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DSCSA Inspection Readiness Scorecard

Large Dispensers

Use this edition if your pharmacy is subject to enhanced Drug Supply Chain Security Act (DSCSA) requirements. Complete one scorecard per location. Pick one recent shipment and one older record, then run the checks with staff on shift.

Pharmacy or location | **Completed by** | **Date**

Score what your team can show

Select one score per check. Use a record or run a drill.

0 Could not show or unsure **1 Partly demonstrated** **2 Demonstrated**

	Readiness check	0	1	2
01	**Authorized trading partners** Show a dated authorization check for one supplier you buy from.	○	○	○
02	**Transaction data at receiving** Show the electronic transaction statement and transaction information with package-level identifiers for one covered shipment.	○	○	○
03	**Receiving and reconciliation** Use your receiving procedure to compare identifiers on received product against the supplier's transaction data.	○	○	○
04	**Missing or mismatched data** Show an exception record or run a drill. Explain who decides to hold product and how the issue is closed.	○	○	○
05	**Six-year access to records** Pull an older record and show how required transaction records stay accessible for six years after the transaction.	○	○	○
06	**Record retrieval drill** Have on-shift staff obtain a recent shipment record using local access or the documented headquarters handoff.	○	○	○
07	**Suspect product quarantine** Show where staff quarantine suspect product, how they keep it out of use, and who they contact.	○	○	○
08	**Suspect product investigation** Show how your lead investigates with trading partners as applicable and documents how the case was resolved.	○	○	○
09	**Illegitimate product response** Run a drill. Identify who sends both required notices and who keeps the product quarantined through disposition.	○	○	○
10	**Procedures and training** Show your current site procedure, training records, and the local and headquarters contacts for DSCSA.	○	○	○

Priority checks A 0 on any of checks 7 to 9 goes at the top of your action plan.

Add your scores and assign follow-up on page 2.

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Your Results and Next Steps

Total score

_____ / 20

Add all ten scores. Use this self-assessment to plan follow-up.
Fix any 0 on checks 7 to 9 first, whatever the total.

17 to 20	10 to 16	0 to 9
Close open gaps and repeat the drill with another shift.	Assign owners to the lowest-scoring checks and retest.	Practice receiving and record retrieval with your DSCSA lead.

Your three priority fixes

	Fix	Owner	Due date
1			
2			
3			

Compare results across locations

FDA's temporary exemptions for eligible larger dispensers ended November 27, 2025. Use the same drill at each site and record how on-shift staff obtain records from headquarters when needed.

Send each site's score, priority gaps, and action plan to headquarters. Compare the same checks across locations and assign a corporate owner for recurring gaps.

Recurring gap or headquarters handoff to test

Retest date

Records requests and notifications

For a covered federal or state request about a recall or a suspect or illegitimate product investigation, provide records within two business days of receipt or within another timeframe FDA sets.

Within 24 hours of an illegitimate product determination, notify FDA through the 3911 platform in CDER NextGen (preferred) or email Form FDA 3911. Separately notify immediate trading partners you have reason to believe may have received the product within the same 24 hours.

Keep suspect product investigation and illegitimate product disposition records for at least six years after each concludes.

How Advasur 360 can help

Advasur 360 helps you compare received product with supplier data, document discrepancies, and retrieve transaction records. Bring one check your team struggled to demonstrate.

Schedule a 30-minute DSCSA Readiness Review calendly.com/j-shaver/360-demo

Federal sources DSCSA Section 582 FDA exemption letter FDA 3911 instructions

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