USP Revisions 797 & 795: Public comment period now open for draft proposal of 201 KAR 2:076 compounding regulation.

USP has revised their compounding standards Chapters 795 (nonsterile preparations) and 797 (sterile preparations) with an anticipated USP implementation date of November 1, 2023, for both. If the Board of Pharmacy adopts these revised standards, updates are required to the current compounding regulation 201 KAR 2:076.

The draft proposal for these changes to 201 KAR 2:076 is available here for review: 2023 amendment 201 KAR 2 076 DRAFT.pdf (ky.gov) The draft regulation includes other changes for clarification and standardization purposes. Public comments on the draft proposal may be submitted by email to the Board of Pharmacy at pharmacy.board@ky.gov All public comments submitted by end of day May 10, 2023, will be reviewed by the Board of Pharmacy at the May 24, 2023, Board of Pharmacy meeting. *Important note: This revised version of 201 KAR 2:076 has not yet been approved by the board. When and if the board approves an amended version, notice will be provided on our website and there will be a 60 day period of public comment along with a public hearing.