MedPro Group
a Berkshire Hathaway company

Checklist

PATIENT SAFETY & RISK SOLUTIONS

Assessing Pharmacy Compounding Services

Pharmacy compounding plays a vital role in patient treatment and care. When drug shortages occur, or when patients have unique needs that standard medications cannot meet, pharmacy compounding often fills the gap. However, the practice of pharmacy compounding has received increased scrutiny in recent years because of concerns about safety, quality, and oversight.

The Institute for Safe Medication Practices advises healthcare organizations and providers to use or prescribe FDA-approved medications and products from pharmaceutical manufacturers whenever possible.[1] When such products are not commercially available or do not meet patients' needs, pharmacy compounding is an option to consider. However, healthcare organizations and providers should carefully assess compounding pharmacies before using their services. This checklist provides a high-level overview of the types of issues 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? (Check the FDA website for warnings.)	☐	☐
Licensure and Credentialing		
Is the pharmacy registered with the FDA as an outsourcing facility under Section 503B of the Federal Food, Drug, and Cosmetic Act (FDCA)?[2]	☐	☐

	Yes	No
Licensure and Credentialing (continued)		
Are the pharmacy, its pharmacists, and technicians licensed/registered by the state? Do they have other appropriate licensure, if required?	☐	☐
Can the pharmacy provide the results of its most recent state board of pharmacy inspection?	☐	☐
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?	☐	☐
Accreditation and Compliance		
Is the pharmacy accredited (e.g., through the Accreditation Commission for Health Care/Pharmacy Compounding Accreditation Board or another accrediting body)?	☐	☐
If the pharmacy cannot provide state board of pharmacy inspection reports, can it provide inspection reports from an accrediting agency?	☐	☐
Does the pharmacy adhere to United States Pharmacopeia–National Formulary standards for sterile compounding (USP <797>)?	☐	☐
Does the pharmacy ensure that all ingredients are 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?	☐ ☐ ☐ ☐ ☐	☐ ☐ ☐ ☐ ☐

	Yes	No
Processes and Procedures (continued)		
Does the pharmacy adhere to safety precautions such as using unique identifiers and barcodes on ingredients, segregating products that have look-alike names and similar packaging, periodically reviewing product expiration dates and the integrity of packaging, and using checklists to reinforce consistent practices?	☐	☐
Does the pharmacy use checklists to reinforce consistent practices among staff?	☐	☐
Are processes and checklists validated through user testing and periodically reviewed/updated as appropriate?	☐	☐
Quality Control and Assurance		
Does the pharmacy require independent double checks on all critical steps of the compounding process, such as calculations, measurements, and mixing?	☐	☐
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?	☐	☐
Does the pharmacy keep detailed documentation of quality control processes and verification of critical steps in the compounding process?	☐	☐

[1] Institute for Safe Medication Practices. (2012, October 18). Sterile compounding tragedy is a symptom of a broken system on many levels. Retrieved from www.ismp.org/newsletters/acutecare/showarticle.aspx?id=34

[2] Title 1 of the Drug Quality and Security Act makes a distinction between pharmacies engaged in traditional compounding and those that are producing and selling sterile medications without patient-specific prescriptions (termed "outsourcing facilities"). Traditional compounding pharmacies are regulated under Section 503A of the FDCA, and state boards of pharmacy continue to have primary oversight over these pharmacies. Outsourcing facilities, on the other hand, are regulated under Section 503B of the FDCA, which requires stricter FDA oversight and adherence to current good manufacturing processes.