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Alliance for Pharmacy Compounding

Compounding the Joy of Living

BEST PRACTICES FOR COMPOUNDING IN IV THERAPY

This document is not specific to particular indications or dosage forms for compounded medications, and it is not intended to be an exhaustive statement on the practice of pharmacy. It should not be relied upon as advice. Pharmacies should seek legal counsel before dispensing compounded medications.

INTRODUCTION

IV therapy services sit at the intersection of medicine, nursing, and pharmacy. Ensuring patient safety and compliance requires that each discipline operates within its defined scope, supported by appropriate licensure, sterile compounding standards, and individualized clinical judgment. This document provides a high-level policy framework for regulatory oversight of IV therapy clinics and the compounding pharmacies that support them. These recommendations are not exhaustive, and pharmacies should check their specific state requirements. Consult with an attorney before compounding sterile medications for use in IV clinics.

ROLES AND SCOPE OF PRACTICE

- Prescribers licensed by each state are responsible for diagnosing and issuing individualized orders for IV therapy. Use of drop-down menus, pre-selected checkboxes, or "menu-based" order forms that patients choose therapy from does not constitute individualized prescribing and falls below the professional standard of care expected in both medicine and pharmacy. Each order must specify all elements of therapy—base fluid, additives, concentration, rate of administration, and monitoring parameters—and be signed or electronically authenticated by the prescriber as required by state law or regulation.

- 503 Pharmacies and 503B outsourcing facilities prepare sterile compounded medications consistent with federal and state law, ensuring quality, traceability, and labeling.

- Nurses (RN/LPN) administer IV medications pursuant to a valid order, monitor patients during infusions, and document outcomes. States vary in whether LPNs may initiate IV access or infuse medications, licensees.

COMPOUNDING AND DISTRIBUTION STANDARDS

- 503A Pharmacies compound pursuant to a patient-specific prescription. When patient-specific compounded IV medications are billed or shipped to a clinic or physician's office for administration, the quantity must be appropriate for a single patient. Multi-dose vials, if used, must be labeled with a discard date that does not exceed 28-days following puncture.

- 503A pharmacies cannot distribute for non-patient specific "office use" in human compounding per FDA Guidance. Their dispensing must be tied to an identified patient, with proper documentation and labeling under USP <797> standards.

- 503B Outsourcing Facilities should be prioritized by prescribers and clinics when sourcing compounded medications intended for office administration or stock use. These facilities are FDA-registered, inspected for current good manufacturing practice (CGMP) compliance, and permitted to compound in bulk for healthcare facilities.

- CSPs should be labeled with osmolarity when applicable to facilitate calculations of admixtures before administration.

- Prior to shipment, the receiving site must attest to compliant storage/handling, including temperature control, beyond-use compliance, and avoidance of insanitary conditions. The pharmacy may audit or suspend shipments if noncompliance is identified.

- If CSPs are compounded in a pharmacy setting but require delivery to the prescriber's office or the patient's place of residence for administration, there must be SOPs in place to ensure that delivery occurs for administration to start within the BUD of the product. This is especially important for immediate-use, as administration must begin within four hours of the start of preparation.

STERILE COMPOUNDING OVERSIGHT

- The addition of any ingredient, such as vitamins, minerals, amino acids, or drugs, to an IV fluid constitutes compounding and should comply with USP <797> and any other state-specific requirements.

- States differ in their enforcement of immediate-use allowances; this category is meant for urgent, time-sensitive situations and not routine retail IV services.

- Oversight should ensure that all sterile preparations are prepared in appropriate environments (ISO 5 primary engineering controls, with buffer and ante rooms as required), by trained and qualified personnel.

<USP> 797 COMPLIANCE AND BEYOND-USE DATING

- USP <797> establishes minimum standards for sterile compounding environments, personnel training, aseptic technique, and quality assurance. These standards apply to both pharmacies and prescribers who prepare compounded sterile preparations (CSPs) for patient administration.

- Category 1 sterile compounding is intended for short-term preparations in settings that lack a full cleanroom suite. It allows only simple admixtures, for example, adding one or two compatible ingredients (such as a vitamin or medication) into a single IV fluid bag for an identified patient. Complex, multi-additive mixtures involving several drugs, multiple container entries, or extended storage periods exceed Category 1 limits and must be prepared in a Category 2 environment with full ISO-classified buffer and ante rooms.

- Distinct from Category 1 is immediate-use compounding, which USP 797 permits under even more restricted conditions: preparations must be administered within four hours of starting the compounding process, require no more than two entries into any single container, and must be prepared in ISO Class 5 or better air quality (or administered immediately if prepared in a lesser environment). Immediate-use is designed for emergency or time-critical clinical situations where waiting for a properly compounded Category 1 or 2 preparation would compromise patient care, think of a code situation in an emergency department or an urgent surgical need. However, immediate-use cannot be used for convenience or to circumvent proper compounding standards, and it requires immediate documentation and administration timelines that make it unsuitable for routine practice.

- Category 1 vs Category 2 environments.
    - Category 1 CSPs are compounded in a segregated compounding area (SCA) without full buffer and ante rooms. Because environmental controls are limited, these products carry shorter beyond-use dates (BUDs), typically 12 hours or less at room temperature and 24 hours refrigerated.
    - Category 2 CSPs are compounded in a fully controlled cleanroom suite with ISO-classified buffer and ante areas, continuous environmental monitoring, and more robust documentation. These enhanced controls allow longer BUDs (e.g., days to weeks), depending on the results of sterility testing, stability data, and storage conditions.

- BUD determination factors. The BUD assigned to a sterile compounded product depends on multiple risk-based factors, including:

    1. Environmental controls (Category 1 vs 2)
    2. Testing (e.g., sterility and endotoxin testing when applicable)
    3. Chemical stability or degradation data from USP monographs, manufacturer documentation, or published studies
    4. Container-closure integrity and handling conditions (light, temperature, multi-dose vs single-dose)
    5. Intended route and clinical context, products for injection or infusion pose greater risk than topical ophthalmic or topical preparations

- Compounders should recognize that USP <797> is not a "one-size-fits-all" rule but a risk-based framework.
- Encourage compliance with USP <797> Category 2 standards for ongoing IV-therapy operations.
- Permit limited Category 1 or immediate-use compounding only when delay would cause patient harm and all USP criteria are met.
- Support continuing education for prescribers and pharmacists on sterile technique, environmental monitoring, and BUD justification.

CLINICAL AND BILLING INTEGRITY

- Each IV therapy must be ordered based on an individualized medical assessment. Menu-based drips or standing orders without a clinical rationale fall below accepted medical and pharmacy standards.
- When a compounded IV medication is provided under a prescription to a specific patient, the prescriber or clinic may not "up-charge" for the medication itself in certain states. However, clinicians may bill patients for legitimate professional services, such as consultation, assessment, IV insertion, and monitoring, consistent with applicable payer and state rules.
- Documentation should include the order, consent, compounding record, administration log, and post-treatment notes.

LICENSURE AND INTER-BOARD COLLABORATION

- IV therapy involves overlapping jurisdiction between boards of medicine, nursing, and pharmacy. Coordination among these entities is critical to prevent regulatory gaps or duplicative oversight.
- State-specific licensure requirements should clarify:
    - Whether IV therapy clinics require a pharmacy permit or other dispensing authority;
    - Which nursing credentials (RN, LPN) may initiate or monitor infusions;
    - What level of medical oversight is required on-site or via telehealth.
    - Policymakers should encourage alignment with existing NABP and NCSBN guidance to maintain patient safety while avoiding unnecessary barriers to access.

MARKETING AND CLINICAL CLAIMS

- Compounded IV therapies are not FDA-approved drugs. Federal law prohibits advertising or labeling compounded preparations in a manner that implies they are approved by, or equivalent to, FDA-approved products. Any health-related claims must be supported by competent scientific evidence and communicated in a way that does not mislead patients or imply unproven therapeutic outcomes.

- Avoiding false or misleading claims. Pharmacies and clinics should not advertise compounded IV infusions as cures or treatments for general wellness or chronic conditions unless supported by substantial clinical data. Statements such as "boosts your immune system," "flushes out toxins," "enhances energy," "anti-aging," or "the fountain of youth" may be considered false or misleading drug claims under both the Federal Food, Drug, and Cosmetic Act (FD&C Act) and the Federal Trade Commission (FTC) Act.

- Permissible language. It is appropriate to describe the service as prescription-only, individualized therapy based on a patient's clinical assessment and medical need. Educational materials may explain the pharmacologic properties of ingredients (e.g., "vitamin C is an essential nutrient involved in collagen synthesis") but should avoid implying diagnostic or therapeutic superiority.

- Regulators and policymakers should encourage IV therapy providers to align advertising and patient communication with truthful, non-misleading, clinically grounded language. Enforcement against false claims protects both patient safety and the credibility of legitimate compounding pharmacies and prescribers.

- Check APC's Best Practices for Marketing Compounded Medications here.

REFERENCES AND RESOUCES

State boards of medicine, pharmacy and nursing have issued numerous advisories and joint statements (e.g., MS Board of Nursing 2025; OH Joint Statement 2025; AZBN 2024; NCBOP/NCBON 2024; WI DSPS 2025). These serve as useful templates for states still developing policy. Additional national guidance is available from NABP (2023 Hydration Resources) and USP <797>.

RESOURCE HIGHLIGHTS

NABP IV Hydration Facilties, 2023: https://nabp.pharmacy/wp-content/uploads/2023/08/Hydration-Resources.pdf

National Council of State Boards of Nursing, 2024:
https://www.ncsbn.org/public-files/presentations/Transcript_2024aprn_ppolk-johnson.pdf

American Spa, 2024: https://www.americanspa.com/medical-spa/iv-therapy-protocols-ensure-compliance

Arizona State Board of Nursing, 2024: https://azbn.gov/sites/default/files/AO-IV-Hydration-Other-Therapies.pdf

Alaska Sample Regulatory Agency Guidance, 2024:
https://www.commerce.alaska.gov/web/Portals/5/pub/Sample_Regulatory_Agency_Guidance.pdf

California Board of Pharmacy, 2024: https://www.pharmacy.ca.gov/publications/iv_hydration_ed.pdf

Georgia Board of Nursing, 2024:
https://sos.ga.gov/sites/default/files/2024-06/iv_hydration_position_statement_04012024.pdf

Kansas Board of Nursing: https://ksbn.kansas.gov/iv-therapy/

Mississippi Board of Nursing, 2025:
https://www.msbn.ms.gov/sites/default/files/IV%20Hydration%20Position%20Statement_2025_1.pdf

Nebraska Board of Nursing, 2023: https://dhhs.ne.gov/licensure/Documents/IVInfusion.pdf

New Mexico Medical Board, 2024:
https://www.nmmb.state.nm.us/wp-content/uploads/2025/01/IV-policy-NMMB-draft-10-21-2024.pdf

New York Dept of Health, 2021:
https://www.health.ny.gov/professionals/protocols_and_guidelines/docs/checklist_for_infusion_therapy_services.pdf

North Carolina Joint Statement, 2024:
https://www.ncbop.org/downloads/ClinicsOfferingWalkInIVTherapies_UpdatedJan2024%20copy.pdf
https://www.ncbon.com/sites/default/files/documents/2024-03/ps-iv-hydration-clinics.pdf

Ohio Joint Statement, 2025:
https://www.pharmacy.ohio.gov/documents/pubs/special/ivtherapy/joint%20regulatory%20statement%20on%20the%20operation%20of%20retail%20iv%20therapy%20clinics%20in%20ohio.pdf

Oregon (OMB), 2024: https://www.oregon.gov/omb/board/philosophy/pages/iv-hydration-therapy.aspx

Rhode Island Dept of Health, 2023:
https://health.ri.gov/sites/g/files/xkgbur1006/files/publications/guidance/Medical-Spa-and-IV-Therapy-Business.pdf

South Carolina Joint Statement, 2023: https://www.llr.sc.gov/bop/news/2023/BOP-IVHydration.pdf

Wisconsin IAC draft 2025, DSPS:
https://dsps.wi.gov/Documents/BoardCouncils/PHM/20250821PHMOpenSession.pdf

Sivakumar A, Forman HP, Wang I, Lurie P, Ross JS. State Policies and Facility Practices of IV Hydration Spas in the US. JAMA Intern Med. Published online October 06, 2025. doi:10.1001/jamainternmed.2025.5028