Drug Supply Chain Security Act (DSCSA) Pharmacy Checklist[1] and Standard Operating Procedures (SOPs) Considerations

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<tr><th>Checklist</th><th>SOP Considerations</th></tr>
<tr><td colspan="2">Preliminary Considerations</td></tr>
<tr><td>Written standard operating procedures ensure compliance with DSCSA.</td><td rowspan="2">Review the following sections to ensure SOPs are comprehensive.</td></tr>
<tr><td>The training record for every staff member reflects training on the most recent standard operating procedures.</td></tr>
<tr><td colspan="2">Authorized Trading Partners (ATPs)</td></tr>
<tr><td>Manufacturers & Re-packagers:
Pharmacies purchasing directly from a manufacturer or re-packager must establish they are buying from an ATP.
Manufacturers and re-packagers must have valid Drug Establishment registration with FDA. To verify this, check FDA’s Drug Establishment Current Registration Site database (DECRS) here.</td><td>The pharmacy SOPs must describe the process and frequency for checking a manufacturer or re-packager registration.<ol type="a">
If the organization has multiple registered facilities, which one(s) will you confirm (all, a few, one)?
What source will you use (e.g., the DECRS directly, a copy of the registration provided by the manufacturer, or a third-party digital credential)?
How often will you check the current validity of their registration?
If this process is conducted for the pharmacy by vendor what are the due diligence steps for evaluating the vendor’s process? Does the vendor accept or waive liability for this task?
What is your process to ensure you only share your DSCSA data with ATPs who have a legitimate reason to request that data?</td></tr>
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[1] This “Pharmacy Checklist” is a general overview of the current requirements for dispensers pursuant to the DSCSA and is largely based on the FDA’s Pharmacists Webinar that can be accessed here. However, it should be noted that the FDA continues to release industry guidance in this space. Please consult the webpage here to access up-to-date regulatory action on the implementation of the DSCSA.

Wholesale Distributors (wholesalers) & Third-Party Logistics Providers (3PLs): ▪ Pharmacies purchasing from wholesalers and 3PLs must establish they are buying from an authorized trading partner. ▪ Wholesalers and 3PLs must have a valid state or federal license and compliance with reporting requirements. ▪ You may check FDA's Wholesale Distributor and Third-Party Logistics Providers Reporting database here. Because this database is self-reported information, you should also check the relevant state licensure database to confirm licensure.	1. The SOPs must describe the process and frequency for checking a wholesaler's or 3PL's registration/permit/license. a. If the organization has multiple licenses (e.g., they may have wholesale distributor and repackager licenses), which one(s) will you confirm? b. What source will you use (e.g., the state board of pharmacy or other applicable regulator, a copy of the license provided by the wholesaler/3PL, a third-party digital credential)? c. How often will you check the current validity of their license? 2. If this process is conducted for the pharmacy by a vendor, what are the due diligence steps for evaluating the vendor's process? Does the vendor accept or waive liability for this task?
Dispensers (Pharmacies): ▪ Pharmacies purchasing from other dispensers must establish that they are buying from an authorized trading partner regardless of whether the transaction meets the tracing data exemption for when specific patient need exists. ▪ Dispensers must have a valid state license/permit.	1. Do you keep a list of criteria to evaluate other dispensers and do you purchase exclusively from authorized trading partners (ATPs)? 2. Is the purchase of a prescription drug from other dispensers compliant with exemptions to "wholesale distribution" including those for Sections 503(e)(4) and 582(d)(1)(A) for meeting a specific patient need? How is specific patient need documented whether your pharmacy is the buyer or seller? (If the purchase does not comply with the exemption, the selling dispenser should meet the requirements of a wholesale distributor) 3. The pharmacy SOPs must describe the process and frequency for checking dispenser permit/license. a. If the dispenser has multiple licenses, which one(s) will you confirm? b. What source will you use (e.g., the state board of pharmacy or other applicable regulator, a copy of the license provided by the dispenser, a third-party digital credential)? c. How often will you check the current validity of their license? 4. If this process is conducted for the pharmacy by a vendor what are the due diligence steps for

	evaluating the vendor's process? Does the vendor accept or waive liability for this task?
Product Identifier (PI) Verification	
• Pharmacies must have a way to verify that a manufacturer made an item with a specific NDC number, lot number, expiration date & serial number. • Make sure that the label on each individual saleable package you receive displays a DSCSA-compliant product identifier including the NDC, lot number, expiration date and serial number.	1. Describe how the pharmacy will be able to verify the item's product identifier. 2. The pharmacy SOPs should describe how the items in an order are inspected for DSCSA-compliant product identifiers (e.g., scan the 2D barcodes on each item as part of the receiving process). 3. The SOPs should describe what happens if a package does not have a DSCSA-compliant identifier. a. Is the package exempted or grandfathered from this requirement? b. Is the next step quarantine and a suspect product investigation or something else? 4. May address using a PDG conformant credential.
Product Tracing	
Respond: ▪ Dispensers must be able to tell an authorized trading partner or regulator who they received an item from and any other dispenser to whom they sold or loaned it. ▪ Dispensers and their authorized trading partners (ATPs) are required to respond to a request for information from an ATP, the Food and Drug Administration, or any other appropriate federal or state official within two business days in the event of a recall or to investigate a suspect or illegitimate product. ▪ Dispensers' product tracing information should be true, accurate and complete.	1. The SOPs should describe how the pharmacy will locate the information about who they purchased a specific NDC and serial number combination from. 2. The SOPs should describe how the pharmacy will ensure these requests get to the right person/people quickly to comply with the 2-day obligation. 3. Does the process differ for requests from ATPs vs. requests from regulators? a. How is the identity of the regulator verified? b. If the trading partner is not a company the pharmacy deals directly with (e.g., a manufacturer), how is it determined to be an authorized trading partner? 4. Who needs to review the tracing response before it is provided? 5. What other investigative or quarantine processes does a request for information trigger? 6. See PDG's tracing flowchart.
Receive: ▪ Pharmacies and other dispensers must receive product tracing data for all transactions in which the pharmacy purchases or otherwise takes ownership of applicable products. (This includes borrowing from a pharmacy that is not part of your organization). There is an exception for transactions between two dispensers when a specific patient need exists.	1. The SOPs should describe the process to verify that the pharmacy receiving the item(s) received the product tracing data required from all authorized trading partners. 2. What is your process to confirm the validity/accuracy of the product tracing data you received compared to the physical product you received?

	a. Will you reconcile every physical package against product TI data, or will you use another method of sampling/auditing physical product against product tracing data? b. How does this process vary based on where your product tracing data is being captured and stored (e.g., by your WD vs. a commercial vendor supplied solution vs. in-house)? 3. Do you have a way to identify which supplier you received an item at the serial number level of detail from while still being able to reply to a request for information from a trading partner, the Food and Drug Administration, or any other appropriate federal or state official within two business days?
Store: ▪ Dispensers must store their product tracing information they receive in paper or electronic format for at least 6 years. ▪ Dispensers must store information about any suspect or illegitimate product investigations for 6 years from the date of the investigation's conclusion.	1. The SOPs should state that the pharmacy's record retention meets or exceeds the 6 years required by DSCSA. 2. The SOPs should reference a written agreement between the pharmacy and a third-party vendor if tracing data is stored on the pharmacy's behalf by a vendor. a. What are the due diligence steps for evaluating the vendor's service? b. What are the steps for accessing product tracing data held by a vendor? c. Does the solution enable you to see not only the Transaction Information (TI) but also the Transaction Statement (TS)? d. What happens to your product tracing data if the vendor service is terminated for any reason? e. What is the process for resetting the 6-year window, if needed due to a suspect or illegitimate product investigation?
Waste Documentation	Will you document the NDC, lot number, expiration date, serial number of items wasted? This is an additional business consideration. Documenting waste is not required by the law, but some DSCSA solution vendors simplify this.
Returns	Will you document the NDC, lot number, expiration date, serial number of items returned?
Recalls	Will you document the NDC, lot number, expiration date, serial number of items recalled?

340B orders	If you are a contract pharmacy for a 340B covered entity, do you have an agreement in place to make sure you receive the product tracing information?
Dropship orders	Do you have an agreement in place to make sure you receive the product tracing information from the distributor even though the distributor did not directly send the item(s) to you? In the case of drop shipments, the items come directly from a manufacturer to the pharmacy even though they were ordered through a distributor and the pharmacy is paying the distributor for it. As the product tracing data transfers by ownership, not by physical control of it, when it is shipped to the pharmacy, the product tracing data is sent to the distributor who then needs to make it available to the pharmacy. The distributor never touches the items so they do not know what the TI is of the items the pharmacy received.
Investigations requested by regulators	1. Who in your organization will be responsible for the intake and response? 2. How will you document your response to the investigation?
Suspect or Illegitimate Product Investigation	
Dispensers must identify and investigate suspect product to determine if it is illegitimate. Likewise, if a dispenser is notified that they received suspect or illegitimate product, they must respond to the notification and conduct any additional investigation, response or notification needed. **Suspect Product is when you have reason to believe that product potentially is:** ▪ Counterfeit, diverted, stolen, subject of fraudulent transaction, intentionally adulterated, or appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans. ▪ FDA examples: Altered product info, mission into on label, looks different than product on shelf, no "Rx only" symbol, bubbling on the label, foreign language, lot numbers or expiration dates do not match the outer/inner container, missing or wrong package inserts, damaged, broken seal, open package, different product names than FDA approved version.	1. The SOPs should describe a process for identifying suspect product. 2. The SOPs should describe a process for investigating suspect product that has been detected/identified, including the steps to ensure suspect product is not put in inventory or dispensed, or returned to supplier before resolution of the investigation without the supplier being informed of the product's suspect status. 3. The SOPs should describe how to complete an investigation report which is maintained for 6 years. 4. Consult with FDA's March 2023 guidance on the agency's interpretation of the terms "counterfeit," "diverted," "stolen," "fraudulent transaction" and "unfit for distribution" in determining whether a product is suspect and/or illegitimate. 5. Describe where the report will be stored. 6. Describe how and when necessary other involved authorized trading partners are notified. 7. How often, and in what manner, is staff trained on the process?

▪ Starting November 27, 2023, pharmacies must verify the product identifier of the suspect product of at least three packages or 10 percent of products under suspect investigation. FDA has given the supply chain an extra year to stabilize the verification process and will delay enforcing this provision until November 27, 2024. Pharmacies should identify a verification service by the effective date of November 27, 2023.	8. Describe what number of the suspect product's packages should have its PI verified.
Illegitimate Product is when you have credible evidence that shows the product is: ▪ Counterfeit, diverted, stolen, subject of fraudulent transaction, intentionally adulterated, or appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans. ▪ Notify the FDA if you have illegitimate product within 24 hours using FDA Form 3911, notify other trading partners within 24 hours, and request notification termination using FDA Form 3911. (Access to the FDA Form 3911 can be found here.)	1. The SOPs should describe the process for securing illegitimate product to ensure it is not put in inventory or dispensed. 2. Who in the supply chain will submit the FDA Form 3911 in situations where numerous trading partners work together to determine whether a product is illegitimate? a. How will the process differ if your organization decides a product is illegitimate vs if a trading partner or regulator makes the determination? b. How will you submit the FDA Form 3911 and notify trading partners within 24 hours? 3. What is your process for determining, based on your investigation, whether the product is legitimate or illegitimate? Who makes the determination?
Other Considerations: ▪ Pharmacies must quarantine suspect and illegitimate product. ▪ The pharmacy may be required to store samples of illegitimate product. ▪ A clerical error or discrepancy in the product tracing information may not be indicative of a suspect product. ○ As a result, the FDA stipulated that if a dispenser purchases a product and identifies a potential clerical error or other discrepancy in the product tracing information received, it should resolve the error or discrepancy within 10 business days. ▪ DSCSA requires use of an electronic verification system starting November 27, 2023. FDA has delayed the enforcement of this provision until November 27, 2024. However, pharmacies should	1. The SOPs should describe the quarantine location or the steps to create a quarantine location when needed for suspect or illegitimate product. 2. The quarantine location may be needed long-term if the pharmacy is required to store samples. 3. If the pharmacy uses a virtual quarantine as a tactic to prevent dispensing suspect or illegitimate product the SOPs should describe that as well. 4. The SOPs should describe the steps for using an electronic verification system to verify the serialized product identifier on the package(s) of suspect or illegitimate product.

identify a verification service by the effective date of November 27, 2023	
Supplier / Wholesaler Distributor (WD) Considerations	
	1. If your WD will store your TI and TS data, do you have an agreement in place with the WD? 2. If you rely on multiple WDs to store your data, how will you manage multiple repositories?

Evaluating DSCSA Solutions Vendors

Most independent pharmacies will rely on one or more vendors to comply with the product tracing data and PI verification requirements of the DSCSA. Here are important questions to ask when evaluating DSCSA solutions vendors.

- ☐ Do you require use of a specific 2D barcode scanner? If yes, do you provide that equipment?
- ☐ Does the software interface with other software applications (e.g., dispensing system, inventory management, wholesaler portal/EDI & EPCIS systems, manufacturing systems) my pharmacy uses?
- ☐ Is there a value-add beyond DSCSA compliance?
- ☐ What is the cost of the software or service? Are the price tiers or discounts?
- ☐ What is the process for importing product tracing data from multiple wholesalers?
- ☐ What is the process for producing product tracing data when my pharmacy sells or loans something to another unrelated dispenser organization?
- ☐ Will the solution receive EPCIS data from my suppliers? (FDA has recommended using GS1's EPCIS data format as a means of exchanging the required transaction information (TI) and transaction statements (TS).
- ☐ Does the solution track whether products are dispensed, sold, returned (saleable), returned (recall), returned (expired), wasted or determined to be illegitimate?
- ☐ How does the solution check to make sure the Transaction Information (TI) sent matches the actual items received?
- ☐ If the solution communicates electronically with a manufacturer, such as for Product Identifier (PI) Verification or Tracing, how does it verify that it is communication with the correct, actual manufacturer or trading partner involved?
- ☐ I have more than one pharmacy location, how does this solution distinguish locations under common ownership?
- ☐ Can the solution match a given product identifier (NDC, lot number, expiration date, serial number) to the Transaction Information (TI) and purchase order number that matches it?
- ☐ How does my pharmacy get support for this solution? What are the helpdesk hours?
- ☐ How will the technology vendor ensure my data is secure? Is my data backed-up?
- ☐ If the solution is a HIPAA business associate due to access to protected health information (PHI), what happens if there is a breach? Does the business associate have an appropriate HIPAA compliance program? Is there monitoring to detect potential HIPAA breaches?
- ☐ Does the vendor have access to master data as defined by the manufacturer?
- ☐ How are vendors identifying grandfathered products or exempt/excepted/waived products that do not have a DSCSA-compliant product identifier?
- ☐ How will you document when an item is sold or loaned to another unrelated dispenser organization under the "patient specific order" exemption?
- ☐ Is there assistance with looking up or obtaining the Global Location Number (GLN)? (Drug wholesalers will rely on having a Global Location Number for all their trading partners. Customers of AmerisourceBergen, Cardinal Health, McKesson, and Smith Drug may already have a GLN and just need to contact customer support to get it and share with other distributors. The GLN is used in electronic tracing data to identify a location or business in the supply chain. To obtain a single GLN from GS1 US for a 1-time fee of $30, visit here. Companies with more than nine locations may opt to license a GS1 company prefix and manage all the GLNs for the company.)
- ☐ Does the vendor provide a place to document, maintain copies of, and track ATP licenses? Does the vendor notify ATPs when stored licenses are expiring? Does the vendor notify the pharmacy when an ATP they are working with has a potentially expired license?

- ☐ Is the vendor available to assist the pharmacy with DSCSA audits?
- ☐ Is the vendor available to assist with the completion of the FDA Form 3911?
- ☐ Does the vendor provide SOPs for their software and compliance with other aspects of the DSCSA?
- ☐ Does the vendor provide employee training on the software and the SOPs (if available)?
- ☐ Does the software permit the searching of received data (e.g., searching received product lot # for recall purposes)?