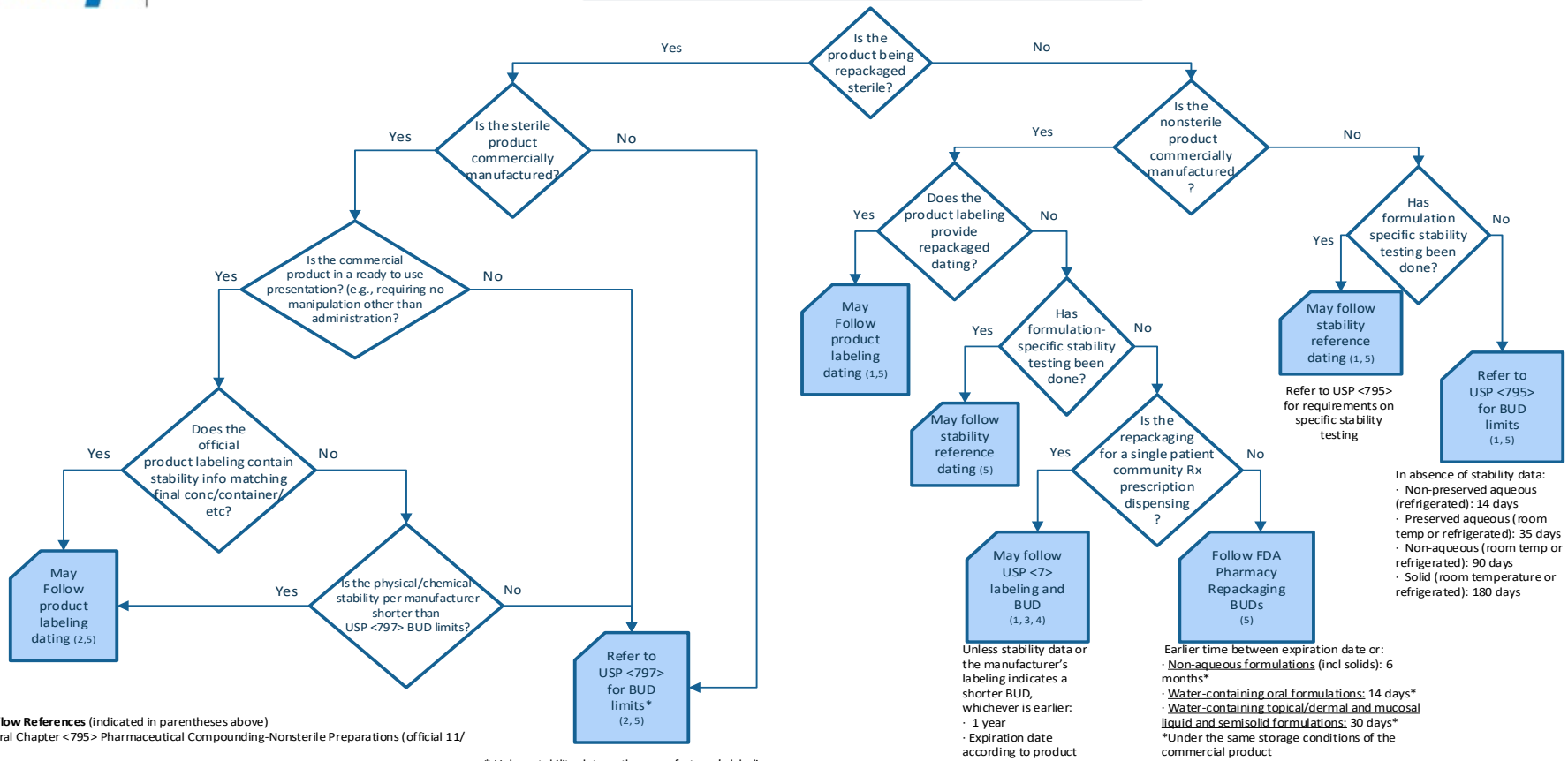
ashp Inpatient Care Practitioners

Repackaging Beyond-Use Date (BUD) Decision Workflow (Revised for 2023 USP <795> and <797> chapter versions)



In absence of stability data:
· Non-preserved aqueous (refrigerated): 14 days
· Preserved aqueous (room temp or refrigerated): 35 days
· Non-aqueous (room temp or refrigerated): 90 days
· Solid (room temperature or refrigerated): 180 days

Unless stability data or the manufacturer's labeling indicates a shorter BUD, whichever is earlier:
· 1 year
· Expiration date according to product label

Earlier time between expiration date or:
· Non-aqueous formulations (incl solids): 6 months*
· Water-containing oral formulations: 14 days*
· Water-containing topical/dermal and mucosal liquid and semisolid formulations: 30 days*
*Under the same storage conditions of the commercial product

Decision Workflow References (indicated in parentheses above)
1. USP General Chapter <795> Pharmaceutical Compounding-Nonsterile Preparations (official 11/1/23)
2. USP General Chapter <797> Pharmaceutical Compounding-Sterile Preparations (official 11/1/23)
3. USP General Chapter <1178> GOOD REPACKAGING PRACTICES (updated December 2020)
4. USP General Chapter <7> Labeling (Official May 2020)
5. FDA. Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities: Guidance. (Jan 2017, https://www.fda.gov/media/90978/download)
6. FDA. Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act: Guidance. (June 2016, https://www.fda.gov/media/94393/download).

* Unless stability data or the manufacturer's labeling indicates a shorter BUD

Category 1 CSPs (SCA): compounding area
· Room Temp: 12 hours
· Fridge: 24 hours
Category 2 CSPs (cleanroom): Aseptically processed CSPs prepared from sterile components without Sterility Testing.
· Room Temp 4 days
· Fridge: 10 days
· Frozen: 45 days
Category 3 CSPs: Additional testing requirements exist.

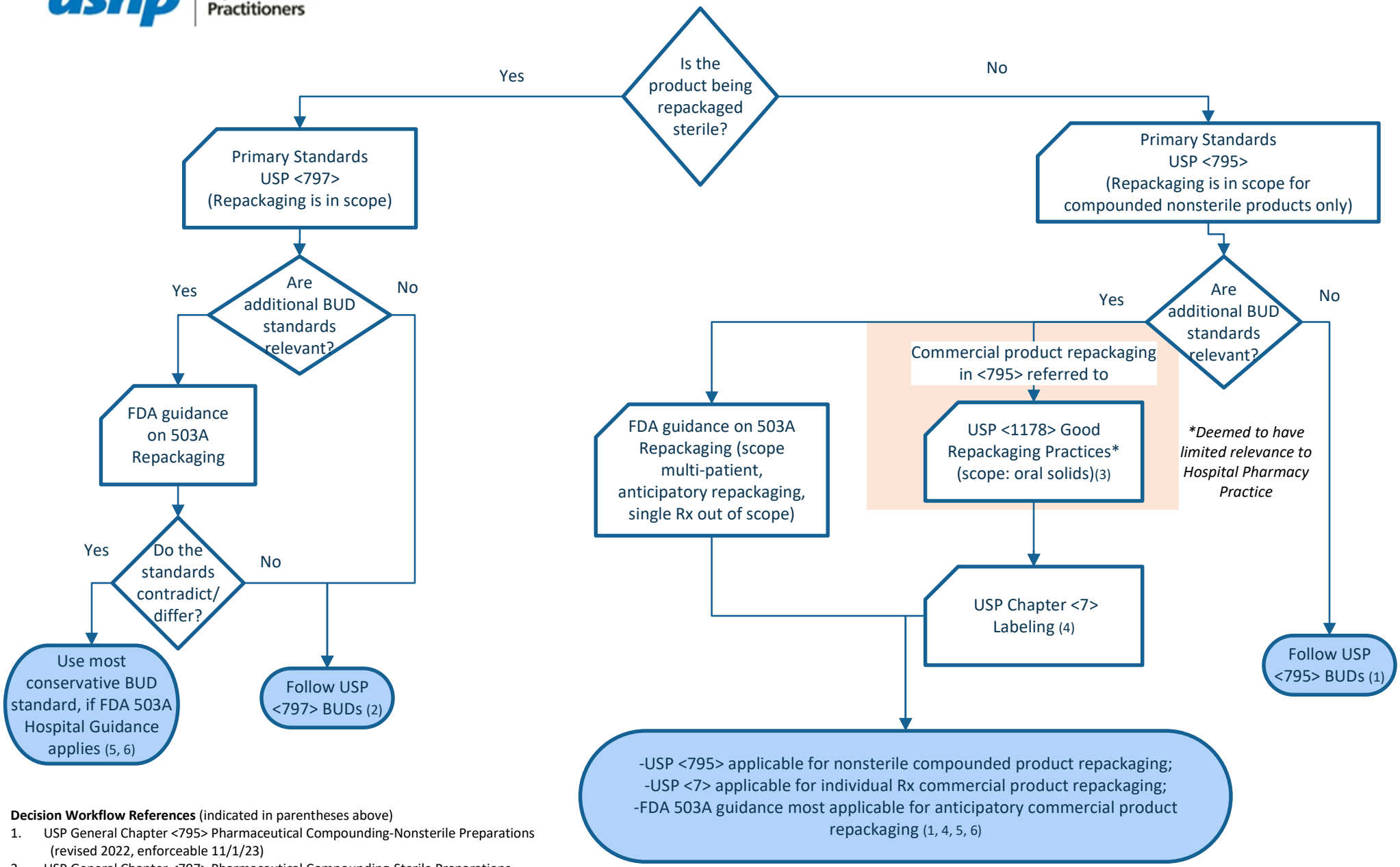
Created by Jamie Tharp
Reviewed by Shannon Buxell, Renee Douglass, Jeff Pilz, and Kayleigh Thompson
October 2024

Repackaging Assumptions:
Repackaging BUD assigned within the institution will not conflict with manufacturer's approved labeling.

The above branches represent maximum allowed BUDs; institutions may choose more conservative BUDs based internal factors and preference. See ASHP's Pharmacist Guide to Assigning a BUD [link here]

Manufacturer product labeling dating may exceed USP <795> or <797> BUD requirements, provided product is prepared as single dose for single patient and approved labeling has all required information(2,5)

Product Repackaging Standards Assessment and Guideline



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