503B: The Better Choice for Practices

> Practices cannot dispense from their office with a 503A, and the FDA does not regulate or measure 503A prescription drug manufacturing processes. In comparison, there are no exclusive 503A benefits. A 503B is the clear choice and advantage for practices focused on patient convenience and Rx safety.

	503B Outsourcing Facilities	503A Traditional Compounding Pharmacies
SAFETY & QUALITY ASSURANCE	• Strict FDA regulation standards • Quality Department must be in place • Every manufacturing process must be validated • Must conduct extensive testing to release drug batches • Operates within state boards of pharmacy regulations	• Operates within state boards of pharmacy regulations
CREATION	• Created as a result of the 2013 Drug Quality and Security Act (DQSA) to provide safe and effective compounded drugs for individuals and Rx distribution at a larger scale	• 503A was enacted in 1997 and revised in 2013 by the DQSA to carve out “traditional” pharmacy compounding for individuals from FDA oversight
PRESCRIPTION REQUIREMENTS	• Does not require patient specific prescriptions • Can be manufactured in large batches	• Must have a patient specific prescription • CANNOT compound large batches
LICENSURE	• Regulated by the FDA • Regulated by the State Boards of Pharmacy	• NOT regulated by the FDA • Regulated by the State Boards of Pharmacy
REGULATORY COMPLIANCE	• Complies with Current Good Manufacturing Practices (CGMP) to ensure quality and safety of drug products • Complies with state boards of pharmacy regulations	• Complies with state boards of pharmacy regulations