

**University Hospital
Pharmacy Department
Gap Analyses and Recommendations
On Compounding Sterile Preparations**

Jane Doe, Pharm.D. Director of Pharmacy Services contracted for my consultation services that included a presentation on current sterile compounding facility standards that promote patient, employee and environmental safety; a review of all University Hospital (UH) pharmacy sites at which sterile pharmaceuticals are compounded, and problem findings for those sites. In October, I visited each of the 12 pharmacy sterile compounding sites in person and interviewed pharmacy personnel. The purpose was to identify issues that may pose risks to patients as compared to current state and national standards for compounding sterile preparations. What follows is a listing of the issues that I encountered.

Executive Summary of General issues

Some problems tended to recur from one site to another. The reason is that an updated and expanded version of the key national sterile compounding standard has just been published, i.e. *USP Chapter 797 Pharmaceutical Compounding – Sterile Preparations*. While the pharmacy compounding facilities were mostly in compliance with the original USP Chapter 797 that became effective in January, 2004, they are not in compliance with the new chapter. The new Chapter 797 became enforceable on June 1, 2008 but it is unclear when the Board of Pharmacy will begin inspecting pharmacies for compliance with the new Chapter 797. However, one Board Inspector said that the Board may expect compliance as soon as December 2008.

Prior to visiting the pharmacy compounding areas, I had reviewed pertinent operating procedures and documentation. At each site, I interviewed responsible staff members and made my observations. The general issues I found were:

- Failure to separate of hazardous and non-hazardous compounding activities. Chapter 797 specifies that hazardous compounding be done in a negative pressure clean room or buffer area to contain inadvertently released hazardous drugs (HDs); while non-hazardous drug compounding must be in a positive pressure buffer area to maintain optimal environmental cleanliness.
- Extension of dating for products currently prepared under immediate-use conditions. Chapter 797 allows compounded sterile preparations (CSPs) for immediate use to be compounded outside primary engineering controls (PECs, like hoods and isolators) and buffer areas as long as the beyond-use date (BUD) is not longer than one hour. Six of 12 pharmacy sterile compounding areas reported compounding exclusively under the immediate use exemption. Upon examination of these sites, all managers of these either do or want to be able to exceed the one hour BUD.
- Failure to maintain environmental monitoring and control (room temperature and relative humidity, pressurization or air velocity and air changes per hour (ACPH)).
- Improper surfaces. Chapter 797 specifies that surfaces of floors, walls, ceilings, fixtures, carts and other equipment be smooth for cleaning, impermeable to liquids; and resistant to disinfectants.

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