MEDICATION STABILITY & STORAGE

Administration of parenteral medications (e.g., intravenous infusions, injections) should begin immediately following preparation—ideally within one (1) hour of beginning preparation.

If extenuating circumstances preclude immediate administration, manufacturer guidelines regarding stability and storage must be followed. However, it is important to note:

- **Storage must not exceed four (4) hours** *unless* the product was prepared in an environment with at least ISO Class 5 air quality in accordance with United States Pharmacopeia (USP) General Chapter <797> pharmacy standards for compounding sterile products.

This is true even if storage/stability information in product labeling indicates that prepared medications may be stored for durations that exceed four (4) hours.

Stability and storage duration data supplied in FDA-approved labeling typically:

- ✓ **Refers to chemical and/or physical stability**
- ✗ **Does not consider preparation procedures used (e.g., aseptic technique)**
- ✗ **Does not refer to microbiological purity or safety**
- ✗ **Does not consider environmental conditions (e.g., ISO air classification)**

The longer a prepared medication is stored before administration, the more time microbial pathogens—which may be introduced via contamination during preparation—have to replicate. While the medication molecules themselves may be physically stable beyond four (4) hours, the infection risk is too great.

This guide is for informational purposes only and is not intended to supersede guidance from the FDA, USP, state/local health departments, or other regulatory authorities.

Updated 6/15/21