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Evaluate 503B Facilities for Outsourced Compounds

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Complete Due Diligence Before Selecting a Compounding Pharmacy and Establishing an Outsourcing Relationship

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THE US HEALTH care system has encountered long-standing, complex challenges, including growing costs, overuse of care, staffing shortages and supply chain weaknesses.

COVID-19 revived these pressures, transforming the health care landscape. Medication and staffing shortages plague hospital systems, and pharmacies are not exempt. Most health systems have experienced high levels of pharmacy technician turnover, with most reporting a minimum turnover rate of 21% last year.[1] In addition, medication shortages of critical medications and infusions create significant workflow barriers that hospitals must address to ensure patient safety.[2] In the face of these obstacles, health systems are turning to 503B compounding facilities to outsource pharmacy needs.

Before 2013, hospitals and surgical centers either compounded medications in house or depended on 503A pharmacies for compounded medications. However, to improve quality after high-profile cases of infections from outsourced compounded products were reported, the Drug Quality and Security Act (DQSA) created FDA-registered 503B outsourcing facilities.[3] Since 2013, 503B outsourcing facilities have produced and provided compounded sterile preparations in large quantities under DQSA. Registered 503B outsourcers must comply with federal and state guidelines, meet strict good manufacturing process standards, and be routinely inspected by the FDA.

However, pharmacy leaders are skeptical of this change in process and must do due diligence when selecting a 503B pharmacy before moving into an outsourcing relationship. A multidisciplinary team should undertake a standardized 503B vendor evaluation process to give administrative and clinical perspectives equal weight and minimize risk.[4] The evaluation should include not only ensuring appropriate licensing and regulatory requirements but also asking probing questions regarding best practices, compliance, and quality assurance.[5]

The first step in evaluating a potential 503B vendor is ensuring that it meets regulatory requirements. In October 2021, the FDA released updated draft guidance for 503B pharmacies recommending that health systems use FDA-registered 503B facilities.[6] Although this recent guidance is only a recommendation, it ensures that health systems meet the requirements for minimizing the risk of contamination and risks associated with low compounding conditions. Because the FDA inspects registered facilities and other regulatory bodies, pharmacists can feel confident in the products they are receiving. The state board may require additional registration of boards of pharmacy (BoP). However, pharmacy leaders should double-check with their state BoP as found through the National Association of Boards of Pharmacy.

Before conducting the vendor interview, however, the multidisciplinary team should review all FDA inspection documents for the 503B facility and pay particular attention if an FDA Form 483 has been filed, as this indicates substandard conditions were found during inspection.[1] Although an FDA Form 483 may not preclude a 503B vendor entirely, it does warrant consideration and may drive additional questions for the vendor. Other documents include audit documents, clean room certifications, and compounding and training records.

Within the compliance domain, questions

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revolve around shifting compounding regulations. If pharmacy leaders are screening vendors to ensure that they are considering only those that are FDA-registered, this will alleviate considerable concerns within this domain. Questions may include how microorganisms and particles are monitored, what primary engineering controls are used, whether the environment is monitored, who the supplier or vendor of materials is, and how they are qualified.

Within the domain of quality assurance, the goal is to ensure that a 503B vendor is consistently producing high-quality compounds. A review of the local BoP may provide additional information on the status of the vendor facility and on disciplinary actions that have been taken.[1]

Questions may include what the compounding process is, how employees are trained, what studies are performed to test the products, and what the quarantining process is.

The final domain for consideration is best practices. Although 503B vendors are relatively new to the health care world, the importance of authority, honesty, and transparency within the quality assurance department remains unchanged.[6] Critical questions for this domain include what the authority and role of the quality assurance department are, what the process is for reporting adverse effects to patients, and whether the quality assurance department can reject or release the product.

Although evaluating a potential 503B vendor may seem daunting, the risks of entering a vendor agreement without a thorough review are far direr. Clinicians remain liable for the compounds and their preparation even if that service is outsourced.[7] The focus on cost-effective care and patient safety has never been more monitored. A thorough evaluation of all potential 503B vendors is the best insurance against liability and the simplest way to ensure patient safety. COVID-19 will continue to affect the health care landscape for years. Outsourcing facilities can play a critical role in the hospital supply of ready-to-use sterile drug products. ■

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