MedPro Group
a Berkshire Hathaway company

Checklist

Assessing Pharmacy Compounding Services

Pharmacy compounding plays a vital role in patient care and treatment. 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 scrutiny because of concerns about safety, quality, and oversight.

The Institute for Safe Medication Practices advises healthcare organizations and providers to use or prescribe U.S. Food and Drug Administration (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, 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.[2]

	Yes	No
History and Experience		
Can the compounding pharmacy provide accurate information about its number of years in business, the approximate number/types of customers served, and the volume of compounded sterile products or preparations produced?	☐	☐
Can the pharmacy provide a list of the requested sterile compounding services that it can provide and the normal terms of service?	☐	☐
Have the pharmacy's staff members ever been investigated or charged with questionable drug-related practices?	☐	☐
Has the FDA ever warned the pharmacy about compliance issues? (Check the FDA website for warnings.)	☐	☐
Does the pharmacy have a history of any violations or disciplinary actions from the FDA, state board of pharmacy, or other regulators?	☐	☐

	Yes	No
History and Experience (continued)		
Does the pharmacy have a history of product liability lawsuits related to its compounded preparations?	☐	☐
Can the pharmacy demonstrate a history of, and an ongoing commitment to, improving patient safety through technology and education?	☐	☐
Can the pharmacy provide proof of professional liability coverage?	☐	☐
Licensure, Registration, and Certification		
Is the pharmacy registered with the FDA as an outsourcing facility under Section 503B of the Federal Food, Drug, and Cosmetic Act (FDCA)?*	☐	☐
If the pharmacy compounds controlled substances, is it registered with the U.S. Drug Enforcement Administration?	☐	☐
Are the pharmacy, its pharmacists, and technicians licensed/registered in appropriate states? Do they have other licensure if required?	☐	☐
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)?	☐	☐
Can the pharmacy provide the results of its most recent FDA and/or state board of pharmacy inspection?	☐	☐

* 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.

	Yes	No
Accreditation and Compliance (continued)		
If the pharmacy cannot provide FDA or 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 use USP-grade ingredients and/or FDA-approved products?	☐	☐
Processes and Procedures		
Does the pharmacy have written policies and procedures for:		
• Facility cleaning and validation?	☐	☐
• Equipment validation?	☐	☐
• Proper gowning and gloving techniques?	☐	☐
• Quality review?	☐	☐
• Product tracking and product recalls?	☐	☐
• Staff training and competency validation?	☐	☐
• Handling customer complaints?	☐	☐
• Emergency preparedness and response?	☐	☐
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?	☐	☐
• Routinely reviewing product expiration dates and the integrity of packaging?	☐	☐
• Using tamper-resistant packaging and containers that maintain the sterility and stability of compounded products?	☐	☐
• Using shipping methods that take into account temperature and light exposure?	☐	☐

	Yes	No
Processes and Procedures (continued)		
Does the pharmacy use checklists to reinforce consistent practices among staff?	☐	☐
Are processes and checklists validated through user testing?	☐	☐
Are processes and checklists periodically reviewed and 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 maintain 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?	☐	☐

Resources

For more information related to this topic, see MedPro's article *Due Diligence of Outsourced Pharmacy Compounding as Part of Infection Prevention Efforts* and *Risk Tips: Managing Drug Shortages*.

Endnotes

[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/resources/sterile-compounding-tragedy-symptom-broken-system-many-levels

[2] American Society of Health-System Pharmacists. (2015). ASHP guidelines on outsourcing sterile compounding services. *American Journal of Health-System Pharmacists, 72,* 1664–1675; American Society of Health-System Pharmacists Research and Education Foundation. (2021). Outsourcing sterile products preparation: Vendor assessment tool. Retrieved from https://outsourcing.ashp.org/; Institute for Safe Medication Practices. (2017, June 15). *Death due to pharmacy compounding error reinforces need for safety focus.* Retrieved from www.ismp.org/resources/death-due-pharmacy-compounding-error-reinforces-need-safety-focus; Rosebush, L., Holmes, L., & Wagner, M. (2022). *Due diligence in drug compounding M&A deals.* LexisNexis Practical Guidance. Retrieved from https://admin.bakerlaw.com/wp-content/uploads/2023/07/Due-Diligence-in-Drug-Compounding-MA-Deals.pdf