



Read this page carefully

**WA Pharmacy Quality Assurance Commission
Pharmacy Self-Inspection Worksheet**

2025 Drug Supply Chain Security Act (DSCSA) – Optional Addendum

Attention: Responsible Pharmacy Manager or Equivalent Manager

Washington law holds the responsible manager (or equivalent manager) responsible for ensuring compliance with all state and federal laws governing the practice of pharmacy. It is recommended that this DSCSA addendum be completed along with other required self-inspection worksheets as applicable, within the month of March and within 30 days of becoming responsible manager (as required by WAC 246-945-005). **Although completing the DSCSA addendum is optional for 2025**, compliance with the provisions of DSCSA is **still required** for entities licensed by the commission (RCW 18.64.026(1)). The following addendum once completed should be kept on file. **Do not send to the commission office.**

The primary objective of this self-inspection worksheet is to provide an opportunity to assess compliance with the federal requirements of the Drug Supply Chain Security Act (DSCSA). This worksheet serves as a starting point for compliance with the federal provisions of the DSCSA. (**Note:** Neither the self-inspection nor a commission inspection evaluates your complete compliance with all laws and rules of the practice of pharmacy.) The ultimate responsibility of compliance to DSCSA rests on each pharmaceutical firm and pharmacy personnel.

Date self- inspection was completed: _____

Name of responsible pharmacy manager or equivalent manager: _____

Signature of responsible pharmacy manager or equivalent manager: _____

Type of pharmaceutical firm: Drug Manufacturer Drug Wholesalers Dispensers (Pharmacies, Health Care Entities)

Name of pharmaceutical firm: _____

Address: _____

Applicable federal or state issued pharmaceutical license(s): _____

To request this document in another format, call 1-800-525-0127. Deaf or hard of hearing customers, please call 711 (Washington Relay) or email doh.information@doh.wa.gov.

General Rule Reference - Applies to all questions through worksheet.

RCW 18.64.026(1): “The commission is authorized to take any of the actions identified in this section against licenses, registrations, permits, or other credentials or approvals issued by the commission under this chapter and chapters 18.64A, 69.38, 69.41, 69.43, 69.45, and 69.50 RCW in any case in which it finds the licensee has failed or refused to comply **with any state or federal statute or administrative rule regulating the license in question** including, but not limited to, Title 69 RCW, this chapter, chapter 18.64A RCW, and administrative rules adopted by the commission, except as otherwise limited in this section.

Purpose of DSCSA:

The Drug Supply Chain Security Act (DSCSA) outlines steps to achieve a secure, interoperable, and electronic way to identify and trace certain prescription drugs at the package level as they move through the supply chain. This helps prevent harmful drugs from entering the U.S. drug supply chain, detect harmful drugs if they do enter the supply chain, and enable rapid response to remove harmful drugs from the supply chain to protect patients.^{1, 2}

Applicability:

Each manufacturer, wholesale distributor, and dispenser (i.e., pharmacies and Health Care Entities (HCEs)) shall comply with the requirements set forth in the DSCSA with respect to the role of such manufacturer, wholesale distributor, or dispenser in a transaction involving drug products. If an entity meets the definition of more than one of the entities listed in the preceding sentence, such entity shall comply with all applicable DSCSA requirements for both entities, but shall not be required to duplicate requirements. See Sec. 582 (1) of FD&C Act.

Exemptions to DSCSA:

The Food & Drug Administration has the authority to grant waivers, exceptions and exemptions from **certain requirements** in section 582 of the Food, Drug and Cosmetic Act (FD&C Act). Please see the FDA website for additional information: <https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/drug-supply-chain-security-act-dscsa-waivers-exceptions-and-exemptions>.

Additional Note on Exemptions:

Meeting an exemption does not exempt a pharmaceutical firm from all obligations under DSCSA. Instead, pharmaceutical firms should carefully review all exemptions issued by the FDA and determine exactly which requirements of the DSCSA are impacted. For example, pharmacies meeting the “small dispensers” exemption are still required to obtain drugs through authorized trading partners, have the duty to identify suspect products, appropriately quarantine, investigate, and alert the FDA and relevant trading partners as required in Section 582(g)(1) and 582(d)(4) of the FD&C Act.

1 - <https://www.fda.gov/drugs/drug-supply-chain-integrity/drug-supply-chain-security-act-dscsa>

2 - <https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/pharmacists-utilize-dscsa-requirements-protect-your-patients>

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Compliant			#	Rule Reference	Notes/Corrective Actions
Yes	No	N/A			
Section 1: Authorized Trading Partners					
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	1.	<p>Title II Food Drug and Cosmetics Act – DSCSA Section 581 (2) – Definitions – Authorized</p> <p>(2) The term ‘authorized’ means – (A) in the case of a manufacturer or repackager, having a valid registration in accordance with section 510; (B) in the case of a wholesale distributor, having a valid license under State law or section 583, in accordance with section 582(a)(6), and complying with the licensure reporting requirements under section 503(e), as amended by the Drug Supply Chain Security Act; (D) in the case of a dispenser, having a valid license under State law.</p>	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	2.	<p>Title II Food Drug and Cosmetics Act – DSCSA Section 582(b)(3), (c)(3), (d)(3), and (e)(3)</p> <p>582(b)(3) Beginning not later than January 1, 2015, the trading partners of a manufacturer may be only authorized trading partners. 582(c)(3) Beginning not later than January 1, 2015, the trading partners of a wholesale distributor may be only authorized trading partners. 582(b)(3) - Beginning not later than January 1, 2015, the trading partners of a dispenser may be only authorized trading partners.</p> <p>Please see definitions of “authorized” in Sec 581(2), “trading partner” Sec 581(23), and “transaction” Sec 581(24).</p> <p>WAC 246-945-595 “It is unlawful for a wholesaler or manufacturer to perform, cause the performance of, or aid and abet any of the following acts in Washington state: (5) The purchase or receipt of a drug from a person that is not authorized to distribute drugs...” (6) The sale or transfer of a drug to a person who is not legally authorized to receive a drug...”</p>	

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<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	3.	Does the pharmaceutical firm have a process in place to routinely verify that trading partners it does business with are authorized trading partners?	WAC 246-945-410(6) "The facility shall create and implement policies and procedures related to: (a) Purchasing, ordering...[of] legend drugs, including controlled substances."	
Section 2: Labeling Requirements of Drug Products Distributed Under DSCSA						
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	4.	<p>Does the pharmaceutical firm only engage in transactions involving products encoded with a product identifier?</p> <p>Please see Section 581(13) of the FD&C Act for exempt drug products.</p>	<p>Title II Food Drug and Cosmetics Act – DSCSA Section 581(13)(14)</p> <p>(13) Product -- The term `product' means a prescription drug in a finished dosage form for administration to a patient without substantial further manufacturing (such as capsules, tablets, and lyophilized products before reconstitution), but for purposes of section 582, does not include blood or blood components intended for transfusion, radioactive drugs or radioactive biological products (as defined in section 600.3(ee) of title 21, Code of Federal Regulations) that are regulated by the Nuclear Regulatory Commission or by a State pursuant to an agreement with such Commission under section 274 of the Atomic Energy Act of 1954 (42 U.S.C. 2021), imaging drugs, an intravenous product described in clause (xiv), (xv), or (xvi) of paragraph (24)(B), any medical gas (as defined in section 575), homeopathic drugs marketed in accordance with applicable guidance under this Act, or a drug compounded in compliance with section 503A or 503B.</p> <p>(14) Product Identifier -- The term `product identifier' means a standardized graphic that includes, in both human readable form and on a machine-readable data carrier that conforms to the standards developed by a widely recognized international standards development organization, the standardized numerical identifier, lot number, and expiration date of the product.</p> <p>(24) Transaction -- In general.--The term `transaction' means the transfer of product between persons in which a change of ownership occurs.</p>	

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				See also FDA Guidance Documented Titled: “Product Identifiers Under the Drug Supply Chain Security Act Questions and Answers” https://www.fda.gov/media/116304/download	
Section 3: Covered Transactions and Product Tracing Information					
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	5.	<p>Title II Food Drug and Cosmetics Act – DSCSA</p> <p>Section 581(24) Transaction “(A) In general.--The term `transaction' means the transfer of product between persons in which a change of ownership occurs. (B) Exemptions.--The term `transaction' does not include-- (i) intracompany distribution of any product between members of an affiliate or within a manufacturer; (ii) the distribution of a product among hospitals or other health care entities that are under common control...”</p> <p>Please see Section 581(24) for a complete list of exemptions.</p> <p>Sec 582(b)(1)(A), (C) Manufacturer Requirements - Product Tracing</p> <p>Sec 582(c)(1)(A)-(B) Wholesaler Requirements – Product Tracing</p> <p>Sec 582(d)(1)(A) Dispenser Requirements – Product Tracing</p> <p>Sec. 582(k) Sunset - The following requirements shall have no force or effect beginning on the date that is 10 years after the date of enactment of the Drug Supply Chain Security Act: “(1) The provision and receipt of transaction history under this section...”</p>	Is product tracing information provided with each transaction where a change in ownership of drug product occurs?
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	6.	<p>Title II Food Drug and Cosmetics Act – DSCSA</p> <p>Manufacturers (b)(1)(A)(ii) – “capture the transaction information (including lot level information), transaction history, and transaction statement for each transaction and maintain such information, history, and statement for not less than 6 years after the date of the transaction.”</p>	Does the pharmaceutical firm capture product tracing information for each transaction?

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				<p>Wholesalers (c)(1)(A)(v)(I) – “capture the transaction information (including lot level information) consistent with the requirements of this section, transaction history, and transaction statement for each transaction described in clauses (i), (ii), and (iii) and maintain such information, history, and statement for not less than 6 years after the date of the transaction.”</p> <p>Dispensers (d)(1)(A)(iii) – “shall capture transaction information (including lot level information, if provided), transaction history, and transaction statements, as necessary to investigate a suspect product, and maintain such information, history, and statements for not less than 6 years after the transaction.”</p>	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	7.	<p>Title II Food Drug and Cosmetics Act – DSCSA</p> <p>Section 582(g)(1) Enhanced Drug Distribution Security “(A) The transaction information and the transaction statements as required under this section shall be exchanged in a secure, interoperable, electronic manner in accordance with the standards established under the guidance issued pursuant to paragraphs (3) and (4) of subsection (h), including any revision of such guidance issued in accordance with paragraph (5) of such subsection...” “(B) The transaction information required under this section shall include the product identifier at the package level for each package included in the transaction. “(C) Systems and processes for verification of product at the package level, including the standardized numerical identifier, shall be required in accordance with the standards established under the guidance issued pursuant to subsection (a)(2) and the guidances issued pursuant to paragraphs (2), (3), and (4) of subsection (h), including any revision of such guidances issued in accordance with paragraph (5) of such subsection, which may include the use of aggregation and inference as necessary. “(D) The systems and processes necessary to promptly respond with the transaction information and transaction statement for a product upon a request by the Secretary (or other appropriate Federal or State official) in the event of a recall or for the purposes of investigating a suspect product or an</p>	<p>Is product tracing information provided in a secure and electronic manner that permits the interoperable exchange of product tracing information?</p> <p>Important Note: Please see additional FDA information on waivers and exemptions from Section 582(g)(1) of DSCSA.</p>

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				<p>illegitimate product shall be required. (E) The systems and processes necessary to promptly facilitate gathering the information necessary to produce the transaction information for each transaction going back to the manufacturer, as applicable, shall be required--..."</p> <p>FDA Guidance Documents titled:</p> <p>“DSCSA Exemptions from Section 582(g)(1) and Other Requirements of the FD&C Act for Certain Trading Partners” https://www.fda.gov/media/182584/download?attachment</p> <p>“DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs Guidance for Industry” https://www.fda.gov/media/171796/download</p>	

Section 4: Suspect and Illegitimate Products

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	8.	<p>Does the pharmaceutical firm have a process in place to identify, quarantine, appropriately investigate, and clear suspect drug products?</p> <p>Title II Food Drug and Cosmetics Act – DSCSA Sec 582(b)4, (c)(4), (d)(4)</p> <p>(A)(i) “...Upon making a determination that a product in the possession or control of the [manufacturer, wholesale distributor, or dispenser] is a suspect product, or upon receiving a request for verification from the Secretary that has made a determination that a product within the possession or control of a [manufacturer, wholesale distributor, or dispenser] is a suspect product...”</p> <p>“(I) quarantine such product within the possession or control of the [manufacturer, wholesale distributor, or dispenser] from product intended for distribution until such product is cleared or dispositioned; and</p> <p>(II) promptly conduct an investigation in coordination with trading partners, as applicable, to determine whether the product is an illegitimate product.”</p>	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	9.	<p>Does the pharmaceutical firm have a process to respond timely and appropriately to requests made by FDA, or other Federal or State officials, in the event of a recall or for the purpose of</p> <p>Title II Food Drug and Cosmetics Act – DSCSA Sec 582</p> <p>Manufacturers (b)(1)(B) – "Upon a request by the Secretary or other appropriate Federal or State official, in the event of a</p>	

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				<p>investigating a suspect or an illegitimate product?</p> <p>recall or for the purpose of investigating a suspect product or an illegitimate product, a manufacturer shall, not later than 1 business day, and not to exceed 48 hours, after receiving the request, or in other such reasonable time as determined by the Secretary, based on the circumstances of the request, provide the applicable transaction information, transaction history, and transaction statement for the product.”</p> <p>Wholesalers (c)(1)(C) – “Upon a request by the Secretary or other appropriate Federal or State official, in the event of a recall or for the purpose of investigating a suspect product or an illegitimate product, a wholesale distributor shall, not later than 1 business day, and not to exceed 48 hours, after receiving the request or in other such reasonable time as determined by the Secretary, based on the circumstances of the request, provide the applicable transaction information, transaction history, and transaction statement for the product.”</p> <p>Dispensers (d)(1)(D) – “Upon a request by the Secretary or other appropriate Federal or State official, in the event of a recall or for the purpose of investigating a suspect or an illegitimate product, a dispenser shall, not later than 2 business days after receiving the request or in another such reasonable time as determined by the Secretary, based on the circumstances of the request, provide the applicable transaction information, transaction statement, and transaction history which the dispenser received from the previous owner, which shall not include the lot number of the product, the initial transaction date, or the initial shipment date from the manufacturer unless such information was included in the transaction information, transaction statement, and transaction history provided by the manufacturer or wholesale distributor to the dispenser.”</p>	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	10.	<p>Title II Food Drug and Cosmetics Act – DSCSA Sec 582</p> <p>Manufacturers (b)(4)(B)(iii) – “Upon the receipt of a notification from the Secretary or a trading partner that a determination has been made that a product is an illegitimate product, a manufacturer shall identify all illegitimate product</p>	

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				<p>subject to such notification that is in the possession or control of the manufacturer, including any product that is subsequently received, and shall perform the activities described in subparagraph (A).”</p> <p>Wholesalers (c)(4)(B)(iii) – “Upon the receipt of a notification from the Secretary or a trading partner that a determination has been made that a product is an illegitimate product, a wholesale distributor shall identify all illegitimate product subject to such notification that is in the possession or control of the wholesale distributor, including any product that is subsequently received, and shall perform the activities described in subparagraph (A).”</p> <p>Dispensers (d)(4)(B)(iii) – “Upon the receipt of a notification from the Secretary or a trading partner that a determination has been made that a product is an illegitimate product, a dispenser shall identify all illegitimate product subject to such notification that is in the possession or control of the dispenser, including any product that is subsequently received, and shall perform the activities described in subparagraph (A).”</p>	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	11.	<p>Title II Food Drug and Cosmetics Act – DSCSA Sec 582(b)4, (c)(4), (d)(4)</p> <p>(B) Illegitimate product.-- (i) In general.--Upon determining, in coordination with the manufacturer, that a product in the possession or control ... is an illegitimate product, the [manufacturer, wholesale distributor, or dispenser] shall--</p> <p>(I) disposition the illegitimate product within [their] possession or control...</p> <p>(II) take reasonable and appropriate steps to assist a trading partner to disposition an illegitimate product not in [their] possession or control...</p> <p>(III) retain a sample of the product for further physical examination or laboratory analysis of the product by the manufacturer or Secretary... as necessary and appropriate.</p> <p>(ii) Making a notification.—“...notify the Secretary and all immediate trading partners that the [manufacturer, wholesale distributor, or dispenser] has reason to believe</p>	<p>If a suspect product is deemed to be illegitimate, does the facility have a process to:</p> <ol style="list-style-type: none"> 1) notify the FDA and immediate trading partners within 24 hours 2) quarantine such product until its disposition 3) retain a sample for further analysis by the manufacturer or regulators

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					may have received such illegitimate product of such determination not later than 24 hours after making such determination.”	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	12.	Does pharmaceutical firm have a process to promptly notify immediate trading partners that a product is not illegitimate?	<p>Title II Food Drug and Cosmetics Act – DSCSA Sec 582</p> <p>Manufacturers (b)(4)(B)(iv) – “Terminating a notification.-- Upon making a determination, in consultation with the Secretary, that a notification is no longer necessary, a manufacturer shall promptly notify immediate trading partners that the manufacturer notified pursuant to clause (ii) that such notification has been terminated.”</p> <p>Wholesalers (c)(4)(B)(iv) – “Terminating a notification.--Upon making a determination, in consultation with the Secretary, that a notification is no longer necessary, a wholesale distributor shall promptly notify immediate trading partners that the wholesale distributor notified pursuant to clause (ii) that such notification has been terminated.”</p> <p>Dispensers (d)(4)(B)(iv) – “Terminating a notification.--Upon making a determination, in consultation with the Secretary, that a notification is no longer necessary, a dispenser shall promptly notify immediate trading partners that the dispenser notified pursuant to clause (ii) that such notification has been terminated.”</p>	
Section 5: Recordkeeping Requirements						
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	13.	Are all records related to DSCSA requirements retained for not less than six (6) years?	<p>Title II Food Drug and Cosmetics Act – DSCSA</p> <p>Sec 582(b)(1), (c)(1), (d)(1) (ii) “capture the transaction information (including lot level information), transaction history, and transaction statement for each transaction and maintain such information, history, and statement for not less than 6 years after the date of the transaction”</p> <p>Sec 582(b)(4)(A), (c)(4)(A), (d)(4)(A)</p>	

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				<p>“(iii) Records.--A manufacturer shall keep records of the investigation of a suspect product for not less than 6 years after the conclusion of the investigation</p> <p>“(iii) Records.--A wholesale distributor shall keep records of the investigation of a suspect product for not less than 6 years after the conclusion of the investigation.”</p> <p>“(iv) Records.--A dispenser shall keep records of the investigation of a suspect product for not less than 6 years after the conclusion of the investigation.”</p> <p>Sec 582(b)(4)(B), (c)(4)(B), (d)(4)(B)</p> <p>“(v) Records.--A manufacturer shall keep records of the disposition of an illegitimate product for not less than 6 years after the conclusion of the disposition.”</p> <p>“(v) Records.--A wholesale distributor shall keep records of the disposition of an illegitimate product for not less than 6 years after the conclusion of the disposition.”</p> <p>“(v) Records.--A dispenser shall keep records of the disposition of an illegitimate product for not less than 6 years after the conclusion of the disposition.”</p> <p>Sec 582(b)(2) – Manufacturers (Product identifiers)</p> <p>“Such manufacturer shall maintain the product identifier information for such product for not less than 6 years after the date of the transaction.”</p>	