

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

On September 28, 2017, the Board issued a statement regarding USP Chapter <800>'s impending application to compounding activities involving Hazardous Medications. That statement is found here: http://www.ncbop.org/PDF/NCBOP_USP_800_Statement.pdf

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 to 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 in the Board's September 29, 2017 statement referenced above, pharmacies that perform any nonsterile or sterile compounding with Hazardous Medications must be in **full** compliance with USP <800> when the chapter becomes official **December 1, 2019** in accordance to NCAC 46. 2801.

Wording for inspection form: The handling of Hazardous Medications, even finished dosage forms, represents a potential risk to all pharmacy staff. USP Chapter <800> sets forth best practices for non-compounding pharmacies in handling Hazardous Medications. During this inspection, the following areas of potential risk to pharmacy staff have been identified:

April 2018