

BOARD OF PHARMACY STATEMENT ON USP CHAPTER <800>

North Carolina pharmacists are likely aware that on Friday, September 29, 2017 the United States Pharmacopeia (“USP”) announced that it is postponing the effective date of General Chapter <800> to December 1, 2019. USP stated that the purpose of the postponement is to “align the official date of General Chapter <800> with the official date of the next revision of General Chapter <797>.” More information here: <http://www.usp.org/compounding/general-chapter-hazardous-drugs-handling-healthcare?platform=hootsuite>

As compounding pharmacists know, federal law – via the Drug Quality and Security Act – requires that a compounding pharmacy comply with USP chapters <795> and <797>. Likewise, Board of Pharmacy Rule 21 NCAC 46.2801 requires that a compounding pharmacy: (1) “comply with the standards established by United States Pharmacopeia chapter <795>, including all United States Pharmacopeia chapters and standards incorporated into chapter <795> by reference and including all subsequent amendments and editions of the same”; and (2) “comply with the standards established by United States Pharmacopeia chapter <797>, including all United States Pharmacopeia chapters and standards incorporated into chapter <797> by reference and including all subsequent amendments and editions of the same”

Accordingly, if and when USP chapter <800> is expressly incorporated into USP chapter <795> or <797>, it will govern compounding activities under both federal and state law. Pharmacists with an interest in this issue are advised to direct comments to USP as appropriate – www.usp.org

North Carolina pharmacies who are licensed in other states should confer with those states’ boards of pharmacies concerning USP <800> enforcement.