

**BOARD STATEMENT ON USP CHAPTER <800> AND NON-COMPOUNDING  
ACTIVITIES INVOLVING HAZARDOUS DRUGS**

As previously stated the Board will be enforcing USP <800> standards through reference for compounding activities involving Hazardous Drugs on November 1, 2023, when the USP Chapters <795> and <797> revision become enforceable

With respect to USP Chapter <800> standards and their application to non-compounding activities involving Hazardous Medications, the Board views compliance as a best practice for pharmacies. As pharmacists know, USP Chapter <800> standards are designed to protect pharmacists, pharmacy staff, patients, and the public from the harmful effects of exposure to Hazardous Medications.

As USP Chapter <800> standards for non-compounding activities become commonly followed, North Carolina law is likely to reflect that doing so is considered standard of practice. In that case, failure to comply may be evidence of negligence. Therefore, you are encouraged to evaluate (and to continue to re-evaluate) to what extent compliance reflects the appropriate standard of care.

Board staff will continue make observations during inspections to help identify potential risk for handling Hazardous Medications, and will provide education on how to comply with USP Chapter <800> standards to minimize risk to pharmacy staff, patients, and the public. These observations regarding USP Chapter <800> compliance in non-compounding activities involving Hazardous Medications will not, by themselves, serve as a basis for disciplinary action by the Board.

Again, as noted, pharmacies that perform any nonsterile or sterile compounding with Hazardous Medications must be in **full** compliance with USP <800> when the chapter becomes enforceable on **November 1, 2023** in accordance to NCAC 46. 2801.

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