reassessed at least every 12 months and documented.

Consider offering continuing education programs focused on HDs and USP <800> standards.

Develop Policies and Procedures:

- Receipt of HDs
- Storage and proper labeling of areas
- Handling and dispensing
- Use of PPE
- Transportation / delivery procedures
- Spill control and remediation
- Deactivation, decontamination, cleaning (e.g., equipment, surfaces, etc.)
- HD waste segregation and disposal
- Personnel training

- Hazardous risk communications to personnel including location of Safety Data Sheets (“SDS”)

Please direct any questions to: Pharmacy.Admin@mass.gov