CHECKLIST
Pharmacy Compounding

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5814 Reed Road, Fort Wayne, IN 46835 | www.medpro.com | 800-463-3776 | 800-334-0588 (NJ/NY)

Pharmacy compounding plays a vital role in patient care. When drug shortages occur, or when patients have unique needs that "one size fits all" medications cannot meet, pharmacy compounding often fills the gap. However, in recent years, recalls of some compounded medications have raised concerns about safety, quality, and oversight.

A 2012 *Medication Safety Alert* from the Institute for Safe Medication Practices advises that, whenever possible, providers should use or prescribe FDA-approved products from pharmaceutical manufacturers.[1] If FDA-approved medications and products are not commercially available, healthcare facilities and providers should carefully assess compounding pharmacies before using their services.

The checklist below provides a high-level overview of the types of factors that should be considered when performing due diligence of compounding services.

	Yes	No
History and Experience		
Does the compounding pharmacy have years of experience?	☐	☐
Have the pharmacy's staff members ever been investigated or charged with questionable practices?	☐	☐
Has the FDA ever warned the pharmacy about compliance issues?	☐	☐
Licensure and Credentialing		
Are the pharmacy and its pharmacists and technicians licensed by the state?	☐	☐
Does the pharmacy provide staff training, and does it have documentation to support training?	☐	☐
Do staff members involved in sterile compounding have aseptic training certificates?	☐	☐

	Yes	No
Accreditation and Compliance		
Is the pharmacy accredited (e.g., through the Pharmacy Compounding Accreditation Board or another accrediting body)?	☐	☐
Does the pharmacy adhere to United States Pharmacopeia (USP) <797> guidelines for sterile compounding?	☐	☐
Does the pharmacy only use ingredients obtained from FDA-registered facilities?	☐	☐
Processes and Procedures		
Does the pharmacy have written policies and procedures for:		
• Equipment validation?	☐	☐
• Proper gowning and gloving techniques?	☐	☐
• Quality review?	☐	☐
• Product tracking and product recalls?	☐	☐
• Handling customer complaints?	☐	☐
Quality Control and Assurance		
Does the pharmacy perform sterility, quality, and integrity testing?	☐	☐
Does the pharmacy routinely perform environmental testing/air sampling?	☐	☐
Does the pharmacy employ an independent laboratory for random quality/sterility analysis?	☐	☐
Documentation		
Does the pharmacy have appropriate licensure documents from state and federal agencies (if applicable)?	☐	☐
Does the pharmacy maintain documentation and certification for the ingredients it purchases?	☐	☐
Does the pharmacy maintain master formula and lot-specific documentation for every compound?	☐	☐

Endnotes

[1] Institute for Safe Medication Practices (ISMP). (2012, Oct. 18). Sterile compounding tragedy is a symptom of a broken system on many levels. *ISMP Medication Safety Alert!* Retrieved from http://www.ismp.org/Newsletters/acutecare/showarticle.asp?id=34