DSCSA Readiness Binder

Alder Creek Family Pharmacy 310 Larkspur Rd, Kelmore, WA 98620 State licence WA-FS-0004471 · WA

Prepared July 28, 2026 · SOP revision 2026-07-28

Determination

> Small dispenser under the FDA exemption — 9 licensed pharmacists and technicians across one location, at or under the 25-employee threshold.

What this binder is

This is the record an inspector reads. It is not a data platform and it does not move EPCIS files — your wholesalers do that. What it does is put in writing, on a date, the things a board inspector or an FDA investigator asks for and that most pharmacies cannot produce on the spot:

1. Exemption determination — what your status was, the basis for it, and what changes on November 27, 2026.
2. Trading partner verification log — every supplier you buy from, verified as authorized, one row each, dated and evidenced.
3. Three standard operating procedures — incoming inspection, suspect and illegitimate product (including the 24-hour Form FDA 3911 clock), and saleable returns.
4. Tracing response runbook — the 24-hour path from a request landing to an answer going out, with a dry run you actually performed.
5. Training attestation — each licensed staff member, signed against this SOP revision date.
6. Records retention plan — six years, per wholesaler, naming where the data actually lives.

Contents

How to use it

Print it. Put it in a physical binder behind the counter, or park the PDFs somewhere your staff can reach in under a minute. Then do the three things the documents ask of you that we cannot do from here:

- Fill in the blanks marked in italics. Some fields need an answer only your wholesaler can give — where your EPCIS data lives, how long they keep it. The documents tell you exactly what to ask and in what form to keep the answer.
- Sign the training attestation. An unsigned attestation is worse than none; it shows you knew to do it.
- Run the dry run in document 06 and write down the date. A runbook nobody has ever executed is a guess.

An inspector is looking for a reasonable, repeatable process supported by records. Blank templates from a trade association are not that. A dated, specific, signed set of documents about *your* pharmacy is.

Prepared for Alder Creek Family Pharmacy on July 28, 2026. This is compliance documentation, not legal advice. You are attesting to its contents — read it before you sign it, and correct anything that does not match how your pharmacy actually operates.

Exemption Status Determination

Alder Creek Family Pharmacy · State licence WA-FS-0004471 (WA) Determination date: July 28, 2026

Determination

> Small dispenser under the FDA exemption — 9 licensed pharmacists and technicians across one location, at or under the 25-employee threshold.

Basis

The exemption is available to a dispenser whose owning corporate entity has 25 or fewer full-time employees licensed as pharmacists or qualified as pharmacy technicians. This pharmacy counted 9 such employees across every location the entity owns, as of 2026-07-28.

The threshold counts full-time employees licensed as pharmacists or qualified as pharmacy technicians employed by the corporate entity that owns the dispenser — not per store, not per location, and not headcount generally. Front-end staff, delivery drivers and unlicensed clerks are not in the count. Every licensed pharmacist and every qualified technician across every location the entity owns is.

This is the single most common way the rule is misread. A three-store owner with nine licensed staff at each location counts twenty-seven, not nine, and does not qualify.

Headcount of record for this determination: 9 across 1 location(s), as of 2026-07-28.

If that number is wrong, this determination is wrong. Correct it and reissue rather than relying on a document that misstates your own facts.

What the exemption did and did not cover

The exemption covered only the enhanced drug distribution security requirements — the electronic, interoperable exchange of transaction information and statements. It never covered the core duties: buying only from authorized trading partners, holding transaction information, quarantining and investigating suspect product, and responding to a tracing request.

Put plainly: the exemption bought small dispensers time on the *electronics*. It never suspended the duty to know who you buy from, to keep your transaction information, to quarantine something that

looks wrong, or to answer when someone asks you to trace a product. Those obligations have been live the entire time, and state boards of pharmacy have already put DSCSA on the inspection surface — this is not solely an FDA matter.

What changes on November 27, 2026

The exemption expires. From that date the enhanced drug distribution security requirements apply to this pharmacy: transaction information and statements must be exchanged in a secure, interoperable, electronic manner, and you must be able to respond to a request for tracing information in that form.

As of this determination, that is 122 days away.

What that does *not* mean: it does not mean you must buy an enterprise serialization platform. For most single-location and small multi-location dispensers, the practical path is that your wholesalers already produce the data and you need to know how to reach it, how long they keep it, and what you do when a request arrives. Document 08 in this binder pins that down per wholesaler; document 06 is the response path.

Actions this determination creates

1. Confirm the headcount above is entity-wide and current. If you hire past the threshold, this determination goes stale — reissue it.
2. Complete the trading partner verification log (document 02) so that every supplier has an evidenced, dated authorized-trading-partner check.
3. Get a written answer from each wholesaler on where your EPCIS/T3 data lives and how long they retain it (documents 02 and 08).
4. Run the tracing dry run in document 06 and record the date you did it.
5. Have every licensed staff member sign document 07 against SOP revision 2026-07-28.

Attestation

I have read this determination. The headcount and locations stated above are accurate for the corporate entity that owns this pharmacy as of the determination date.

Name	J. Marchetti
Title	Pharmacist-in-Charge
Signature	
Date	

Prepared by DoseTrace for Alder Creek Family Pharmacy on July 28, 2026. This determination is based on the facts you supplied. It is compliance documentation, not legal advice.

Trading Partner Verification Log

Alder Creek Family Pharmacy · State licence WA-FS-0004471 (WA) Log opened July 28, 2026 · 2 trading partner(s) of record

Why this document exists

You may only buy prescription drugs from an authorized trading partner — a wholesaler, manufacturer or repackager holding a valid licence or registration. This has been true throughout the exemption period. When an inspector asks how you know your suppliers are authorized, the answer needs to be a document, not a recollection.

One row per supplier. Each row carries its own evidence and its own date.

The log

TRADING PARTNER	TYPE	LICENSE / DEA ON FILE	ATP VERIFIED HOW	VERIFIED ON	EPCIS / T3 DATA LOCATION	RETENTION
Kelmore Drug Supply, Inc.	Wholesale distributor	WA-WD-0002218	State board licence lookup	2026-07-06	Supplier portal — Documents › DSCSA	6 years
Torvald Pharmaceutical Distribution LLC	Wholesale distributor	WA-WD-0007740	FDA registration lookup	2026-07-06	*ask the wholesaler in writing*	*ask the wholesaler in writing*

How to complete a row

License / DEA on file. The wholesaler's state licence number for WA, or its FDA registration. Keep a copy of the licence itself with this binder — a number in a table with no document behind it is thin.

ATP verified how. Name the check you actually performed. Acceptable: "verified on the WA board of pharmacy licence lookup", "FDA Drug Establishments Current Registration Site", "wholesaler supplied current licence certificate". Not acceptable: "known supplier", "we've used them for years".

Verified on. The date you performed the check. Re-verify annually and when a licence lapses. Add a new dated row rather than overwriting the old one — the history is the evidence.

EPCIS / T3 data location. Where your transaction information from this partner actually lives: a portal, an SFTP drop, a solution provider they pay for on your behalf, or an email attachment. Ask in writing

and keep the reply.

Retention. How long that partner keeps the data available to you. This matters because your obligation runs six years and their portal may not. Where their retention is shorter than six years, you need your own copy — note that in document 08.

Re-verification schedule

TRIGGER	ACTION
Annually	Re-check every partner's licence status, add a dated row
New supplier	Verify BEFORE the first order, not after
Licence lapse or suspension noticed	Stop ordering, quarantine product in transit, document the decision
Change of ownership at the wholesaler	Re-verify — the licence may not carry over

Attestation

The checks recorded above were performed on the dates shown, against the sources named.

Name	J. Marchetti
Title	Pharmacist-in-Charge
Signature	
Date	

Prepared by DoseTrace for Alder Creek Family Pharmacy on July 28, 2026. Compliance documentation, not legal advice.

SOP — Incoming Product Inspection

Alder Creek Family Pharmacy · SOP revision 2026-07-28 · Effective July 28, 2026

Purpose

To ensure every prescription drug received at this pharmacy arrives from an authorized trading partner, with the transaction information required by the Drug Supply Chain Security Act, and that anything failing those checks is stopped before it reaches the shelf.

Scope

All prescription drug product received at Alder Creek Family Pharmacy, from any source, including wholesaler deliveries, transfers from another pharmacy under common ownership, and direct manufacturer shipments. Over-the-counter product outside the DSCSA definition is out of scope.

Responsibility

The receiving staff member performs the inspection. The Pharmacist-in-Charge is accountable for the procedure being followed and for any decision to quarantine.

Procedure

1. Confirm the sender is on the trading partner log. Before opening, check the delivering entity against document 02 of this binder. A delivery from a supplier not on the log stops here and goes to the Pharmacist-in-Charge.

1. Confirm transaction information accompanied the shipment. For each product, the transaction information and transaction statement must be available — in the shipment, in the wholesaler's portal, or in the data feed named for that partner in document 02. If it is absent, the product is quarantined under document 04 until it is produced.

1. Inspect the physical shipment. Check for: - packaging damage, resealing, mismatched lot or expiry printing - product that does not match the transaction information (different NDC, strength, count, or quantity) - missing or altered product identifiers on saleable units - temperature excursion indicators where the product requires them

1. Reconcile quantity and identity against the transaction information. A discrepancy is not a paperwork problem — it is a suspect-product trigger. Go to document 04.

1. Record the receipt. Log the date, the supplier, the invoice or shipment reference, who inspected, and the outcome. A receipt log with no exceptions ever recorded reads as a log nobody keeps.
1. Store the transaction information. Retain per document 08 — six years, in a place you can reach without the wholesaler's help.

When something fails

Do not shelve it, do not dispense it, do not return it to the driver on the spot. Quarantine it physically and follow document 04. Returning suspect product without documenting it destroys the record you would need later.

Receipt log

DATE	SUPPLIER	INVOICE / REF	INSPECTED BY	TI PRESENT?	EXCEPTIONS	OUTCOME

Review

This SOP is reviewed at least annually and whenever a supplier, a data source, or the applicable requirements change. The revision date at the top governs; staff training under document 07 is tied to it.

Prepared by DoseTrace for Alder Creek Family Pharmacy, SOP revision 2026-07-28. Compliance documentation, not legal advice.

SOP — Suspect and Illegitimate Product

Alder Creek Family Pharmacy · SOP revision 2026-07-28 · Effective July 28, 2026

Purpose

To quarantine and investigate product suspected of being counterfeit, diverted, stolen, intentionally adulterated, or otherwise unfit for distribution — and, where the suspicion is confirmed, to notify FDA and affected trading partners within the required 24 hours.

This is the procedure inspectors ask about most often, because it is the one with a clock on it.

Definitions in plain terms

Suspect product — you have reason to believe it may be counterfeit, diverted, stolen, intentionally adulterated, or unfit. Reason to believe is a low bar and deliberately so.

Illegitimate product — the investigation has established credible evidence that it is one of those things. Suspicion confirmed.

Triggers

Any of these makes product suspect immediately:

- quantity, identity, lot or expiry does not reconcile against the transaction information
- packaging shows damage, tampering, resealing, or printing inconsistent with the manufacturer's
- the product identifier will not verify, or verifies to something else
- delivery from an entity not on the trading partner log
- a price or availability that does not match the market for that product
- an FDA or manufacturer alert naming that product, lot, or supplier
- a patient or staff member reports appearance, taste, or effect inconsistent with the product

Procedure — suspect product

1. Quarantine physically and immediately. Move it to the designated quarantine location, separated from saleable stock and clearly marked. Do not dispense it. Do not return it to the supplier while the investigation is open.

1. Record the trigger. Date, time, who identified it, product name, NDC, lot, expiry, quantity, supplier, and what specifically prompted the suspicion. Write it while it is fresh.
1. Notify the Pharmacist-in-Charge. They own the investigation from here.
1. Investigate. Validate the transaction information for the product. Verify the product identifier against the manufacturer where one is present. Contact the supplier and ask them to account for the discrepancy in writing. Check whether FDA or the manufacturer has issued anything relevant.
1. Reach a conclusion and write it down. Either the product is cleared — record the basis and return it to saleable stock — or it is illegitimate, and the clock starts.

Procedure — illegitimate product (24-hour clock)

Once you have credible evidence the product is illegitimate:

1. Notify FDA within 24 hours using Form FDA 3911, submitted electronically. Record the submission date, time, and confirmation reference in the log below.
1. Notify affected trading partners within 24 hours — the supplier it came from, and anyone you supplied it to.
1. Keep it quarantined. Do not destroy or return it until you have consulted FDA guidance and the manufacturer, and never in a way that erases the record.
1. If you dispensed any of it, work with the Pharmacist-in-Charge on patient notification. Record what was decided and why.
1. Terminate the notification when cleared. If FDA or the manufacturer subsequently determines the product is not illegitimate, file a termination notice — also on Form 3911 — and record it.

Suspect / illegitimate product log

DATE FOUND	PRODUCT / NDC	LOT	QTY	SUPPLIER	TRIGGER	INVESTIGATION OUTCOME	3911 FILED (DATE/TIME/REF)	PARTNERS NOTIFIED

What "within 24 hours" means for a pharmacy that closes

The clock does not pause overnight or over a weekend. If the determination lands on a Friday afternoon, the notification goes out on Friday. Name a backup below so the clock never depends on one person being reachable.

ROLE	NAME	REACHABLE AT
Pharmacist-in-Charge	J. Marchetti	
Backup for 24-hour notifications		

Review

Reviewed at least annually and whenever the applicable requirements or the notification mechanism change. Staff training under document 07 is tied to this revision date.

Prepared by DoseTrace for Alder Creek Family Pharmacy, SOP revision 2026-07-28. Compliance documentation, not legal advice.

SOP — Saleable Returns

Alder Creek Family Pharmacy · SOP revision 2026-07-28 · Effective July 28, 2026

Purpose

To ensure product returned to this pharmacy, or returned by this pharmacy to a wholesaler, is verified before it re-enters saleable stock — and that the transaction information travels with it.

Returns are where counterfeits historically entered the legitimate supply chain. That is the whole reason this procedure exists.

Scope

Prescription drug product returned from a patient, from another location under common ownership, or being sent back to a wholesaler as saleable. Product returned for destruction is out of scope for resale purposes but still requires a record.

Rule this pharmacy follows

Product dispensed to a patient does not return to saleable stock. Once it has left our control we cannot attest to its handling, storage, or identity. It is documented and destroyed per state board requirements, not restocked.

The procedure below therefore governs unopened, never-dispensed product only.

Procedure — receiving a saleable return

1. Confirm the product never left our control as a dispensed prescription. If it did, it is not saleable; document and destroy.

1. Confirm identity. Verify the product identifier — NDC, serial number, lot, expiry — against the original transaction information for that unit. If the unit cannot be matched to a transaction record we hold, treat it as suspect under document 04.

1. Inspect physically. Packaging integrity, tamper evidence, storage-sensitive indicators, expiry date remaining. Anything short of intact goes to quarantine.

1. Confirm storage conditions were maintained for the whole period it was out of our stock. If that cannot be established — particularly for refrigerated product — it is not saleable.

1. Record the return in the log below before restocking.

1. Restock or quarantine. There is no third option and no "probably fine".

Procedure — returning product to a wholesaler

1. Confirm the wholesaler is on the trading partner log (document 02).
2. Provide the transaction information for the units being returned; keep your copy.
3. Record the return: date, product, lot, quantity, wholesaler, reference number.
4. Keep the record for six years per document 08.

Returns log

DATE	DIRECTION	PRODUCT / NDC	LOT	EXPIRY	QTY	FROM / TO	IDENTITY VERIFIED AGAINST	OUTCOME

Review

Reviewed at least annually and whenever a wholesaler's returns process changes. Staff training under document 07 is tied to this revision date.

Prepared by DoseTrace for Alder Creek Family Pharmacy, SOP revision 2026-07-28. Compliance documentation, not legal advice.

Tracing Response Runbook

Alder Creek Family Pharmacy · SOP revision 2026-07-28 · Effective July 28, 2026

What this is for

When FDA, a state board of pharmacy, or a trading partner asks you to trace a product, you have a short window to produce transaction information for it. This runbook is the path from the request landing to the answer going out, written down before you need it, and tested once so you know it works.

The failure mode is not that pharmacies refuse to answer. It is that the request arrives, and nobody knows which wholesaler's portal holds the data, or who has the login, or that the portal only keeps two years.

Who does what

ROLE	NAME	REACHABLE AT
Primary responder	J. Marchetti (Pharmacist-in-Charge)	
Backup responder		
Person who holds portal credentials		

Fill in the backup. A runbook that names one person is a runbook that fails on their day off.

The path

Hour 0 — request arrives. Log it immediately: who asked, how they asked, what product, what lot, what date range, and what deadline they stated. Acknowledge receipt in writing so there is a record you responded.

Hour 0–2 — identify the source. Look up the product in your receipt log (document 03) to find which trading partner supplied it and when. That tells you which data source in document 02 holds the transaction information.

Hour 2–8 — retrieve the transaction information. Pull it from the location named for that partner in document 02. If the portal will not produce it, escalate to the wholesaler contact on file the same day — do not wait to see if it resolves itself.

Hour 8–20 — assemble and check. Confirm the transaction information covers the product, lot, and period asked about. Note any gap explicitly rather than sending an incomplete answer that looks complete.

Before hour 24 — send. Send the response in the form requested. Record what you sent, to whom, when, and by what channel. Keep a copy with this binder.

If you cannot produce it

Say so, in writing, within the window — and say what you do have, what is missing, and what you are doing to get it. A prompt partial answer with a stated gap is a defensible position. Silence is not, and neither is an answer that quietly omits what you could not find.

Response log

DATE RECEIVED	REQUESTER	PRODUCT / LOT	DEADLINE GIVEN	SOURCE USED	DATE SENT	GAPS NOTED

Dry run — do this once, now

A runbook nobody has executed is a guess. Pick one product you received in the last ninety days and walk the whole path as if a request had arrived. You are testing three things: that you can find which wholesaler supplied it, that you can actually reach the transaction information, and that the credentials work.

Product used for the dry run
Date of dry run
Time from start to retrieved information
What broke or was slower than expected
Fixed by
Run by

Write the date in. An undated dry run is the same as no dry run, and it is the specific thing that separates this binder from a template.

Review

Reviewed at least annually, after every real request, and whenever a wholesaler changes how data is delivered.

Prepared by DoseTrace for Alder Creek Family Pharmacy, SOP revision 2026-07-28. Compliance documentation, not legal advice.

Staff Training Attestation

Alder Creek Family Pharmacy · Training on SOP revision 2026-07-28 · July 28, 2026

Why the revision date matters

Inspectors check that training records reflect the *current* procedures. A signed training sheet from two revisions ago documents that staff were trained on something you no longer do. Every time an SOP in this binder is revised, this sheet is reissued and re-signed against the new revision date.

The revision this sheet attests to is 2026-07-28.

What staff were trained on

DOCUMENT	TOPIC	KEY POINT STAFF MUST BE ABLE TO STATE
02	Trading partner verification	We buy only from suppliers on the log; a delivery from anyone else stops at receiving
03	Incoming product inspection	Check the sender, check that transaction information exists, reconcile against the shipment
04	Suspect and illegitimate product	Quarantine first; FDA notification on Form 3911 runs on a 24-hour clock that does not pause for weekends
05	Saleable returns	Dispensed product does not return to saleable stock; identity is verified against transaction information before restocking
06	Tracing response	Who responds, where the data lives, and the 24-hour path
08	Records retention	Six years; where each wholesaler's data lives and how long they keep it

Attestation

I have been trained on the standard operating procedures listed above at revision 2026-07-28. I understand what I am responsible for, and I know who to escalate to when product is suspect.

NAME	ROLE / LICENCE	SIGNATURE	DATE
J. Marchetti	Pharmacist-in-Charge		
R. Adeyemi	Staff pharmacist		
T. Bledsoe	Pharmacy technician		

Trainer

Trained by	J. Marchetti
Title	Pharmacist-in-Charge
Date of training	
Signature	

Re-training triggers

- Any SOP revision in this binder
- New licensed staff, before they receive product unsupervised
- After any suspect-product event or tracing request, as a debrief
- Annually regardless

Prepared by DoseTrace for Alder Creek Family Pharmacy, SOP revision 2026-07-28. Compliance documentation, not legal advice.

Records Retention Plan

Alder Creek Family Pharmacy · Prepared July 28, 2026 · 2 trading partner(s)

The obligation

Transaction information and transaction statements must remain available for six years from the date of the transaction. "Available" means available to you — not available in principle from a wholesaler who may have changed portals, been acquired, or purged their archive.

This document names, per wholesaler, where your data actually is and how long it stays there. Where their retention is shorter than six years, you need your own copy, and this plan says so.

Where the data lives

TRADING PARTNER	DATA LOCATION (PORTAL / SFTP / FEED / EMAIL)	THEIR STATED RETENTION	YOUR ACCESS ROUTE
Kelmore Drug Supply, Inc.	Supplier portal — Documents › DSCSA	6 years	*ask in writing*
Torvald Pharmaceutical Distribution LLC	*ask in writing*	*ask in writing*	*ask in writing*

The gap to check

Go down the retention column. Any partner keeping data for less than six years is a gap, and it is the most common one — portals routinely hold two or three years, not six. For each gap:

1. Export your transaction information from that partner at least annually.
2. Store the export in the local archive named below.
3. Record the export date in the log at the bottom of this document.

If a wholesaler will not state a retention period in writing, treat it as a gap and export regardless. An unanswered question is not a short answer.

Local archive

Where exports are stored	
Backed up to	
Who can retrieve them	
Format kept	

A folder on one workstation with no backup is not an archive. If that machine is the only copy, the retention plan fails the first time it dies.

What else is retained for six years

RECORD	WHERE KEPT	RETENTION
Transaction information and statements	Per the table above	6 years
Receipt / incoming inspection log (doc 03)	This binder	6 years
Suspect and illegitimate product log, and any Form 3911 filed (doc 04)	This binder	6 years
Returns log (doc 05)	This binder	6 years
Tracing requests received and responses sent (doc 06)	This binder	6 years
Trading partner verification evidence (doc 02)	This binder	6 years, including superseded dated rows
Training attestations (doc 07)	This binder	6 years, all revisions

Superseded records are kept, not replaced. The history is the evidence.

Annual export log

DATE	PARTNER	PERIOD EXPORTED	STORED WHERE	BY WHOM

Attestation

The locations and retention periods recorded above reflect written answers from each trading partner, or are marked as outstanding where no written answer has been received.

Name	J. Marchetti
Title	Pharmacist-in-Charge
Signature	
Date	

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