



6-month DSCSA implementation roadmap for pharmacies.

Get compliant and operational before the November 2026 deadline

The FDA's final enforcement deadline for small dispensers is November 27th, 2026. Waiting to implement a compliance solution will result in onboarding bottlenecks, staff confusion, and potential disruptions of your services. Use this roadmap to get your pharmacy fully compliant, tested, and operational before the deadline.

Phase 1: Assessment + solution selection [month 1]

Understand your current gaps, organize your supplier information, and evaluate the right compliance provider.

Goals:

- Understand basic DSCSA requirements for your specific pharmacy.
- Conduct an internal audit of how you currently receive and store prescription drug inventory.
- Identify all suppliers and confirm they are Authorized Trading Partners (ATP).
- Select a dispenser-focused DSCSA solution (e.g., Pharmacy Pro).
- Secure budget approval and execute the software contract.

Action steps:

- ☐ List every wholesaler, distributor, and manufacturer you purchase prescription products from.
- ☐ Map your current receiving workflow: What exactly happens when prescription products arrive at the pharmacy? Who receives shipments? How is the product currently logged?
- ☐ Schedule demos with compliance software providers. Ensure the software can automatically receive EPCIS data (electronic tracking files) from your specific suppliers.
- ☐ Draft initial DSCSA SOPs covering receiving/scanning, exception management (example: physical product arrives but no data - what do you do?), as well as suspect product handling and quarantine procedures.



Need help with SOP drafting?

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Risks if Delayed:

Selecting software at the last-minute limits your options and forces you to accept generic, clunky systems that disrupt your pharmacy's workflow.

Common Mistakes to Avoid:

Assuming your wholesaler's web portal makes you compliant. Under DSCSA, a wholesaler can provide the compliant transaction data and other tools that a dispenser needs, but the wholesaler does not make the dispenser "fully compliant" by itself. Compliance responsibilities are shared among trading partners.

For example, a wholesale distributor is responsible for providing the required transaction data and tracing information when ownership changes.

However, the dispenser (pharmacy, hospital pharmacy, etc.) still has its own obligations, including:

- Receiving and maintaining required transaction records.
- Ensuring it only does business with authorized trading partners.
- Having procedures to identify, quarantine, investigate, and report suspect or illegitimate products.
- Being able to retrieve and provide tracing information when requested.
- Meeting electronic interoperability and verification requirements applicable to dispensers.

FDA and industry guidance consistently note that even when a dispenser uses a wholesaler's portal or a third-party service to store and manage DSCSA data, the dispenser remains accountable for compliance.

Phase 2: Implementation + workflow configuration [months 2-3]

Select a compliance solution, focus on technical setup, establish connections with your suppliers, and draft your internal rulebook.

Goals:

- Audit your Pharmacy Management System (PMS) for EPCIS readiness.
- Purchase a DSCSA compliance solution if not already in place.
- Complete technical onboarding with your software provider.
- Set up user access for your clinical and administrative staff.
- Establish and test connections with your suppliers - ensure your software is successfully receiving test data from your primary wholesalers (interoperability).
- Review drafted DSCSA SOPs to make adjustments to procedures and operational workflows where needed and then proceed to publishing finalized SOPs.

Operational validation milestones:

- ☐ Connection Established: Ensure your software is successfully receiving test data from your primary wholesalers.
- ☐ Workflow Mapped: Finalize whether the front desk, the operations manager, or the clinical staff will be responsible for scanning/verifying inbound products.
- ☐ SOPs Written: Document step-by-step instructions for receiving inventory, handling damaged boxes, and verifying serial numbers.

Staff involvement steps:

Bring your front-line staff into the conversation. Explain why the receiving process is changing, so they understand the importance of supply chain security and patient safety.

Phase 3: Training + testing + go-live readiness [months 4-5]

Dedicate time to hands-on workflow practice. Before you go live, your team must be confident in using the system under real-world clinic conditions.

Goals:

- Conduct comprehensive staff training sessions for all administrative and clinical staff.
- Practice exception handling procedures - physical product arrives with no accompanying data in the system. How do you handle that?
- Execute mock suspect product verification and quarantine exercises.
- Test EPCIS data retrieval for an FDA audit scenario - can your team pull a product's full transaction history in a timely manner?
- Stress-test your serialized receiving workflows with a large delivery.
- Review data accuracy with your software provider.



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Testing checkpoints:

- ☐ Mock Verification: Scan a random product from your inventory. Can your team pull up its entire transaction history in a timely manner?
 - ☐ Mock Recall: Pretend a specific lot has been recalled. Can your system instantly identify if you have that lot in stock?
 - ☐ Exception Handling: Test what happens if a physical product arrives, but the electronic data from the wholesaler is missing. Does your team know how to quarantine the product electronically?
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Phase 4: Go-live + ongoing maintenance [month 6 and beyond]

Going live is not the finish line: it is the beginning of sustained compliance. Refine your processes, stay current on regulatory changes, and build a culture of ongoing compliance within your clinic.

Goals:

- Operate fully on your DSCSA-compliant system in a live clinical environment.
- Identify and resolve any real-world workflow gaps that have not surfaced during testing.
- Build staff confidence and consistency in day-to-day compliance habits.
- Stay informed on any regulatory updates or enforcement guidance from the FDA.

Action steps:

- ☐ Refine SOPs based on real-world experience and staff feedback from the first weeks of live operation.
- ☐ Monitor FDA guidance updates and industry communications related to DSCSA enforcement.
- ☐ Conduct ongoing staff training as team members change and system features are updated.
- ☐ Review transaction data regularly - check records for accuracy and flag any anomalies for follow-up.

Ideal goal: Be fully operational 30 days before November 2026

Your ultimate goal is to complete this 6-month roadmap with a minimum 30-day buffer before the FDA's November 2026 deadline.

What happens if you delay implementation?

- Implementation Backlogs: Thousands of pharmacies and other dispensers will panic-buy software in late 2026, causing massive delays in onboarding and technical support.
- Supply Chain Disruptions: If you cannot electronically receive transaction data by the deadline, your wholesalers may be legally prohibited from shipping products to your pharmacy.
- Audit Vulnerability: Operating without an electronic system, after the deadline, leaves your pharmacy exposed to FDA warning letters, fines, and potential licensing issues.

Take action today

Don't let compliance slow down your pharmacy. Start your roadmap today with Pharmacy Pro - the DSCSA solution built to run quietly in the background so you can stay focused on patient care.