Louisiana Board of Pharmacy **Policies & Procedures**

Title: Compounding of Drugs by Nurses Policy No. I.A.25

Approved: 11-14-2018 Revised:

1. The Louisiana Pharmacy Practice Act defines compounding:

   "Compounding" means the preparation, mixing, assembling, packaging, or labeling of a drug or device by a pharmacist for his patient as the result of a practitioner's prescription drug order or initiative based on the practitioner/patient/ pharmacist relationship in the course of professional practice, or including the preparation of drugs or devices in anticipation of prescription drug orders to be received by the compounding pharmacist based on routine, regularly observed prescribing patterns. Compounding does not include the compounding of drug products that are essentially copies of a commercially available product.

   [La. R.S. 37:1164(7)]

2. In addition to the authority to compound drugs provided within the pharmacy law, similar authority to compound drugs is provided to physicians (via the medical practice act), dentists (via the dental practice act), and veterinarians (via the veterinary medical practice act), but only for their own patients. Those practitioners may not compound drugs for persons other than their own patients. No other healthcare personnel have statutory authority to compound drugs for anyone.

3. Given the definition of compounding in the Pharmacy Practice Act, reconstitution (mixing of diluents and drug) could be construed as compounding. However, the Board of Pharmacy has consistently interpreted that definition such that the preparation of medication for emergency or immediate administration to a patient shall not be construed as compounding. This interpretation is grounded in the provisions of the Federal Food, Drug and Cosmetic Act, from which the following statement is abstracted: *"Compounding does not include mixing, reconstituting, or similar acts that are performed in accordance with the directions contained in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with that labeling."*

4. During the 1990s, the Boards of Nursing and Pharmacy developed an understanding and agreement relative to the preparation of medications for administration by a nurse, when waiting for a pharmacist to compound that medication might not be in the patient's best interest. In those situations – primarily in surgery, emergency departments, and critical care patient areas, the compounding of medication for immediate administration in an emergency situation is referred to as *"preparation of medication for immediate administration."* The Board of Pharmacy does not object to this technical intrusion into the practice of pharmacy. It is the pharmacy board's understanding the Board of Nursing permits nurses to engage in that activity when the nurse has received training in that activity and that activity occurs in compliance with the facility's policies and procedures governing that activity.

5. The federal drug law referenced above recognizes the United States Pharmacopeia (USP) as the only authority for the establishment of purity and safety standards for drugs used within the United States. In addition to the individual drug monographs in the USP, the USP has also established general standards for the use and manipulation of those drugs. Relevant to this discussion is *USP Chapter 797 ~ Pharmaceutical Compounding – Sterile Preparations*. As indicated in the introductory section of that Chapter, the standards are not only applicable to drug preparation activities in pharmacies but in **all areas** where drugs are prepared. Further, the standards are not only applicable to pharmacists but to **all personnel** involved in the preparation of drugs. The use of an injectable route of administration presents more risk to a patient than the use of any other route. There are many other risk factors such as the availability of a sterile environment for the preparation of the drug, the use of gowning and gloving, the length of the storage time between preparation and administration of the drug, the level of complexity of the medication formula [one drug vs multiple drugs], the use of single dose vials vs multiple dose vials vs ampuls, the use of non-sterile ingredients, etc. USP Chapter 797 contains a general discussion of all the risks inherent in the compounding of sterile medication, and then presents standards stratified by three risk levels: low, medium, and high.

   - Examples of low-risk compounding include (1) single-volume transfers of sterile dosage forms from ampuls, bottles, bags, and vials using sterile syringes with sterile needles, other administration devices, and other sterile containers. The solution content of ampuls should be passed through a sterile filter to remove any particles. (2) simple aseptic measuring and transferring with not more than three packages of manufactured sterile products, including an infusion or diluents solution to compound drug admixtures and nutritional solutions.

   - Examples of medium-risk compounding include (1) compounding of total parenteral nutrition fluids using manual or automated devices during which there are multiple injections, detachments, and attachments of nutrient source products to the device or machine to deliver all nutritional components to a final sterile container, (2) filling of reservoirs of injection and infusion devices with more than three sterile drug products and evacuation of air from those reservoirs before the filled device is dispensed, and (3) transfer of volumes from multiple ampuls or vials into one or more final sterile containers.

   - Examples of high-risk compounding include (1) dissolving nonsterile bulk drug and nutrient powders to make solutions that will be terminally sterilized, (2) exposing the sterile ingredients and components use to prepare and package the compounded sterile preparation to room air quality worse than ISO Class 5 for more than one hour, (3) measuring and mixing sterile ingredients in nonsterile devices before sterilization is performed, and (4) assuming without appropriate evidence or direct determination that packages of bulk ingredients contain at least 95% by weight of their active chemical ingredient and have not been contaminated or adulterated between uses.

The higher the risk, the more rigorous the safety standard required by USP. Among all the risks, the most significant one that can be managed is time, more specifically, the amount of time between the preparation of the drug and its administration to the patient. The longer the period of storage and delay before administration, the greater is the opportunity for growth of an offending organism that might have been inadvertently introduced by the preparer. Therefore, in addition to the three risk level categories, there is a category for immediate-use compounded sterile preparation. The immediate use of a product effectively manages the time risk; therefore, there is a waiver from many of the safety standards for immediate use preparations. The following information is abstracted directly from USP Chapter 797:

The immediate-use provision is intended only for those situations where there is a need for emergency or immediate patient administration of a compounded sterile preparation (CSP). Such situations may include cardiopulmonary resuscitation, emergency room treatment, preparation of diagnostic agents, or critical therapy where the preparation of the CSP under conditions described for Low-Risk Level CSPs subjects the patient to additional risk due to delays in therapy. Immediate-use CSPs are not intended for storage for anticipated needs or batch compounding. Preparations that are medium-risk level and high-risk level CSPs shall not be prepared as immediate-use CSPs.

*Immediate-use CSPs are exempt from the requirements described for Low-Risk Level CSPs only when **all** of the following criteria are met:*

***(1)** The compounding process involves simple transfer of not more than three commercially manufactured packages of sterile nonhazardous products or diagnostic radiopharmaceutical products from the manufacturers' original containers and not more than two entries into any one container or package (e.g., bag, vial) of sterile infusion solution or administration container/device. For example, anti-neoplastic drugs shall not be prepared as immediate-use CSPs because they are hazardous drugs.*

***(2)** Unless required for the preparation, the compounding procedure is a continuous process not to exceed one hour.*

***(3)** During preparation, aseptic technique is followed and, if not immediately administered, the finished CSP is under continuous supervision to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, mix-ups with other CSPs, and direct contact of outside surfaces.*

***(4)** Administration begins not later than one hour following the start of the preparation of the CSP.*

***(5)** Unless immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the CSP shall bear a label listing patient identification number, the names and amounts of all ingredients, the name or initials of the person who prepared the CSP, and the exact on-hour Beyond Use Date and time.*

***(6)** If administration has not begun within one hour following the start of preparing the CSP, the CSP shall be promptly, properly, and safely discarded. Compounding in worse than ISO Class 5 conditions increases the likelihood of microbial contamination, and administration durations of microbially contaminated CSPs exceeding a few hours increase the potential for clinically significant microbial colonization and thus for patient harm, especially in critically ill or immunocompromised patients.*

*Opened or needle-punctured single-dose containers, such as bags, bottles, syringes, and vials of sterile products and CSPs **shall be used within 1 hour if opened in worse than ISO Class 5 air quality**, and any remaining contents must be discarded.*

6. In summary, the Board of Pharmacy has recognized the ***preparation of medication for immediate administration*** by persons other than pharmacists and deferred any enforcement against this technical intrusion into the practice of pharmacy. This recognition is grounded in the federal drug law and federal quality standards for the safety of drugs. Where such medications are prepared, federal standards govern that activity regardless of the person performing those manipulations. The Board of Pharmacy and the Board of Nursing have agreed to limit opportunities for these activities to emergent situations where any delay in the administration of the medication while waiting for the pharmacist to compound that preparation would not be in the patient's best interest.