# Executive Summary

## FDA Enforcement Now Includes Primary Care Practices

### 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 administers drug products in-office is subject to FDA supply chain compliance inspections — not just manufacturers, wholesale distributors, and retail pharmacies. Primary care practices may not administer the highest-cost drugs in medicine, but they administer a wide variety of Rx drug products daily — and the FDA's inspection methodology applies equally regardless of practice size, specialty, or drug cost.

### The Drug Products at Issue in Primary Care Practices

If your practice purchases and administers any of the following, federal drug supply chain requirements apply — regardless of practice size or patient volume:

**Injectable Medications & In-Office Treatments**

- Corticosteroids (triamcinolone, methylprednisolone, dexamethasone)
- Vitamin B12 (cyanocobalamin) — injectable
- Testosterone (cypionate, enanthate) — injectable
- Toradol (ketorolac) — injectable NSAID
- Phenergan (promethazine) / Zofran (ondansetron) — injectable antiemetics
- Lidocaine / Bupivacaine — local anesthetics for in-office procedures

**Weight Management & Metabolic Therapies**

- GLP-1 agonists (semaglutide, tirzepatide) — branded and compounded
- Saxenda (liraglutide) — weight management injectable
- Peptide therapies (BPC-157, Ipamorelin, Sermorelin) — if dispensed
- Compounded weight loss formulations from 503A/503B facilities
- Ozempic / Wegovy / Mounjaro / Zepbound — if stocked in-office
- NAD+ and vitamin IV infusions with Rx components — if offered

**Vaccines & Preventive Biologics**

- Influenza vaccines — all in-office stocked formulations
- Pneumococcal vaccines (Prevnar 20, Pneumovax 23)
- Shingrix (zoster vaccine recombinant) — two-dose series
- Tdap / Td boosters — Adacel, Boostrix, Tenivac
- HPV vaccine (Gardasil 9) — multi-dose series
- COVID-19 vaccines — any stocked for in-office administration

**Chronic Disease & Specialty Injectables**

- Depo-Provera (medroxyprogesterone) — contraceptive injectable
- Prolia (denosumab) — osteoporosis biologic
- Forteo / Tymlos (teriparatide / abaloparatide) — bone anabolic agents
- Dupixent (dupilumab) — if administered in-office for atopic dermatitis
- Allergy immunotherapy serums — custom-prepared Rx products
- Iron infusion products (Injectafer, Venofer) — if infusion services offered

### Why Enforcement Has Reached Primary Care

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. Primary care practices are now in scope not because they dispense high-cost specialty drugs, but because the FDA's inspection methodology is universal — it applies to any practice that purchases and administers prescription drug products, regardless of volume or cost.

> ***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 manufacturer shipment records against practice purchase records and patient administration logs. The gap triggered a formal citation. That methodology works on any practice that purchases prescription drugs — including a primary care office that stocks injectables, vaccines, GLP-1s, or compounded products.*

### What FDA Inspectors Now Evaluate

- Purchasing only from FDA-authorized trading partners — with written verification on file
- Transaction documentation tying each drug product received to a specific patient administration event
- Alignment between purchase invoices, inventory logs, and administration or vaccine records
- Lot number and expiration date traceability — including vaccines and cold chain products
- Written procedures for managing suspect, recalled, or temperature-compromised product
- A defined, repeatable compliance process backed by written policies — not informal staff knowledge

## Where Primary Care Practices Are Exposed

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

- Vaccine and injectable vendors assumed to be authorized but never formally verified against the FDA ATP registry
- GLP-1 and weight management drug products — including compounded semaglutide and tirzepatide — purchased from unverified or non-registered sources
- No reconciliation between units of injectable medications received and units administered to patients — a gap visible to FDA from upstream shipment data
- Vaccine cold chain documentation maintained for VFC or payer audit purposes but not structured to meet FDA supply chain standards
- Compounded products sourced from 503A compounding pharmacies or unregistered 503B facilities without verification of current FDA registration
- Allergy serum and immunotherapy products prepared externally and administered without transaction documentation linking the product to a verified authorized source
- No written procedure for handling recalled, suspect, or returned drug product — leaving front desk or nursing staff to improvise during an inspection
- In-house dispensing of samples or Rx products to patients without documentation that satisfies FDA supply chain traceability requirements

## A Note on GLP-1s, Compounded Weight Loss Drugs, and FDA Risk

*The rapid growth of GLP-1 prescribing and in-office weight management programs has introduced a new and specific compliance risk for primary care practices. Many practices are now stocking or dispensing compounded semaglutide or tirzepatide — products that have been the subject of significant FDA enforcement activity around unauthorized compounding facilities.*

***The exposure is direct:** A primary care practice that purchases compounded GLP-1 products from a 503A compounding pharmacy or an unregistered 503B facility — or that cannot produce transaction documentation showing it purchased from an FDA-authorized trading partner — is in the same documentation gap as any other practice the FDA has cited. The GLP-1 enforcement environment is active, and primary care practices dispensing or administering these products are no longer below the regulatory radar.*

## 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-administration reconciliation analysis
- Lot number and expiration traceability for all in-office Rx products
- Storage and handling review — including vaccine cold chain
- 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 administration
- GLP-1 and weight management drug documentation protocols
- Vaccine and cold chain compliance documentation alignment
- In-house dispensary or med spa crosswalk where applicable
- Ongoing readiness support and compliance validation

**Why both programs matter:** The audit finds the gap. The remediation closes it. For most primary care practices — particularly those offering in-office weight management programs, stocking compounded products, or managing vaccine cold chain documentation — 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 primary care practices.**

The question is not whether these requirements apply.

**The question is whether your documentation can withstand inspection.**