Executive Summary

FDA Enforcement Now Includes Rheumatology 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. Rheumatology practices that administer high-cost biologics and infusion therapies in-office are directly in scope, and the documentation standards the FDA now evaluates go well beyond what most practices currently maintain.

The Drug Products at Issue in Rheumatology 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 administer under a buy-and-bill arrangement:

Biologics & TNF Inhibitors

- Humira (adalimumab) and biosimilars (Hadlima, Hyrimoz, Cyltezo, Yusimry)
- Enbrel (etanercept) and biosimilars (Eticovo, Erelzi)
- Remicade (infliximab) and biosimilars (Inflectra, Renflexis, Avsola)
- Simponi / Simponi Aria (golimumab) — SC and IV formulations
- Cimzia (certolizumab pegol)
- Orencia (abatacept) — SC and IV formulations

IL Inhibitors & Targeted Therapies

- Actemra (tocilizumab) — IV and SC — IL-6 inhibitor
- Kevzara (sarilumab) — IL-6 receptor antagonist
- Cosentyx (secukinumab) — IL-17A inhibitor
- Taltz (ixekizumab) — IL-17A inhibitor
- Tremfya (guselkumab) — IL-23 inhibitor
- Rituxan (rituximab) — anti-CD20, administered in-office

Bone, Joint & Supportive Agents

- Prolia / Xgeva (denosumab) — bone-modifying biologic
- Zometa / Reclast (zoledronic acid) — IV bisphosphonate infusion
- Benlysta (belimumab) — IV and SC — lupus
- Saphnelo (anifrolumab) — IV — systemic lupus erythematosus
- Krystexxa (pegloticase) — IV — chronic refractory gout
- Corticosteroids (methylprednisolone, triamcinolone) — injectable

Emerging & Compounded Products

- Biosimilar substitutions — any FDA-approved interchangeable biologic
- Hyaluronic acid joint injections (Synvisc, Euflexxa, Monovisc, Gel-One)
- Platelet-rich plasma (PRP) preparations with Rx components
- Compounded corticosteroid preparations from 503A/503B facilities
- Investigational agents administered under clinical trial protocols
- Upcoming biosimilar entrants across all TNF and IL inhibitor classes

Why Enforcement Has Reached Rheumatology 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. Rheumatology practices are particularly exposed because the biologics they administer are among the highest-cost drugs in the entire U.S. drug supply — and the rapid expansion of biosimilar alternatives has made lot-level traceability and authorized trading partner verification more complex, and more critical, than ever.

> ***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 rheumatology practices — where a single variance involving a high-cost biologic or an unverified biosimilar source creates a finding that is both visible and difficult to defend.*

What FDA Inspectors Now Evaluate

- Purchasing only from FDA-authorized trading partners — including verification of biosimilar distributors
- Transaction documentation linking each biologic or infusion agent received to a specific patient administration event
- Reconciliation between units purchased, units administered, and current on-hand inventory
- Lot number and expiration date traceability — particularly critical given biosimilar interchangeability substitutions
- Cold chain and refrigeration documentation for temperature-sensitive biologics
- Written procedures for handling suspect, recalled, or temperature-compromised product

Where Rheumatology Practices Are Exposed

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

- Biologic and biosimilar vendor credentials assumed valid but never formally verified against the FDA ATP registry
- High-cost TNF inhibitors and IL inhibitors received without transaction documentation linking the invoice to the specific patient administration event
- Biosimilar substitutions administered without documentation identifying the specific biosimilar lot, interchangeability designation, and dispensing record
- No reconciliation between units received, units administered, and on-hand inventory — creating variance the FDA can identify from upstream manufacturer data alone
- Cold chain logs maintained informally — not structured to meet FDA supply chain documentation standards for temperature-sensitive biologics
- Compounded corticosteroid preparations sourced without verification of 503A/503B facility registration status
- No written procedure for handling recalled, suspect, or returned biologic product — a gap that becomes acute during biosimilar recall events
- Buy-and-bill documentation that satisfies payer requirements but does not meet FDA lot-level traceability and ATP verification standards

A Note on Biosimilars and FDA Inspection Risk

Rheumatology practices are now managing a rapidly expanding biosimilar landscape across every major biologic class. As of 2026, there are more than a dozen FDA-approved adalimumab biosimilars alone. Each biosimilar product carries its own lot number, product identifier, and authorized trading partner chain — and each substitution event must be documented separately to meet FDA supply chain requirements.

***The compliance risk is compounding:** A practice that switches between a reference biologic and a biosimilar — or between two biosimilars — without updating its vendor verification, transaction documentation, and lot-level records for each product creates a documentation gap at every substitution point. FDA inspectors evaluating rheumatology practices are specifically trained to look for this pattern. Claritas builds the documentation infrastructure to handle biosimilar complexity without disrupting clinical workflows.*

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 biologics
- Cold chain and refrigeration log review
- Biosimilar substitution documentation review
- Suspect and compromised product procedure review
- 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
- Biosimilar interchangeability and substitution documentation protocols
- Cold chain and temperature excursion documentation procedures
- Payer audit crosswalk — 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 rheumatology practices — particularly those managing multiple biologic and biosimilar products, operating infusion suites, or navigating buy-and-bill arrangements — 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 rheumatology practices.

The question is not whether these requirements apply.

The question is whether your documentation can withstand inspection.