Executive Summary

FDA Enforcement Now Includes Oncology & Infusion 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. Oncology and infusion practices, which routinely handle some of the highest-cost drug products in medicine, are among the highest-priority targets as enforcement moves downstream.

The Drug Products at Issue in Oncology & Infusion Practices

If your practice purchases and administers any of the following, federal drug supply chain requirements apply — regardless of whether you operate a pharmacy or dispense under a buy-and-bill arrangement:

Chemotherapy & Targeted Agents

- Taxanes (paclitaxel, docetaxel, Abraxane)
- Platinum agents (carboplatin, cisplatin, oxaliplatin)
- Anthracyclines (doxorubicin, epirubicin, liposomal doxorubicin)
- Alkylating agents (cyclophosphamide, ifosfamide, bendamustine)
- Antimetabolites (gemcitabine, fluorouracil, pemetrexed)
- Topoisomerase inhibitors (irinotecan, etoposide, topotecan)

Monoclonal Antibodies & Checkpoint Inhibitors

- Anti-PD-1/PD-L1 (Keytruda, Opdivo, Tecentriq, Imfinzi)
- Anti-CTLA-4 (Yervoy — ipilimumab)
- Anti-HER2 (Herceptin, Perjeta, Kadcyla, Enhertu)
- Anti-VEGF (Avastin — bevacizumab and biosimilars)
- Anti-CD20 (Rituxan, Gazyva — and biosimilars)
- Anti-EGFR (Erbitux, Vectibix)

Biologics, Biosimilars & Supportive Agents

- Biosimilars — all FDA-approved biosimilar references
- G-CSF / GM-CSF (Neulasta, Neupogen, Granix, Zarxio)
- Erythropoiesis agents (Procrit, Aranesp, Retacrit)
- Iron infusion products (Injectafer, Venofer, Monoferric)
- IV immunoglobulin (IVIG — Gamunex, Privigen, Octagam)
- Antiemetics and supportive Rx infusion agents

Hormone Therapies, CAR-T & Emerging Agents

- LHRH agonists / antagonists (Lupron, Eligard, Firmagon)
- Bone-modifying agents (Zometa, Xgeva — zoledronic acid, denosumab)
- CAR-T cell therapies (Kymriah, Yescarta, Carvykti)
- ADC therapies (Enhertu, Padcev, Trodelvy)
- Oral oncolytics dispensed or administered in-office
- Compounded chemotherapy preparations from 503B facilities

Why Enforcement Has Reached Oncology Practices

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. Oncology practices administering high-cost chemotherapy, biologics, and CAR-T therapies represent the single highest dollar-value exposure category in downstream enforcement — making documentation gaps both more visible to regulators and more consequential when found.

> ***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. The same methodology applies directly to oncology and infusion practices — where a single variance between what was received and what was administered on a $50,000 biologic course creates a finding that is both visible and difficult to explain.*

What FDA Inspectors Now Evaluate

- Purchasing only from FDA-authorized trading partners — with written verification on file
- Transaction documentation linking each drug product received to a specific patient administration event

- Reconciliation between units purchased, units administered, and current on-hand inventory — including partial vials
- Lot number and expiration date traceability for every drug product, including cold chain and temperature-sensitive agents
- Written procedures for handling suspect, recalled, or temperature-compromised product
- A defined, repeatable compliance process backed by written policies — not informal staff knowledge

Where Oncology Practices Are Exposed

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

- Specialty distributor and GPO vendor credentials assumed valid but never formally verified against the FDA ATP registry
- High-cost chemotherapy and biologic agents received without transaction documentation linking the invoice to the specific patient administration event
- Partial vial usage and dose rounding not reconciled — creating unit variance the FDA can identify from upstream shipment data alone
- Cold chain and temperature excursion logs maintained for internal purposes but not structured to meet FDA supply chain documentation standards
- Compounded chemotherapy sourced from 503B outsourcing facilities without verification of current FDA registration status
- 340B program drug purchases documented for CMS compliance but not cross-referenced to FDA supply chain requirements — a gap regulators are increasingly aware of
- No written procedure for handling suspect, recalled, or returned product — leaving staff to improvise during an inspection
- Buy-and-bill records that satisfy payer audit requirements but do not meet FDA lot-level traceability and ATP verification standards

A Note on 340B Programs and FDA Inspections

Many oncology practices participate in the 340B drug pricing program, which creates its own documentation requirements around drug acquisition, eligibility, and dispensing. These records are maintained for CMS and HRSA compliance — but they are not the same as FDA supply chain compliance documentation.

***The gap is specific:** 340B compliance verifies that eligible patients received drugs purchased at 340B prices. FDA supply chain compliance verifies that every drug product purchased — at any price — came from an authorized source, carries a valid product identifier at the lot level, and can be reconciled without unexplained variance. A practice that is fully 340B-compliant can still fail an FDA supply chain inspection. Claritas bridges that gap without disrupting the documentation workflows your team already maintains.*

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 — including cold chain products
- Storage, handling, and temperature log 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 administration
- Cold chain and temperature excursion documentation protocols
- 340B program documentation crosswalk where applicable
- Payer audit alignment — buy-and-bill records vs. FDA requirements
- Ongoing readiness support and compliance validation

Why both programs matter: The audit finds the gap. The remediation closes it. For most oncology and infusion practices — particularly those administering high-cost biologics, participating in 340B, or managing cold chain drug products across multiple infusion suites — 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 oncology and infusion practices.

The question is not whether these requirements apply.

The question is whether your documentation can withstand inspection.