

Executive Summary

FDA Enforcement Now Includes Medically Integrated Dispensaries

How This Change Affects Your Practice

What changed: The Drug Supply Chain Security Act (DSCSA) is now being enforced at the medical practice level. Any practice that purchases, stores, or dispenses drug products in-office is subject to FDA supply chain compliance inspections — not just manufacturers, wholesale distributors, and retail pharmacies. MIDs sit squarely in the FDA’s definition of a dispenser, and enforcement has arrived.

The Drug Products at Issue in Medically Integrated Dispensaries

If your practice purchases and dispenses any of the following to patients, federal drug supply chain requirements apply — regardless of specialty or practice model:

<p>Oncology & Infusion Therapies</p> <ul style="list-style-type: none"> • Monoclonal antibodies (Herceptin, Avastin, Keytruda, Opdivo) • Biosimilars — any FDA-approved biosimilar to a reference biologic • Checkpoint inhibitors (pembrolizumab, nivolumab, atezolizumab) • Supportive agents (filgrastim, epoetin alfa, darbepoetin) • Iron infusion products (Injectafer, Venofer, Monoferic) • IV immunoglobulin (IVIg — Gamunex, Privigen, Octagam) 	<p>Rheumatology & Specialty Injectables</p> <ul style="list-style-type: none"> • Biologics (Humira, Enbrel, Remicade, Simponi, Orencia) • IL-6 inhibitors (Actemra, Kevzara) • JAK inhibitors dispensed in-office • Corticosteroids (methylprednisolone, triamcinolone) • Hyaluronic acid joint injections (Synvisc, Euflexxa, Monovisc) • Denosumab (Prolia, Xgeva) — bone health biologics
<p>Neurology, Urology & Other Specialty</p> <ul style="list-style-type: none"> • MS therapies (Ocrevus, Tysabri, Lemtrada — infused) • Enzyme replacement therapies (Fabrazyme, Myozyme, Cerezyme) • Botulinum toxin (Botox — therapeutic indications) • Ketamine infusions (compounded and branded) • Testosterone and hormone injectables 	<p>Weight Management & Emerging Dispensary Products</p> <ul style="list-style-type: none"> • GLP-1 agonists (semaglutide, tirzepatide — branded and compounded) • Peptide therapies (BPC-157, Ipamorelin, Sermorelin, CJC-1295) • NAD+ infusions and compounded IV therapies • Vitamin and nutrient IV infusions with Rx components • Compounded products from 503A/503B facilities

Why Enforcement Has Reached MIDs

The DSCSA, enacted in 2013, was implemented in phases. For nearly a decade, enforcement focused on manufacturers, wholesalers, and national serialization systems. With those controls now in place, regulatory focus has shifted downstream to the final point in the supply chain: the practice itself. MIDs that purchase high-cost specialty drugs and biologics are among the highest-value targets in that downstream enforcement picture.

***The proof point:** In January 2026, the FDA issued its first publicly documented inspection finding against a physician-owned practice — a med spa in Texas — for failures in how injectable drug products were purchased, tracked, and documented. FDA investigators cross-referenced what the practice administered to patients against manufacturer shipment records. The gap triggered a formal citation. MIDs dispensing high-cost biologics and specialty agents carry substantially greater dollar variance exposure — making documentation gaps both more visible and more consequential under this same methodology.*

What FDA Inspectors Now Evaluate

- Purchasing only from FDA-authorized trading partners — with written verification on file
- Transaction documentation tying each product received to a specific dispense event or patient record
- Reconciliation between units purchased, units dispensed, and current on-hand inventory
- Lot number and expiration date traceability for every drug product in stock

- Written procedures for handling suspect, illegitimate, or compromised product
- A defined, repeatable compliance process backed by written policies — not informal staff knowledge

Where MIDs Are Exposed

Most practices do not fail due to intent. They fail due to execution.

- Vendor credentials for specialty distributors assumed valid but never formally verified against the FDA ATP registry
- High-cost biologics and infusion agents received without transaction documentation linking the invoice to the specific dispense event
- No reconciliation between units purchased, units dispensed, and on-hand inventory — creating variance the FDA can identify from upstream data alone
- Compounded products sourced from 503A compounding pharmacies or unregistered 503B facilities without verification
- Informal or inconsistent documentation across providers, treatment rooms, or satellite locations
- No written procedure for handling suspect, recalled, or temperature-compromised product — leaving staff to improvise during an inspection
- Buy-and-bill drug documentation that satisfies payer requirements but does not meet FDA supply chain standards

A Note on Payer Audits and FDA Inspections

Many MIDs already maintain drug purchase records to satisfy Medicare, Medicaid, and commercial payer audit requirements under buy-and-bill arrangements. These records are a strong foundation — but they are not the same as FDA supply chain compliance documentation.

The gap is specific: Payer audits verify that what was billed was purchased and administered. FDA inspections verify that what was purchased came from an authorized source, was properly identified at the lot level, and can be reconciled without unexplained variance. A MID that passes every payer audit can still fail an FDA inspection. Claritas bridges that gap without duplicating the documentation work your team already does.

The Claritas Axis Solution: Two Programs, One Path to Defensibility

Program 1

The Drug Supply Chain Readiness Audit

- Vendor authorization verification against FDA ATP registry
- Purchasing and receiving controls review
- Purchase-to-dispensing reconciliation analysis
- Lot number and expiration traceability assessment
- Storage and handling review
- Suspect and compromised product procedure review
- Documentation gap analysis
- Formal risk-ranked findings report
- Prioritized remediation roadmap

Program 2

Structured Remediation Support

- Written SOPs built to FDA inspection standards
- Documentation templates for purchasing, receiving, and dispensing
- Workflow alignment tailored to MID operations
- Payer audit crosswalk — aligning supply chain records with billing
- Multi-location documentation coordination
- Ongoing readiness support and compliance validation

Why both programs matter: The audit finds the gap. The remediation closes it. For most MIDs — particularly those dispensing high-cost biologics, compounded therapies, or operating across multiple treatment locations — the path to defensibility requires both. The structured remediation program is designed to follow directly from audit findings so nothing falls through the cracks.

Bottom Line

FDA enforcement now includes medically integrated dispensaries.

The question is not whether these requirements apply.

The question is whether your documentation can withstand inspection.