Read this Page Carefully

Pharmacy Quality Assurance Commission

2021 Wholesaler Self-Inspection Worksheet

Attention: Responsible Manager

Wholesalers are responsible for ensuring compliance with all applicable state and federal laws. Failure to complete this annual worksheet within the month of March or within 30 days of becoming responsible manager (as required by WAC 246-945-005) may result in disciplinary action.

Following your self-inspection and completion of the worksheet(s), please review it with your staff, correct any deficiencies noted, sign and date the worksheet(s), and file it so it will be readily available to commission inspectors. **Do not send to the commission office**. You are responsible for ensuring your completed worksheet(s) is available at the time of inspection.

The primary objective of this worksheet, and your self-inspection, is to provide an opportunity to identify and correct areas of non-compliance with state and federal law. (Note: Neither the self-inspection nor a commission inspection evaluates your complete compliance with all laws and rules of the practice of pharmacy.) The inspection worksheet also serves as a necessary document used by commission inspectors during an inspection to evaluate a wholesaler's level of compliance.

When a Commission inspector discovers an area of non-compliance, they will issue an Inspection Report with Noted Deficiencies. The wholesaler must provide a written response (plan of correction) addressing all areas of non-compliance. Identifying and correcting an area of non-compliance prior to a commission inspection, or during an inspection, may eliminate that item from being included as a deficiency on an Inspection Report. Do not *assume* compliance with any statement; take the time to personally verify that compliance exists. If you have any questions, please contact your inspector.

A common reason for issuing an Inspection Report with Noted Deficiencies is either not having or not being able to readily retrieve required documents and records. Because commission inspections are unscheduled, it is common for the designated person to be absent or unavailable. For this reason, you are asked to provide a list of the specific locations of required documents. Having all required documents and records maintained in a well-organized and readily retrievable manner (a binder is recommended) reduces the chance that you will receive an Inspection Report with Noted Deficiencies.

By answering the questions and referencing the appropriate laws/rules/CFR provided, you can determine whether you are compliant with many of the rules and regulations. If you have corrected any deficiencies, please write corrected and the date of correction by the appropriate question. Questions highlighted in blue are questions that will be focused on during routine wholesaler inspections.

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Washington State Department of Health

2021 Wholesaler Self-Inspection Worksheet

All wholesaler responsible managers **must** complete and sign this self-inspection worksheet annually within the month of March or within 30 days of becoming the responsible manager. The form must be available for inspection as required by WAC 246-945-005. **Do not send to the commission office**.

Date Wholesaler Self-Inspection was performed: _____

Change in Responsible Manager and effective date of change: _____

Print Name of Responsible Manager: _____

Signature of Responsible Manager: _____

Responsible Manager E-mail: _____

Wholesaler: _____ Telephone: _____ Fax: _____

Address: _____ DEA #: _____

Wholesaler License #: _____

Endorsements:

☐ Controlled Substances ☐ Export Wholesaler

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Document and Record Review Where are the following items located inside the wholesaler (be as specific as possible, there can be many filing cabinets and binders)? The documentation listed below are required by rule references to be available during inspection, by listing the location of these documents you are also confirming your compliance with the referenced rule.	
	Rule Reference
Wholesaler Self-Inspection Worksheet for last two years Location:	WAC 246-945-005(4)(a) "The responsible pharmacy manager, or equivalent manager, shall sign and date the completed self-inspection worksheet(s), and maintain completed worksheets for two years from the date of completion." WAC 246-945-005(4)(b) "When a change in responsible pharmacy manager, or equivalent manager occurs, the new responsible pharmacy manager, or equivalent manager, shall conduct a self-inspection as required under this section. The new responsible pharmacy manager, or equivalent manager, shall sign and date the self-inspection worksheet(s) within thirty days of becoming responsible pharmacy manager, or equivalent manager, and maintain completed worksheets for two years from the date of completion."
Wholesaler License Location:	RCW 18.64.046(1) "The owner of each place of business which sells legend drugs and nonprescription drugs, or nonprescription drugs at wholesale shall pay a license fee to be determined by the secretary, and thereafter, on or before a date to be determined by the secretary as provided in RCW 43.70.250 and 43.70.280, a like fee to be determined by the secretary, for which the owner shall receive a license of location from the department, which shall entitle such owner to either sell legend drugs and nonprescription drugs or nonprescription drugs at wholesale at the location specified…"
DEA Registration Location:	WAC 246-945-040(2) "A separate registration is required for each place of business, as defined in 21 C.F.R. Sec. 1301.12, where controlled substances are manufactured, distributed, or dispensed."

Document and Record Review Where are the following items located inside the wholesaler (be as specific as possible, there can be many filing cabinets and binders)? The documentation listed below are required by rule references to be available during inspection, by listing the location of these documents you are also confirming your compliance with the referenced rule.	
Current Biennial Controlled Substance Inventory Location:	21 C.F.R. 1304.04(h)(1) "Inventories and records of controlled substances listed in Schedules I and II shall be maintained separately from all of the records of the registrant; and. (2) Inventories and records of controlled substances listed in Schedules III, IV, and V shall be maintained either separately from all other records of the registrant or in such form that the information required is readily retrievable from the ordinary business records of the registrant." WAC 246-945-420(2) "A facility shall conduct an inventory of controlled substances every two years." WAC 246-945-420(3)(a) "Within thirty days of designating a responsible pharmacy manager. The incoming responsible pharmacy manager, or designee, shall conduct a complete controlled substance inventory. (b) On the effective date of an addition of a substance to a schedule of controlled substances. Each facility that possesses the substance shall take an inventory of the substance on hand, and thereafter, include the substance in each inventory."
Power of Attorney for staff authorized to order controlled substances Location:	WAC 246-945-040(1) "The commission adopts 21 C.F.R. as its own." 21 C.F.R. 1305.05(a) "A registrant may authorize one or more individuals, whether or not located at his or her registered location, to issue orders for Schedule I and II controlled substances on the registrant's behalf by executing a power of attorney for each such individual, if the power of attorney is retained in the files, with executed Forms 222 where applicable, for the same period as any order bearing the signature of the attorney. The power of attorney must be available for inspection together with other order records."

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Document and Record Review Where are the following items located inside the wholesaler (be as specific as possible, there can be many filing cabinets and binders)? The documentation listed below are required by rule references to be available during inspection, by listing the location of these documents you are also confirming your compliance with the referenced rule.	
Schedule II Invoices for the last two years Location:	WAC 246-945-040(3)(a) "Every registrant shall keep and maintain inventory records required by 21 C.F.R. Sec. 1304.04. Registrants are also required to keep a record of receipt and distribution of controlled substances. Records shall include: Invoices, orders, receipts, or any other document regardless of how titled, establishing the date, supplier, and quantity of drug received, and the name of the drug;" WAC 246-945-040(4) "Credential holders and pharmaceutical firms shall maintain records for Schedule II drugs separately from all other records."
Schedule III-V Invoices for the last two years Location:	WAC 246-945-040(3)(a) "Every registrant shall keep and maintain inventory records required by 21 C.F.R. Sec. 1304.04. Registrants are also required to keep a record of receipt and distribution of controlled substances. Records shall include: Invoices, orders, receipts, or any other document regardless of how titled, establishing the date, supplier, and quantity of drug received, and the name of the drug;" WAC 246-945-040(5) "Credential holders and pharmaceutical firms may maintain records for Schedule III, IV, and V drugs either separately or in a form that is readily retrievable from the business records of the registrant."

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Document and Record Review Where are the following items located inside the wholesaler (be as specific as possible, there can be many filing cabinets and binders)? The documentation listed below are required by rule references to be available during inspection, by listing the location of these documents you are also confirming your compliance with the referenced rule.	
Completed loss by theft or destruction forms (DEA Form 106) for the last two years Location:	WAC 246-945-040(3)(c) "In the event of a significant loss or theft, two copies of DEA 106 (report of theft or loss of controlled substances) must be transmitted to the federal authorities and a copy must be sent to the commission." 21 C.F.R. 1301.76(b) "The registrant shall notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substances within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft..."
Suspicious Order Reports Location: ***Wholesalers may apply to the commission for an exemption from the reporting requirements if they do not distribute controlled substances or drugs of concern.***	WAC 246-945-585(1) "(a)Suspicious orders shall be submitted electronically through a commission approved system or to the commission or within five business days of the order being identified as suspicious by the wholesaler, and must include, but not necessarily limited to:(i) Customer name; (ii) Customer address; (iii) Customer DEA registration number; (iv) State license number(s); (v) Transaction date; (vi) Drug name; (vii) NDC number; (viii) Quantity ordered; and (ix) Indication of whether the drug was shipped, and if not, the factual basis for the refusal to supply. (b) Zero reports shall be submitted if no suspicious orders have been identified in a calendar month, and such reports shall be submitted within fifteen business days of the end of the calendar month."

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Document and Record Review Where are the following items located inside the wholesaler (be as specific as possible, there can be many filing cabinets and binders)? The documentation listed below are required by rule references to be available during inspection, by listing the location of these documents you are also confirming your compliance with the referenced rule.	
Completed CII order forms (DEA Form 222) and/or finalized CSOS documentation for the last two years Location:	WAC 246-945-040(6) "A federal order form is required for each distribution of a Schedule I or II controlled substance. Credential holders and pharmaceutical firms must keep and make readily available these forms and other records to the commission or its designee." 21 C.F.R. 1305.13(b) "A supplier may fill the order, if possible and if the supplier desires to do so, and must record on the original DEA Form 222 its DEA registration number and the number of commercial or bulk containers furnished on each item and the date on which the containers are shipped to the purchaser. If an order cannot be filled in its entirety, it may be filled in part and the balance supplied by additional shipments within 60 days following the date of the DEA Form 222. No DEA Form 222 is valid more than 60 days after its execution by the purchaser, except as specified in paragraph (f) of this section." 21 C.F.R. 1305.13(d) "The supplier must retain the original DEA Form 222 for the supplier's files in accordance with §1305.17(c). Any supplier who is not required to report acquisition/disposition transactions to the Automation of Reports and Consolidated Orders System (ARCOS) under §1304.33(c) (such as a practitioner) must make and submit a copy of the original DEA Form 222 to DEA, either by mail to the Registration Section, or by email to DEA.Orderforms@usdoj.gov. The copy must be forwarded at the close of the month during which the order is filled. If an order is filled by partial shipments, the copy must be forwarded at the close of the month during which the final shipment is made or the 60-day validity period expires." 21 C.F.R. 1305.13(e) "The purchaser must record on its copy of the DEA Form 222 the number of commercial or bulk containers furnished on each item and the dates on which the containers are received by the purchaser." 21 C.F.R. 1305.22(g) "When a purchaser receives a shipment, the purchaser must create a record of the quantity of each item received and the date received. The record must be electronically linked to the original order and archived."

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Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
General Licensing						
			1	Does the wholesaler have a current license?	RCW 18.64.046(1) "The owner of each place of business which sells legend drugs and nonprescription drugs, or nonprescription drugs at wholesale shall pay a license fee to be determined by the secretary, and thereafter, on or before a date to be determined by the secretary as provided in RCW 43.70.250 and 43.70.280, a like fee to be determined by the secretary, for which the owner shall receive a license of location from the department, which shall entitle such owner to either sell legend drugs and nonprescription drugs or nonprescription drugs at wholesale at the location specified..." WAC 246-945-246(1) "Every wholesaler who engages in wholesale distribution into, out of, or within Washington state must be licensed by the commission before engaging in wholesale distribution of drugs. Entities required to be licensed as a wholesaler includes: (a) In-state and out-of-state pharmaceutical wholesalers; (b) Out-of-state manufacturer that distribute or sell drugs into Washington; (c) Virtual wholesalers; (d) Out-of-state virtual manufacturers that distribute or sell drugs into Washington; (e) Outsourcing facilities required to be registered with the FDA as an outsourcing facility as defined in 21 U.S.C. Sec. 353b(d)(4)(A) that are located in Washington, or distribute or sell drugs into Washington; and (f) Reverse distributors."	

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Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
			2	Does the wholesaler have a current DEA registration?	WAC 246-945-040(2) "A separate registration is required for each place of business, as defined in 21 C.F.R. Sec. 1301.12, where controlled substances are manufactured, distributed, or dispensed."	
General Standards						
			3	Does the wholesaler maintain a current list of all persons responsible for drug access, distribution, handling, and their training?	WAC 246-945-580 "(1) A wholesaler must establish and maintain a list of officers, directors, managers, a designated representative, and other persons responsible for wholesale drug distribution, storage, and handling and must include a description of each individual's duties and a summary of their qualifications. (2) A wholesaler must employ personnel in sufficient numbers and with adequate education, training, and experience to safely and lawfully engage in wholesale drug distribution activities."	
			4	Is the facility appropriately constructed and equipped to accommodate cleaning, maintenance, and operations?	WAC 246-945-560(1) "Facilities used for wholesale drug distribution must: (a) Be of suitable size, construction, and location to accommodate cleaning, maintenance, and proper operations…"	
			5	Does the facility have adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security?	WAC 246-945-560(1) "Facilities used for wholesale drug distribution must: (b) Have storage areas that provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security…" WAC 246-945-565(2) "If no storage requirements are established for a drug, the drug may be held at "controlled" room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected."	

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Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
			6	Does the facility have a quarantine area for drugs that are unsuitable for distribution?	WAC 246-945-560(1) "Facilities used for wholesale drug distribution must: (c) Have a quarantine area for storage of drugs that are outdated, damaged, deteriorated, misbranded, adulterated, counterfeit, or suspected of being counterfeit, otherwise unfit for distribution, or that are in immediate or sealed secondary containers that have been opened;…" WAC 246-945-565 (5) Drugs that are outdated, damaged, deteriorated, misbranded, or adulterated must be physically separated from other drugs in a designated quarantine area until destroyed or returned to the original manufacturer or third party returns processor. (6) Used drugs and those whose immediate or sealed outer or sealed secondary containers have been opened are adulterated and must be quarantined. (7) Drugs must be quarantined under any condition that causes doubt as to a drug's safety, identity, strength, quality, or purity unless under examination, testing, or other investigation the drug is proven to meet required standards."	
			7	Is the facility maintained in a clean and orderly condition?	WAC 246-945-560(1) "Facilities used for wholesale drug distribution must: (d) Be maintained in a clean and orderly condition;…"	
			8	Is the facility free from infestation?	WAC 246-945-560(1) "Facilities used for wholesale drug distribution must: (e) Be free from infestation of any kind;…"	
			9	Does the facility have secure and confidential storage of information?	WAC 246-945-560(1) "Facilities used for wholesale drug distribution must: (g) Provide for the secure and confidential storage of information with restricted access and policies and procedures to protect the integrity and confidentiality of information;…"	

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Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
			10	Does the facility have a method of inventory control to detect theft, counterfeiting, or drug diversion?	WAC 246-945-560(1) "Facilities used for wholesale drug distribution must: (h) Provide and maintain appropriate inventory controls in order to detect and document any theft, counterfeiting, or diversion of drugs."	
			11	Is the outside of the facility well lit and is it appropriately secured with limited access?	WAC 246-945-560(2) "Facilities used for wholesale drug distribution must be secure from unauthorized entry, as follows: (a) Access from outside the premises must be kept to a minimum and well controlled; (b) The outside perimeter of the premises must be well lit; (c) Entry into areas where drugs are held must be limited to authorized personnel; (d) Facilities must be equipped with an alarm system to detect entry after hours; and (e) Facilities must be equipped with security systems sufficient to protect against theft, diversion, or record tampering."	
			12	Does the facility have temperature and humidity monitoring devices? **Must follow two-year recordkeeping requirements**	WAC 246-945-565(3) "Temperature and humidity recording equipment, devices, and/or logs shall be used to document proper storage of drugs."	
			13	Are refrigerators temperatures maintained between 2- 8°C (36-46°F)? ** Electronic monitoring is acceptable. **	WAC 246-945-410(2) "The facility shall be properly equipped to ensure the safe, clean, and sanitary condition necessary for the proper operation, the safe preparation of prescriptions, and to safeguard product integrity."	
			14	Are freezers between -25°& -10°C (-13° & 14°F)?	WAC 246-945-410(2) "The facility shall be properly equipped to ensure the safe, clean, and sanitary condition necessary for the proper operation, the	

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Yes	No	N/A				
					safe preparation of prescriptions, and to safeguard product integrity."	
			15	Are controlled substances stored separately from noncontrolled substances and secured?	WAC 246-945-565(4) "Controlled substance drugs should be isolated from noncontrolled substance drugs and stored in a secured area." 21 C.F.R. 1301.72 "(a) Schedules I and II. Raw material, bulk materials awaiting further processing, finished products which are controlled substances listed in Schedule I or II (except GHB that is manufactured or distributed in accordance with an exemption under section 505(i) of the Federal Food Drug and Cosmetic Act which shall be subject to the requirements of paragraph (b) of this section), and sealed mail-back packages and inner liners acquired in accordance with part 1317 of this chapter, shall be stored in one of the following secured areas: (1) Where small quantities permit, a safe or steel cabinet; (i) Which safe or steel cabinet shall have the following specifications or the equivalent: 30 man-minutes against surreptitious entry, 10 man-minutes against forced entry, 20 man-hours against lock manipulation, and 20 man-hours against radiological techniques; (ii) Which safe or steel cabinet, if it weighs less than 750 pounds, is bolted or cemented to the floor or wall in such a way that it cannot be readily removed; and (iii) Which safe or steel cabinet, if necessary, depending upon the quantities and type of controlled substances stored, is equipped with an alarm system which, upon attempted unauthorized entry, shall	

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Yes	No	N/A				
					transmit a signal directly to a central protection company or a local or State police agency which has a legal duty to respond, or a 24-hour control station operated by the registrant, or such other protection as the Administrator may approve. (2) A vault constructed before, or under construction on, September 1, 1971, which is of substantial construction with a steel door, combination or key lock, and an alarm system; or (3) A vault constructed after September 1, 1971: (i) The walls, floors, and ceilings of which vault are constructed of at least 8 inches of reinforced concrete or other substantial masonry, reinforced vertically and horizontally with 1⁄2 -inch steel rods tied 6 inches on center, or the structural equivalent to such reinforced walls, floors, and ceilings; (ii) The door and frame unit of which vault shall conform to the following specifications or the equivalent: 30 man-minutes against surreptitious entry, 10 man-minutes against forced entry, 20 man-hours against lock manipulation, and 20 man-hours against radiological techniques; (iii) Which vault, if operations require it to remain open for frequent access, is equipped with a "day-gate" which is self-closing and self-locking, or the equivalent, for use during the hours of operation in which the vault door is open; (iv) The walls or perimeter of which vault are equipped with an alarm, which upon unauthorized entry shall transmit a signal directly to a central station protection company, or a local or State police agency which has a legal duty to respond, or a 24-hour control station operated by the registrant, or such other protection as the Administrator may	

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Yes	No	N/A				
					approve, and, if necessary, holdup buttons at strategic points of entry to the perimeter area of the vault; (v) The door of which vault is equipped with contact switches; and (vi) Which vault has one of the following: Complete electrical lacing of the walls, floor and ceilings; sensitive ultrasonic equipment within the vault; a sensitive sound accumulator system; or such other device designed to detect illegal entry as may be approved by the Administration. (b) Schedules III, IV and V. Raw material, bulk materials awaiting further processing, and finished products which are controlled substances listed in Schedules III, IV, and V, and GHB when it is manufactured or distributed in accordance with an exemption under section 505(i) of the FFDCA, shall be stored in the following secure storage areas: (1) A safe or steel cabinet as described in paragraph (a)(1) of this section; (2) A vault as described in paragraph (a)(2) or (3) of this section equipped with an alarm system as described in paragraph (b)(4)(v) of this section; (3) A building used for storage of Schedules III through V controlled substances with perimeter security which limits access during working hours and provides security after working hours and meets the following specifications: (i) Has an electronic alarm system as described in paragraph (b)(4)(v) of this section, (ii) Is equipped with self-closing, self-locking doors constructed of substantial material commensurate with the type of building construction, provided,	

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Yes	No	N/A				
					however, a door which is kept closed and locked at all times when not in use and when in use is kept under direct observation of a responsible employee or agent of the registrant is permitted in lieu of a self-closing, self-locking door. Doors may be sliding or hinged. Regarding hinged doors, where hinges are mounted on the outside, such hinges shall be sealed, welded or otherwise constructed to inhibit removal. Locking devices for such doors shall be either of the multiple-position combination or key lock type and: (a) In the case of key locks, shall require key control which limits access to a limited number of employees, or; (b) In the case of combination locks, the combination shall be limited to a minimum number of employees and can be changed upon termination of employment of an employee having knowledge of the combination; (4) A cage, located within a building on the premises, meeting the following specifications: (i) Having walls constructed of not less than No. 10 gauge steel fabric mounted on steel posts, which posts are: (a) At least one inch in diameter; (b) Set in concrete or installed with lag bolts that are pinned or brazed; and (c) Which are placed no more than ten feet apart with horizontal one and one-half inch reinforcements every sixty inches; (ii) Having a mesh construction with openings of not more than two and one-half inches across the square, (iii) Having a ceiling constructed of the same material, or in the alternative, a cage shall be erected which	

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Yes	No	N/A				
					reaches and is securely attached to the structural ceiling of the building. A lighter gauge mesh may be used for the ceilings of large enclosed areas if walls are at least 14 feet in height, (iv) Is equipped with a door constructed of No. 10 gauge steel fabric on a metal door frame in a metal door flange, and in all other respects conforms to all the requirements of 21 CFR 1301.72(b)(3)(ii), and (v) Is equipped with an alarm system which upon unauthorized entry shall transmit a signal directly to a central station protection agency or a local or state police agency, each having a legal duty to respond, or to a 24-hour control station operated by the registrant, or to such other source of protection as the Administrator may approve; (5) An enclosure of masonry or other material, approved in writing by the Administrator as providing security comparable to a cage; (6) A building or enclosure within a building which has been inspected and approved by DEA or its predecessor agency, BND, and continues to provide adequate security against the diversion of Schedule III through V controlled substances, of which fact written acknowledgment has been made by the Special Agent in Charge of DEA for the area in which such building or enclosure is situated; (7) Such other secure storage areas as may be approved by the Administrator after considering the factors listed in §1301.71(b)…"	
			16	Are shipments inspected upon arrival and prior to departure from the facility?	WAC 246-945-570 "(1) Each outside shipping container must be visually examined on receipt for identity and to avoid acceptance of drugs that are contaminated or otherwise unfit for distribution.	

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Yes	No	N/A				
					(2) Outgoing shipments must be inspected to verify the accuracy and product integrity of the shipment contents."	
			17	Does the facility verify that the person they purchase drug stock from is authorized to distribute drugs?	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 to that purchaser or recipient…"	
			18	Does the facility verify that the person to whom they distribute is authorized to receive drug stock?	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: (6) The sale or transfer of a drug to a person who is not legally authorized to receive a drug…"	
Policies and Procedures						
			19	Does the wholesaler have policies and procedures in place for the following: (a) Receipt (b) Security (c) Storage (d) Inventory (e) Transport (f) Shipping (g) Report of losses (h) Inventory records (i) Recalls (j) Staff training (k) Suspicious order monitoring (l) Emergent need (m) Integrity and confidentiality of information	WAC 246-945-590 "Wholesalers shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, transport, and shipping and wholesale distribution of drugs, including policies and procedures for identifying, recording, and reporting losses or thefts and for correcting all errors and inaccuracies in inventories. Wholesalers shall include the following in their written policies and procedures: (1) A procedure to be followed for handling recalls and withdrawals of drugs. Such procedure shall be adequate to deal with recalls and withdrawals due to: (a) Any action initiated at the request of FDA or any other federal, state, or local law enforcement or other government agency, including the commission; or	

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Yes	No	N/A				
					(b) Any volunteer action by the manufacturer to remove defective or potentially defective drugs from the market. (2) A procedure to ensure that wholesalers prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of a strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency. (3) A procedure to ensure that any outdated drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed in accordance with federal and state laws, including all necessary documentation and the appropriate witnessing. This procedure shall provide for written documentation of the disposition of outdated drugs. (4) A procedure for the destruction of outdated drugs in accordance with federal and state laws. (5) A procedure for the disposing and destruction of containers, labels, and packaging to ensure that the containers, labels, and packaging cannot be used in counterfeiting activities, including all necessary documentation, and the appropriate witnessing of the destruction of any labels, packaging, immediate containers, or containers in accordance with all applicable federal and state requirements. (6) A procedure for identifying, investigating, and reporting significant drug inventory discrepancies involving counterfeit, suspect of being counterfeit, contraband, or suspect of being contraband, in the inventory and reporting of such discrepancies as required to the FDA, commission and/or appropriate federal or state agency upon discovery of such discrepancies.	

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Yes	No	N/A				
					(7) A procedure for reporting criminal or suspected criminal activities involving the inventory of drug(s) as required to the commission, FDA, and if applicable, DEA. (8) Procedures addressing: (a) The design and operation of the suspicious order monitoring and reporting system; (b) Mandatory annual training for staff responsible for identifying and reporting suspicious orders and potential diversion activities. Such training must include the following: (i) The wholesaler's suspicious order monitoring system; (ii) The process to collect all relevant information on customers in accordance with WAC 246-960-330; and (iii) The requirement and process for submission of suspicious order and information on customers who engage in potential diversion activities. (9) A procedure for timely responding to customers who submit purchase orders for patients with emergent needs." WAC 246-945-560(1) "Facilities used for wholesale drug distribution must: (g) Provide for the secure and confidential storage of information with restricted access and policies and procedures to protect the integrity and confidentiality of information…"	
Recordkeeping						
			20	Are complete records of receipt and distribution of drugs maintained?	WAC 246-945-575 "Wholesalers and other entities engaged in wholesale drug distribution must establish and maintain inventories and records of transactions pertaining to the receipt and distribution	

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Yes	No	N/A				
					or other disposition of drugs. The records must include at least: (a) The source of the drugs, including the name and principal address of the seller or transferor; (b) The identity and quantity of the drugs received and distributed or disposed of; and (c) The dates of receipt and distribution or other disposition of the drugs."	
			21	Are records of suspicious orders maintained and reported to the Pharmacy Commission in the appropriate time?	WAC 246-945-585(1) "Wholesalers shall design and operate a system to identify and report suspicious orders of controlled substances and drugs of concern to the commission. (a) Suspicious orders shall be submitted electronically through a commission approved system or to the commission or within five business days of the order being identified as suspicious by the wholesaler, and must include, but not necessarily limited to: (i) Customer name; (ii) Customer address; (iii) Customer DEA registration number; (iv) State license number(s); (v) Transaction date; (vi) Drug name; (vii) NDC number; (viii) Quantity ordered; and (ix) Indication of whether the drug was shipped, and if not, the factual basis for the refusal to supply. (b) Zero reports shall be submitted if no suspicious orders have been identified in a calendar month, and such reports shall be submitted within fifteen business days of the end of the calendar month."	
Controlled Substances						

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Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
			22	Are complete records of controlled substance maintained?	WAC 246-945-040(3) "Registrants are also required to keep a record of receipt and distribution of controlled substances. Records shall include: (a) Invoices, orders, receipts, or any other document regardless of how titled, establishing the date, supplier, and quantity of drug received, and the name of the drug; (b) Distribution records, including invoices, or any other document regardless of how titled from wholesalers, manufacturers, or any other entity to which the substances were distributed and prescriptions records for dispensers;	
			23	Are records of Schedule II drugs maintained separately from all other controlled substance records?	WAC 246-945-040(4) "Credential holders and pharmaceutical firms shall maintain records for Schedule II drugs separately from all other records." 21 C.F.R 1304.04(h) "Each registered pharmacy shall maintain the inventories and records of controlled substances as follows: (1) Inventories and records of all controlled substances listed in Schedule I and II shall be maintained separately from all other records of the pharmacy."	
			24	Does the wholesaler have completed DEA 222 forms or their electronic equivalent for each acquisition or distribution of Schedule II drugs?	WAC 246-945-040(6) "A federal order form is required for each distribution of a Schedule I or II controlled substance. Credential holders and pharmaceutical firms must keep and make readily available these forms and other records to the commission or its designee."	
			25	Are records of Schedule III-V drugs maintained either separately or in a form that is	WAC 246-945-040(5) "Credential holders and pharmaceutical firms may maintain records for Schedule III, IV, and V drugs either separately or in a	

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Yes	No	N/A				
				readily retrievable from other records?	form that is readily retrievable from the business records of the registrant." 21 C.F.R 1304.04(h)(3) "…Inventories and records of Schedules III, IV, and V controlled substances shall be maintained either separately from all other records of the pharmacy or in such form that the information required is readily retrievable from ordinary business records of the pharmacy."	
			26	Is an inventory of controlled substances being performed every two years? An inventory of controlled substances must be completed within 30 days of a new responsible manager or on the effective date of the addition of a substance to a schedule of controlled substances.	WAC 246-945-420(2) "A facility shall conduct an inventory of controlled substances every two years." WAC 246-945-420(3)(a) "Within thirty days of designating a responsible pharmacy manager. The incoming responsible pharmacy manager, or designee, shall conduct a complete controlled substance inventory. (b) On the effective date of an addition of a substance to a schedule of controlled substances. Each facility that possesses the substance shall take an inventory of the substance on hand, and thereafter, include the substance in each inventory." 21 C.F.R. 1304.11(a) "Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken, and shall be maintained in written, typewritten, or printed form at the registered location. An inventory taken by use of an oral recording device must be promptly transcribed. Controlled substances shall be deemed to be "on hand" if they are in the possession of or under the control of the registrant, including substances returned by a customer, ordered by a customer but not yet invoiced, stored in a warehouse	

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Yes	No	N/A				
					on behalf of the registrant, and substances in the possession of employees of the registrant and intended for distribution as complimentary samples. A separate inventory shall be made for each registered location and each independent activity registered, except as provided in paragraph (e)(4) of this section. In the event controlled substances in the possession or under the control of the registrant are stored at a location for which he/she is not registered, the substances shall be included in the inventory of the registered location to which they are subject to control or to which the person possessing the substance is responsible. The inventory may be taken either as of opening of business or as of the close of business on the inventory date and it shall be indicated on the inventory."	
			27	Does the wholesaler have power of attorney forms for ordering Schedule II controlled substances?	21 C.F.R. 1305.05(a) "A registrant may authorize one or more individuals, whether or not located at his or her registered location, to issue orders for Schedule I and II controlled substances on the registrant's behalf by executing a power of attorney for each such individual, if the power of attorney is retained in the files, with executed Forms 222 where applicable, for the same period as any order bearing the signature of the attorney. The power of attorney must be available for inspection together with other order records."	
			28	Has the wholesaler reported a loss of controlled substances in the previous 24 months to the DEA and the Pharmacy Commission?	21 CFR 1301.76(b) "The registrant shall notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substances within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft."	

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Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					WAC 246-9945-040(3)(c) “In the event of a significant loss or theft, two copies of DEA 106 (report of theft or loss of controlled substances) must be transmitted to the federal authorities and a copy must be sent to the commission; …”	

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