The FDA Doesn’t Need to Show Up to Find a Problem

What the FDA’s new Remote Regulatory Assessment program means for medical practices that purchase, store, or administer prescription drug products in-office.

What Is a Remote Regulatory Assessment?

On June 26, 2025, the FDA finalized its guidance on Remote Regulatory Assessments — making clear that remote oversight is now a permanent part of how the agency monitors compliance. An RRA is a formal evaluation of an FDA-regulated establishment conducted entirely remotely, without an investigator physically entering the facility.

RRAs are not inspections in the traditional sense — but they carry the same weight. The FDA uses them to request records, conduct virtual interviews, review electronic databases, and livestream facility operations. What the agency finds during an RRA directly determines whether a physical inspection follows.

How the FDA Uses an RRA Against a Medical Practice

1 **The FDA requests your records remotely.**
Under Section 704(a)(4) of the Federal Food, Drug, and Cosmetic Act, the FDA has mandatory authority to request records from any establishment it oversees — including medical practices that purchase and administer prescription drug products. Participation in a mandatory RRA is not optional.

2 **Investigators compare your records against upstream supply chain data.**
Manufacturers and distributors already report transaction data to the FDA. Before your practice receives a single request, investigators have access to what was shipped to you, when, in what quantities, and from which source. Your records either reconcile with that external picture — or they don’t.

3 **Gaps in your documentation become findings.**
If your purchase records, administration logs, vendor credentials, or written procedures do not align with what the FDA already knows, those discrepancies are documented. The RRA report is formalized, shared with the practice, and used to determine next steps — which may include a physical inspection, warning letter, or enforcement action.

4 **Declining a voluntary RRA triggers escalation.**
If a practice declines to participate in a voluntary RRA, the FDA is authorized to escalate — including scheduling a physical inspection based on the agency’s risk assessment of the establishment. Declining is not a defense. It is a signal.

What Records the FDA Requests During an RRA

The FDA’s final guidance is specific about the categories of records it may request. For a medical practice that purchases and administers prescription drug products, the request typically covers three areas:

PURCHASING RECORDS	ADMINISTRATION RECORDS	POLICIES & PROCEDURES
• Invoices from every drug vendor • Proof of authorized trading partner status • Transaction statements and histories • Dates, quantities, lot numbers received	• Patient-level administration logs • Reconciliation of units purchased vs. used • Inventory on-hand documentation • Waste and disposal records where applicable	• Written SOP for suspect/recalled product • Staff training documentation • Named personnel for each compliance role • Corrective action history if applicable

What Happens When a Practice Can’t Produce the Records

> ***The proof point:*** *In January 2026, the FDA issued its first publicly documented inspection finding against a physician-owned aesthetics practice — a med spa in Texas. Investigators cross-referenced manufacturer shipment records against the practice's purchase documentation and patient administration logs. Volume discrepancies were found. An unlabeled vial with no product identifier was identified. Formal findings were issued for failure to transact with authorized trading partners and failure to maintain valid product identifiers. The inspection methodology required no tip, no complaint, and no prior relationship with the practice — only data the FDA already had from the upstream supply chain.*

The RRA framework formalizes and scales exactly this methodology. A practice that cannot produce clean, reconciled, policy-backed documentation in response to a records request is not protected by being small, being busy, or never having been inspected before. The documentation gap is the finding — and the RRA surfaces it before the inspector ever arrives.

The Direct Connection to Drug Supply Chain Compliance

> *Legal analysts at ArentFox Schiff noted directly after the final guidance was published: "Given DSCSA's considerable electronic documentation requirements, Remote Regulatory Assessments may prove to be a go-to tool for the FDA to evaluate DSCSA compliance at both domestic and foreign establishments." The RRA is not a separate compliance program. It is the mechanism by which the FDA evaluates whether your drug supply chain documentation holds up — remotely, efficiently, and without warning.*

The Bottom Line

The FDA now has a formal, permanent mechanism to evaluate your compliance records without setting foot in your practice.

An RRA request is not a warning. It is not a preliminary step. It is the evaluation — and your documentation either passes or it doesn't.

The only preparation that matters is knowing where your gaps are before the FDA asks.

Source: FDA Final Guidance — "Conducting Remote Regulatory Assessments: Questions and Answers" (June 26, 2025, Federal Register Docket No. FDA-2022-D-0810). ArentFox Schiff client alert, July 3, 2025. Ropes & Gray LLP client alert, July 3, 2025. This document is for informational purposes only and does not constitute legal advice.