Division of Professional Licensing
UTAH DEPARTMENT OF COMMERCE

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CLASS C WHOLESALER / DISTRIBUTOR / MANUFACTURER INSPECTION

☐ Opening ☐ Random

INFORMATION

Pharmacy Name: _____ Date: _____

Facility Owners(s): _____
(owner/sole proprietor name or names of all partner/LLC partners or name of corporation and state of incorporation, attach a sheet if necessary)

License Number: _____ Exp Date: _____

C.S. License Number: _____ Exp Date: _____

DEA Registration: _____ Exp Date: _____

Facility FEIN # (Tax ID): _____ FDA Registration: _____

Facility Email: _____

Facility Phone Number: _____ Fax: _____

Facility Toll Free Number: _____

Affiliated Websites: _____

Facility Hours: Monday-Friday: _____ Saturday: _____ Sunday: _____

Facility Address: _____

City: _____ State: _____ Zip: _____

Responsible Person: _____ Phone Number: _____

INSPECTION

	YES	NO	
1	☐	☐	The licensed facility need not be under the supervision of a licensed pharmacist, but shall be under the supervision of a designated representative who meets the following criteria: is at least 21 years of age; has been employed full time for at least three years in a pharmacy or with a pharmaceutical wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to prescription drugs; is employed by the facility full time in a managerial level position; is actively involved in and aware of the actual daily operation of the pharmaceutical wholesale distribution; is physically present at the facility during regular business hours, except when the absence of the designated representative is authorized, including but not limited to, sick leave and vacation leave; and is serving in the capacity of a designated representative for only one licensee at a time. [UAC R156-17b-615 (4) (a-f)]

2 ☐ ☐ Each pharmaceutical wholesaler or manufacturer that distributes or manufacturers drugs or medical devices in Utah shall be licensed by the Division. A separate license shall be obtained for each separate location engaged in the distribution or manufacturing of prescription drugs. Business names cannot be identical to the name used by another unrelated wholesaler licensed to purchase drugs and devices in Utah. Manufacturers distributing only their own FDA-approved: prescription drugs or prescription drugs that are co-licensed products satisfy the requirement in Subsection (1) by registering their establishment with the FDA pursuant to 21 CFR Part 207 and submitting the information required by 21 CFR Part 205 including any amendments thereto, to the Division; or devices or devices that are co-licensed products, including products packaged with devices, such as convenience kits, that are exempt from the definition of transaction in 21 USC sec. 360eee (24)(B)(xii-xvi) satisfy the requirement in Subsection (1) by registering their establishment with the FDA pursuant to 21 CFR. [UAC R156-17b-615 (1,2)]

3 ☐ ☐ All pharmaceutical wholesalers and manufacturers shall publicly display or have readily available all licenses and the most recent inspection report administered by the Division. [UAC R156-17b-615 (6)]

4 ☐ ☐ The facility shall be of suitable size and construction to facilitate cleaning, maintenance and proper operations. [UAC R156-17b-615 (7) (a)]

5 ☐ ☐ The facility shall have storage areas designed to provide adequate lighting, ventilation, sanitation, space, equipment and security conditions. [UAC R156-17b-615 (7) (b)]

6 ☐ ☐ The facility shall have the ability to control temperature and humidity within tolerances required by all prescription drugs and prescription drug precursors handled or used in the distribution or manufacturing activities of the applicant or licensee. [UAC R156-17b-615 (7) (c)]

7 ☐ ☐ The facility shall provide for a quarantine area for storage of prescription drugs and prescription drug precursors that are outdated, damaged, deteriorated, misbranded, adulterated, opened or unsealed containers that have once been appropriately sealed or closed or in any other way unsuitable for use or entry into distribution or manufacturing. [UAC R156-17b-615 (7) (d)]

8 ☐ ☐ The facility shall be maintained in a clean and orderly condition. [UAC R156-17b-615 (7) (e)]

9 ☐ ☐ The facility shall be free from infestation by insects, rodents, birds or vermin of any kind. [UAC R156-17b-615 (7) (f)]

11 ☐ ☐ The facility shall be secure from unauthorized entry. [UAC R156-17b-615 (8) (a)]

12 ☐ ☐ The facility shall limit access from the outside to a minimum in conformance with local building codes, life and safety codes and control access to persons to ensure unauthorized entry is not made. [UAC R156-17b-615 (8) (b)]

13 ☐ ☐ The facility shall limit entry into areas where prescription drugs, prescription drug precursors, or prescription drug devices are held to authorized persons who have a need to be in those areas. [UAC R156-17b-615 (8) (c)]

14 ☐ ☐ The facility shall be well lighted on the outside perimeter. [UAC R156-17b-615 (8) (d)]

15 ☐ ☐ The facility shall be equipped with an alarm system to permit detection of entry and notification of appropriate authorities at all times when the facility is not occupied for the purpose of engaging in distribution or manufacturing of prescription drugs. [UAC R156-17b-615 (8) (e)]

16 ☐ ☐ The facility shall be equipped with security measures, systems, and procedures necessary to provide reasonable security against theft and diversion of prescription drugs or alteration or tampering with computers and records pertaining to prescription drugs or prescription drug precursors. [UAC R156-17b-615 (8) (f)]

17 ☐ ☐ Each facility shall provide the storage of prescription drugs, prescription drug precursors, and prescription drug devices in accordance with the following: [UAC R156-17b-615 (9) (a-c)]

☐ all prescription drugs and prescription drug precursors shall be stored at appropriate temperature, humidity and other conditions in accordance with labeling of such prescription drugs or prescription drug precursors or with requirements in the USP-NF.

☐ if no storage requirements are established for a specific prescription drug, prescription drug precursor, or prescription drug devices, the products shall be held in a condition of controlled temperature and humidity as defined in the USP-NF to ensure that its identity, strength, quality and purity are not adversely affected.

☐ there shall be established a system of manual, electromechanical or electronic recording of temperature and humidity in the areas in which prescription drugs, prescription drug precursors, and prescription drug devices are held to permit review of the record and ensure that the products have not been subjected to conditions that are outside of established limits.

18 ☐ ☐ The facility who is engaged in pharmaceutical wholesale distribution of prescription drugs for human use that leave, or have ever left, the normal distribution channel shall, before each pharmaceutical wholesale distribution of such drug, provide a pedigree to the person who receives such drug. A retail pharmacy or pharmacy warehouse shall comply with the requirements of this section only if the pharmacy engages in pharmaceutical wholesale distribution of prescription drugs. The pedigree shall be maintained by the purchaser and pharmaceutical wholesaler for five years from the date of sale or transfer and be available for inspection or use upon a request of an authorized officer of the law; and include all necessary identifying information concerning each sale in the chain of distribution of the product from the manufacturer, through acquisition and sale by any pharmaceutical wholesaler until sale to a pharmacy or other person dispensing or administering the prescription drug. At a minimum, the necessary chain of distribution information shall include: [UAC R156-17b-615 (10) (a,b)]

☐ name, address, telephone number, and if available, the email address of each owner of the prescription drug, and each pharmaceutical wholesaler of the prescription drug;

☐ name and address of each location from which the product was shipped, if different from the owner's;

☐ transaction dates;

☐ name of prescription drug;

☐ dosage form and strength of the prescription drug;

☐ size of the container;

☐ number of containers;

☐ lot number of the prescription drug;

☐ name of the manufacturer of the finished dose form;

☐ National Drug Code (NDC) number.

19 ☐ ☐ The facility shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of the prescription drugs. These records shall include pedigrees for all prescription drugs that leave the normal distribution channel. [UAC R156-17b-615 (11) (a)]

20 ☐ ☐ The facility shall upon receipt, each outside container containing prescription drugs, prescription drug precursors, or prescription drug devices shall be visibly examined for identity and to prevent the acceptance of prescription drugs, prescription drug precursors, or prescription drug devices that are contaminated, reveal damage to the containers or are otherwise unfit for distribution: [UAC R156-17b-615 (11) (b) (i,ii)]

☐ prescription drugs, prescription drug precursors, or prescription drug devices that are outdated, damaged, deteriorated, misbranded, adulterated or in any other way unfit for distribution or use in manufacturing shall be quarantined and physically separated from other prescription drugs, prescription drug precursors or prescription drug devices until they are appropriately destroyed or returned to their supplier.

☐ any prescription drug or prescription drug precursor whose immediate sealed or outer secondary sealed container has been opened or in any other way breached shall be identified as such and shall be quarantined and physically separated from other prescription drugs and prescription drug precursors until they are appropriately destroyed or returned to their supplier.

21 ☐ ☐ Each outgoing shipment shall be carefully inspected for identity of the prescription drug products or devices and to ensure that there is no delivery of prescription drugs or devices that have been damaged in storage or held under improper conditions: [UAC R156-17b-615 (11) (c) (i-ii)]

☐ if the conditions or circumstances surrounding the return of any prescription drug or prescription drug precursor cast any doubt on the product's safety, identity, strength, quality or purity, then the drug shall be appropriately destroyed or returned to the supplier, unless examination, testing or other investigation proves that the product meets appropriate and applicable standards related to the products safety, identity, strength, quality and purity.

☐ returns of expired, damaged, recalled, or otherwise non-saleable prescription drugs shall be distributed by the receiving pharmaceutical wholesale distributor only to the original manufacturer or a third party returns processor that is licensed as a pharmaceutical wholesale distributor under this chapter.

☐ returns or exchanges of prescription drugs (saleable or otherwise), including any redistribution by a receiving pharmaceutical wholesaler, shall not be subject to the pedigree requirements, so long as they are exempt from the pedigree requirement under the FDA's Prescription Drug Marketing Act guidance or regulations.

22 ☐ ☐ Each licensee under this act and pharmacies or other persons authorized by law to dispense or administer prescription drugs for use by a patient shall be accountable for administering their returns process and ensuring that all aspects of their operation are secure and do not permit the entry of adulterated and counterfeit drugs. [UAC R156-17b-615 (11) (d)]

23 ☐ ☐ A manufacturer or pharmaceutical wholesaler shall furnish prescription drugs only to a person licensed by the Division or to another appropriate state licensing authority to possess, dispense or administer such drugs for use by a patient. [UAC R156-17b-615 (12)]

24 ☐ ☐ Prescription drugs furnished by a manufacturer or pharmaceutical wholesaler shall be delivered only to the business address of a person described in Subsections R156-17b-102(20)(c) and R156-17b-615, or to the premises listed on the license, or to an authorized person or agent of the licensee at the premises of the manufacturer or pharmaceutical wholesaler if the identity and authority of the authorized agent is properly established. [UAC R156-17b-615 (13)]

25 ☐ ☐ Each facility shall establish and maintain records of all transactions regarding the receipt and distribution or other disposition of prescription drugs and prescription drug precursors and shall make inventories of prescription drugs and prescription drug precursors and required records available for inspection by authorized representatives of the federal, state and local law enforcement agencies in accordance with the following: [UAC R1456-17b-615 (14) (a-g)]

☐ there shall be a record of the source of the prescription drugs or prescription drug precursors to include the name and principal address of the seller or transferor and the address of the location from which the drugs were shipped.

☐ there shall be a record of the identity and quantity of the prescription drug or prescription drug precursor received, manufactured, distributed or shipped or otherwise disposed of by the specific product and strength.

☐ there shall be a record of the dates of receipt and distribution or other disposal of any product.

☐ there shall be a record of the identity of persons to whom distribution is made to include name and principal address of the receiver and the address of the location to which products were shipped.

☐ inventories of prescription drugs and prescription drug precursors shall be made available during regular business hours to authorized representatives of federal, state and local law enforcement authorities.

☐ required records shall be made available for inspection during regular business hours to authorized representatives of federal, state and local law enforcement authorities and such records shall be maintained for a period of two years following disposition of the products.

☐ records that are maintained on site or immediately retrievable from computer or other electronic means shall be made readily available for authorized inspection during the retention period; or if records are stored at another location, they shall be made available within two working days after request by an authorized law enforcement authority during the two year period of retention.

26 ☐ ☐ Each facility shall establish, maintain and adhere to written policies and procedures that shall be followed for the receipt, security, storage, inventory, manufacturing, distribution or other disposal of prescription drugs or prescription drug precursors, including policies and procedures for identifying recording and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. In addition, the policies shall include the following: [UAC R156-17b-615 (15) (a-g)]

☐ a procedure whereby the oldest approved stock of a prescription drug or precursor product is distributed or used first with a provision for deviation from the requirement if such deviation is temporary and appropriate.

☐ a procedure to be followed for handling recalls and withdrawals of prescription drugs adequate to deal with recalls and withdrawals due:

☐ to any action initiated at the request of the FDA or other federal, state or local law enforcement or other authorized administrative or regulatory agency;

☐ any voluntary action to remove defective or potentially defective drugs from the market; or

☐ any action undertaken to promote public health, safety or welfare by replacement of existing product with an improved product or new package design.

☐ a procedure to prepare for, protect against or handle any crisis that affects security or operation of any facility in the event of strike, fire, flood or other natural disaster or other situations of local, state or national emergency.

☐ a procedure to ensure that any outdated prescription drugs or prescription drug precursors shall be segregated from other drugs or precursors and either returned to the manufacturer, other appropriate party or appropriately destroyed.

☐ a procedure for providing for documentation of the disposition of outdated, adulterated or otherwise unsafe prescription drugs or prescription drug precursors and the maintenance of that documentation available for inspection by authorized federal, state or local authorities for a period of five years after disposition of the product.

☐ a procedure for identifying, investigating and reporting significant drug inventory discrepancies (involving counterfeit drugs suspected of being counterfeit, contraband, or suspect of being contraband) and reporting of such discrepancies within three (3) business days to the Division and/or appropriate federal or state agency upon discovery of such discrepancies.

☐ a procedure for reporting criminal or suspected criminal activities involving the inventory of drugs and devices to the Division, FDA and if applicable, Drug Enforcement Administration (DEA), within three (3) business days.

27 ☐ ☐ Each facility shall establish, maintain and make available for inspection by authorized federal, state and local law enforcement authorities, lists of all officers, directors, managers and other persons in charge which lists shall include a description of their duties and a summary of their background and qualifications. [UAC R156-17b-615 (16)]

28 ☐ ☐ Each facility shall comply with laws including: [UAC R156-17b-615 (17) (a-c)]

☐ operating within applicable federal, state and local laws and regulations.

☐ permitting the state licensing authority and authorized federal, state and local law enforcement officials, upon presentation of proper credentials, to enter and inspect their premises and delivery vehicles and to audit their records and written operating policies and procedures, at reasonable times and in a reasonable manner, to the extent authorized by law.

☐ obtaining a controlled substance license from the Division and registering with the Drug Enforcement Administration (DEA) if they engage in distribution or manufacturing of controlled substances and shall comply with all federal, state and local regulations applicable to the distribution or manufacturing of controlled substances.

29 ☐ ☐ Each facility shall be subject to and shall abide by applicable federal, state and local laws that relate to the salvaging or reprocessing of prescription drug products. [UAC R156-17b-615 (18)]

30 ☐ ☐ A Class C pharmacy may not be located in the same building as a separately licensed Class A, B, D, or E pharmacy unless the separately licensed pharmacy is a third-party logistics provider; or the two pharmacies are located in different suites as recognized by the United States Postal Service. [UAC R156-17b-615 (19) (a) (i,ii)]

31 ☐ ☐ Two Class C pharmacies may be located at the same address in the same suite if the pharmacies are under the same ownership; have processes and systems for separating all aspects of the operation; and have traceability with a clear audit trail that distinguishes a pharmacy's purchases and distributions. [UAC R156-17b-615 (19) (b) (i-iii)]

32 ☐ ☐ All records relating to Schedule II controlled substances received, purchased, administered or dispensed by the practitioner shall be maintained separately from all other records of the pharmacy or practice. Records shall be maintained by the licensee for a period of five years. [UAC R156-37-602(3, 5)]

33 ☐ ☐ All records relating to Schedule III, IV, V controlled substances received, purchased, administered or dispensed by the practitioner shall be maintained separately from all other records of the pharmacy or practice. Records shall be maintained by the licensee for a period of five years. [UAC R156-37-602(3, 6)]

34 ☐ ☐ Requirement for annual controlled substances inventory shall be within 12 months following the inventory date of each year and may be taken within four days of the specified inventory date and shall include all stocks including out-of-date drugs and drugs in automated pharmacy systems. [UAC R156-17b-605 (4)]

35 ☐ ☐ Requirements for taking the initial controlled substances inventory shall include the following: pharmacies having stock of controlled substances shall take an inventory, including out-of-date drugs and drugs in automated pharmacy systems, on the opening day of business. if a pharmacy commences business with no Schedule I or II controlled substances, the pharmacy shall record this fact as the initial inventory and shall document Schedule I and II controlled substance inventory separately from an inventory reporting no Schedule III, IV, and V controlled substances. The initial inventory shall serve as the pharmacy's inventory until the next completed inventory as specified in Subsection (4) of this section. [UAC R156-17b-605 (3) (a-c)] ☐ **N/A**

36 ☐ ☐ General Requirements for inventory of a pharmacy shall include: [UAC R156-17b-605 (2)(a)(b)(c)(e)(f)(i)(j)]

☐ the PIC shall be responsible for taking all required inventories, but may delegate the performance of the inventory to another person or persons;

☐ the inventory records shall be maintained for a period of five years and be readily available for inspection

☐ the inventory records shall be filed separately from all other records

☐ the inventory may be taken either as the opening of the business or the close of business on the inventory date;

☐ the person taking the inventory and the PIC shall indicate the time the inventory was taken and shall sign and date the inventory with the date the inventory was taken. The signature of the PIC and the date of the inventory shall be documented within 72 hours or three working days of the completed initial, annual, change of ownership and closing inventory.

☐ the inventory of Schedule I and II controlled substances shall be listed separately from the inventory of Schedule III, IV and V controlled substances;

☐ if the pharmacy maintains a perpetual inventory of any of the drugs required to be inventories, the perpetual inventory shall be reconciled on the date of the inventory.

37 ☐ ☐ All pharmacies shall maintain a perpetual inventory of all Schedule II controlled substances that shall be reconciled according to facility policy. [UAC R156-17b-605(6)]

38 ☐ ☐ The pharmacy does reconcile its controlled substance inventory to account for shortages of controlled substances. [UAC R156-17b-603 (3) (k) & R156-37-502(4)]

39 ☐ ☐ Any facility who experiences any theft, including diversion, or significant loss of controlled substances shall immediately file the appropriate forms with the Drug Enforcement Administration, with a copy to the Division directed to the attention of the Investigation Bureau Division; and report the incident to the local law enforcement agency. [UAC R156-37-602 (2)]

COMMENTS

☐ By checking this box it is indicated that the undersigned Division Investigator has reviewed the above inspection report and comments made with the undersigned "Responsible Party."

Signature of Responsible Party: _____ Date: _____

Name of Responsible Party (Print): _____

Signature of Division Investigator: _____ Date: _____

Name of Division Investigator (Print): _____

Revised 3/2025