MARYLAND
Department of Health
Wes Moore, Governor ● Aruna Miller, Lt. Governor ● Laura Herrera Scott, M.D., M.P.H., Secretary

MARYLAND BOARD OF PHARMACY
4201 Patterson Avenue, Baltimore, Maryland 21215-2299
Neil Leikach, Board President ● Deena Speights-Napata, Executive Director

WHOLESALE DISTRIBUTORS OF PRESCRIPTION DRUGS AND DEVICES INSPECTION FORM

1. PERMITS AND LICENSES

Corporate Wholesale Distributor Name_____
Wholesale Distributor Name-Doing Business As (d/b/a) or Trade Name _____
_____
Street Address_____
Business Telephone Number _____**Business Fax Number** _____
Maryland Permit Number _____ **Expiration** _____
License, Registration or Permit numbers issued by another state or federal authority
_____
_____
CDS Registration Number _____ **Expiration** _____
DEA Registration Number _____ **Expiration** _____
States of Licensure_____
Hours of Operation: _____
Inspection Date: _____ **Arrival Time:** _____ **Departure Time:** _____
Type of Inspection: Annual Follow-up Previous Date: _____
Name of Inspector: _____

2. PERSONNEL (COMAR 10.34.22.02)

Name of Designated Representative who is the primary contact of the wholesale distributor with the Board and is actively involved in, and aware of, the daily operation of the wholesale distributor. COMAR 10.34.22.02(8)

_____

Yes No

☐☐ The Designated Representative is physically present, except for an authorized absence, at the facility of the wholesale distributor during regular business hours. COMAR 10.34.22.03D (3)

☐☐ The Designated Representative is a full time management level employee of the wholesale distributor. COMAR 10.34.22.03D (3)

Name of Immediate Supervisor of the Designated Representative_____
_____

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Yes No

☐☐ The Immediate Supervisor is actively involved in, and aware of, the daily operations of the wholesale distributor. COMAR 10.34.22.03D (4)

☐☐ The Immediate Supervisor is a full time management level employee of the wholesale distributor. COMAR 10.34.22.03D(4)

☐☐ The wholesale distributor maintains a list of responsible individuals (officers, directors, managers, the designated representative, and others in charge if wholesale distribution, storage, and handling). The list includes: (attach list) COMAR 10.34.22.07C

Yes No

☐☐ The description of the duties of the responsible parties

☐☐ A summary of the qualifications of the responsible parties

3. PERSONNEL TRAINING

Yes No

☐☐ All personnel employed in wholesale distribution have documented education and experience to assume the corresponding responsibilities. COMAR 10.34.22.04A

The Designated Representative:

Yes No

☐☐ Is aware of, and knowledgeable about, all policies and procedures pertaining to the operations of the wholesale distributor, including applicable State and federal laws. COMAR 10.34.22.04C(1)

☐☐ Has had documented education sufficient to ensure that operations of the wholesale distributor are in compliance with applicable State and federal laws COMAR 10.34.22.04C(2); and

☐☐ Has received this education provided by qualified in-house specialists, outside counsel, or consulting specialists with capabilities to help ensure compliance with all applicable State and federal laws and regulations. COMAR 10.34.22.04C(2).

☐☐ Maintains current working knowledge of the requirements for wholesale distributors. COMAR 10.34.22.04C(3)

☐☐ Assures an ongoing training program for personnel to ensure compliance with applicable State and federal laws. COMAR 10.34.22.04C(3)

☐☐ Maintains all personnel training records and makes all records available for inspection. COMAR 10.34.22.04C(4)

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4. STORAGE AND HANDLING OF PRESCRIPTION DRUG AND DEVICES

The facilities at which the prescription drugs or devices are stored, warehoused, handled, held, offered, marketed, or displayed COMAR 10.34.22.06A:

Yes No

☐☐ Is of suitable size and construction to facilitate appropriate cleaning, maintenance and proper operation.

☐☐ Is maintained in a clean and orderly manner

☐☐ Is free from infestation by insects, rodents, birds, or vermin.

☐☐ The prescription drugs or devices storage area is equipped with:

Yes No

- ☐☐ Proper Equipment
- ☐☐ Humidity Control
- ☐☐ Adequate Lighting
- ☐☐ Appropriate Sanitation
- ☐☐ Sufficient Space
- ☐☐ Appropriate Temperature
- ☐☐ Appropriate Ventilation

Yes No

☐☐ The prescription drug or devices storage area is maintained at the appropriate temperature as established by labeling of the drug or device; or set forth in an official compendium; or at a controlled temperature that ensures identity, strength, quality and purity of the drug or devices are maintained. COMAR 10.34.22.06C

☐☐ The facility uses appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and logs to document proper storage of prescription drugs or devices. COMAR 10.34.22.06C(3)

The wholesale distributor, upon receipt of a prescription drug or device, visually examines each outside shipping container to: COMAR 10.34.22.06D(1)

Yes No

- ☐☐ Assure identity
- ☐☐ To prevent the acceptance of prescription drugs or devices that are contaminated or therwise unfit for distribution

☐☐ The visual examination performed upon receipt of a prescription drug or device is adequate to reveal container damage that would suggest possible contamination or other damage to the contents. COMAR 10.34.22.06D(2)

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The wholesale distributor carefully inspects each outgoing shipment to: COMAR 10.34.22.06D(2)

Yes No

☐☐ Assure the identity of the prescription drug or device product

☐☐ To ensure there is no delivery of a prescription drug or device that has been damaged in storage or held under improper conditions

Yes No

☐☐ The wholesaler distributor maintains records of the examination of incoming and outgoing prescription drug and device products. COMAR 10.34.22.06D(4)

☐☐ The wholesale distributor identifies, marks or has a quarantine area that physically separates prescription drugs and devices that are adulterated, damaged deteriorated, misbranded, outdated or in immediate or sealed secondary containers that have been opened from other prescription drugs and devices. COMAR 10.34.22.06E

5. SECURITY COMAR 10.34.22.06B

The facility is designed to prevent unauthorized entry through:

Yes No

☐☐ Controlled access from outside the premises

☐☐ The outside perimeter of the premises is well lit.

☐☐ The entry into areas where prescription drugs and devices are held are limited to authorized personnel

The facility is equipped with:

Yes No

☐☐ An alarm system to detect entry after hours.

☐☐ A security system that provides protection against theft and diversion.

☐☐ A security system to protect the integrity and confidentiality of data and documents.

☐☐ A video monitoring system for all entrances and exits, or alternate acceptable security.

☐☐ Appropriate software to facilitate the identification of evidence of tampering with computers or electronic records.

☐☐ An inventory management and control system that protects against, detects, and documents any instances of theft, diversion, or counterfeiting.

☐☐ An ongoing security data and documentation retention program which is readily available to the Board, an agent of the Board, or federal and other State law enforcement officials.

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6. PRESCRIPTION DRUG OR DEVICE DISTRIBUTION RECORDS COMAR 10.34.22.07

Yes No

☐☐ The wholesale distributor maintains, for up to 3 years from the date of their creation, inventories and records of transactions regarding the receipt and distribution or disposition of prescription drugs and devices

The documentation of inventory and records of transactions include:
Yes No

☐☐ The source of the prescription drugs and devices

☐☐ The name and principal address of the seller or transferor

☐☐ The address of the location from which the prescription drugs or devices were shipped

☐☐ The identity and quantity of the prescription drugs and devices received and distributed or disposed of

☐☐ The dates of receipt and distribution or other disposition of the prescription drugs or devices

☐☐ The pedigrees, if required by Health Occupations Article §12-6C-10, Annotated Code of Maryland, for prescription drugs that are wholesale distributed outside the normal distribution channel.

☐☐ The wholesale distributor makes records readily available for review at the inspection site, by computer or other means. If no:
Yes No

☐☐ The wholesale distributor makes available within 5 business days of the request, records kept at a central location apart from the inspection site and not electronically retrievable

☐☐ The wholesale distributor has established and maintains procedures for reporting counterfeit and contraband or suspected counterfeit and contraband drugs or devices or counterfeiting to the Board and the FDA.

☐☐ The wholesale distributor maintains a system and records for the mandatory reporting to the Board, the FDA and where applicable the DEA, significant inventory losses of prescription drugs and devices where it is known or suspected that diversion is occurring or has occurred.

The wholesale distributor has established, maintained, and adheres to written policies and procedures for:
Yes No

☐☐ the receipt, security, storage, inventory and distribution of prescription drugs or devices

☐☐ identifying, recording and reporting losses or thefts

☐☐ correcting errors and inaccuracies in inventories

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The wholesale distributor has included in the written policy and procedure:

Yes No

☐☐ A procedure by which the oldest approved and unexpired stock of a prescription drug and device is distributed first

☐☐ Procedures to be followed for adequate handling of a recall and withdrawal of a prescription drug or device

Yes No

☐☐ A procedure to ensure that the wholesale distributor is prepared for, protected against, and is able to handle a crisis that affects security or operation of a facility in the event of a strike, fire, flood, catastrophic health emergency, terrorist activities, other natural disaster or other situations of local, State or national emergency

☐☐ A procedure to ensure that an outdated prescription drug and device is segregated from other drugs or devices and either returned to the manufacturer or destroyed.

☐☐ The wholesale distributor maintains documentation of the disposition of outdated prescription drugs or devices for up to 2 years after the disposition of the outdated prescription drugs and devices.

☐☐ 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, which includes:

Yes No

☐☐ all necessary documentation, maintained for a minimum of 3 years

☐☐ the appropriate witnessing of the destruction of any labels, packaging, immediate containers in accordance with applicable State and federal laws

Yes No

☐☐ A procedure for identifying, segregating, investigating, and reporting prescription drug inventory discrepancies involving counterfeit, suspect of being counterfeit, contraband, and suspect of being contraband, in the inventory and reporting of such discrepancies within 5 business days to the Board and appropriate federal or State agency upon discovery of such discrepancies.

Yes No N/A

☐ ☐ ☐ If the wholesale distributor performs prescription drug product salvaging and reprocessing, policies and procedures are in place to perform due diligence on transactions.

☐ ☐ ☐ If the wholesale distributor performs prescription device product salvaging or reprocessing, policies and procedures are in place to perform due diligence on transactions.

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7. DUE DILIGENCE COMAR 10.34.22.07

Yes No

☐☐ The wholesale distributor has had transactions with persons not licensed by the Board or not certified by a third party recognized by the Board. If yes, the wholesale distributor has policies and procedures to ensure:

Yes No

☐☐ Verification of alternate licensure

☐☐ Verification of identity

☐☐ Verification of recent inspections by a state or third party entity recognized by the Board

INSPECTOR'S COMMENTS:

Inspector Signature_____

Designated Representative Name: (Print)_____
Date: _____

Designated Representative Signature:_____

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