Education for all Compounders

The California State Board of Pharmacy (Board) is aware of a number of clinics that offer walk-in intravenous (IV) hydration services. IV hydration is, as the name implies, administered directly to the patient's bloodstream, thereby bypassing many of the body's natural defenses. This can result in severe or life-threatening reactions if the IV mixture is compounded (mixed) or administered in an unsafe manner. Retail IV therapy, commonly referred to as "IV hydration," "IV nutrient therapy," or "vitamin infusion," is provided in a number of different types of businesses including med spas and IV therapy clinics. Board inspections of some locations have revealed violations of legal requirements, including purchasing products from unlicensed sources and compounding requirements including national standards. The Board is providing information as education to all healthcare providers on some legal requirements to safely provide such services. The Board notes that this is not intended to be a comprehensive legal document and health care providers should seek guidance from their regulatory agencies to gain a full understanding of all legal requirements.

Did you know…..

The U.S. Food & Drug Administration (FDA) defines compounding as "the process of combining, mixing, or altering ingredients to create a medication tailored to the needs of an individual patient. Compounding includes the combining of two or more drugs. Compounded drugs are not FDA-approved." FDA has FAQs available on its website.

The United States Pharmacopeia (USP) describes the minimum requirements which apply to all persons who prepare compounded preparations (CPs) and all places where CPs are prepared. This includes but is not limited to pharmacists, pharmacy technicians, nurses, nurse practitioners, physicians, physician assistants, dentists, naturopathic doctors, and chiropractors in all places, including but not limited to hospitals and other healthcare institutions, medical and surgical patient treatment sites, infusion facilities, pharmacies, and physician or veterinarian practice sites. **Note**: USP standards **DO NOT** establish authority to compound. You will need to confirm with your respective healing arts board to confirm if state law allows you to compound and under what circumstances.

What does this mean for you….

If you are compounding it must be in compliance with the applicable USP chapters, no matter what or where you compound.

If you are compounding a **sterile** preparation (CSP), your practices need to be compliant with the requirements in USP Chapter 797 – Pharmaceutical Compounding – Sterile Preparations.

Things to know about sterile compounding.

Compounders **must** understand and comply with the requirements in USP Chapter 797 including:

- Personnel training and evaluation
- Personal hygiene and garbing
- Facilities and engineering controls
- Certification and recertification
- Microbiological air and surface monitoring
- Cleaning, disinfecting and applying sporicidal disinfectants and sterile 70%
- Equipment, supplies and components
- Sterilization and depyrogenation
- Master formulation and compounding records
- Release inspections and testing
- Labeling
- Establishing beyond-use dates
- Use of conventionally manufactured products as components
- Use of CSPs as components
- Standard operating procedures
- Quality assurance and quality control
- CSP handling, storage, packaging, shipping and transport
- Documentation

Note: If you are compounding a non-sterile preparation (CNSP), your practices need to be compliant with the requirements in USP Chapter 795 – Pharmaceutical Compounding Nonsterile Preparations.

The Board strongly recommends that prior to purchasing products for IV hydration, a license search is performed to ensure the entity from which the products will be purchased is appropriately licensed with the Board.

Consistent with its authority (Business and Professions Code section 4008(a)), the Board will be conducting inspections at locations where drugs and devices are compounded, prepared, furnished, dispensed, or stored. Board inspectors will identify themselves with a Board-issued badge and provide a business card and will provide a receipt for any records taken. If requested, the inspector will leave a copy of the inspection report with the healthcare provider on the premises. The inspector can also answer questions about compounding requirements.

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