**Section 1510.120 Minimum Requirements for the Storage and Handling of Prescription Drugs and for the Establishment and Maintenance of Prescription Drug Distribution Records**

The following are minimum requirements for the storage and handling of prescription drugs, and for the establishment and maintenance of prescription drug distribution records by wholesale drug distributors and third-party logistics providers, and their officers, agents, representatives and employees:

a) Facilities. All facilities at which prescription drugs are stored, warehoused, handled, held, offered, marketed or displayed shall:

1) Be of suitable size and construction to facilitate cleaning, maintenance and proper operations;

2) Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment and security conditions;

3) Have a quarantine area for storage of prescription drugs that are outdated, damaged, deteriorated, misbranded or adulterated, or that are in immediate or sealed secondary containers that have been opened;

4) Be maintained in a clean and orderly condition; and

5) Be free from infestation by insects, rodents, birds or vermin of any kind.

b) Security. All facilities used for wholesale drug distribution shall:

1) Be secure from unauthorized entry.

A) Access from outside the premises shall be kept to a minimum and be well controlled.

B) The outside perimeter of the premises shall be well-lighted.

C) Entry into areas where prescription drugs are held shall be limited to authorized personnel;

2) Be equipped with an alarm system to detect entry after hours; and

3) Be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

c) Storage. All prescription drugs shall be stored at appropriate temperatures and under appropriate conditions, in accordance with requirements, if any, in the labeling of those drugs, or with requirements in the current edition of an official compendium such as the United States Pharmacopoeia and National Formulary.

1) If no storage requirements are established for a prescription 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.

2) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices and/or logs shall be utilized to document proper storage of prescription drugs.

3) The recordkeeping requirements in subsection (f) shall be followed for all stored drugs.

d) Examination of Materials

1) Upon receipt, each outside shipping container shall be visually examined to identify the product and to prevent the acceptance of contaminated prescription drugs or prescription drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

2) Each outgoing shipment shall be carefully inspected to identify the prescription drug products and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions.

3) The recordkeeping requirements in subsection (f) shall be followed for all incoming and outgoing prescription drugs.

e) Returned, Damaged and Outdated Prescription Drugs

1) Prescription drugs that are outdated, damaged, deteriorated, misbranded or adulterated shall be quarantined and physically separated from other prescription drugs until they are destroyed or returned to their supplier.

2) Any prescription drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified accordingly and shall be quarantined and separated from other prescription drugs until they are either destroyed or returned to the supplier.

3) If the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality or purity, the drug shall be destroyed or returned to the supplier unless examination, testing or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety or, identity, strength, quality or purity, the wholesale drug distributor and/or third-party logistics provider shall consider, among other things:

A) the conditions under which the drug has been held, stored or shipped before or during its return; and

B) the condition of the drug and its container, carton or labeling because of the storage or shipping.

4) The recordkeeping requirements in subsection (f) shall be followed for all outdated, damaged, deteriorated, misbranded or adulterated prescription drugs.

f) Recordkeeping

1) Wholesale drug distributors and third-party logistics providers shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs. These records shall include the following information:

A) The source of the drugs, including the name and principal address of the seller or transferor and the address of the location from which the drugs were shipped;

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.

2) Inventories and records shall be made available, for a period of 2 years following disposition of the drugs, for inspection and photocopying by drug compliance investigators or any authorized official of any drug enforcement governmental agency charged with enforcement of this Part.

3) Records described in this Section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within 2 working days after a request by an authorized official of any federal, state and local agencies charged with enforcement of this Part.

g) Written Policies and Procedures. Wholesale drug distributors and third-party logistics providers shall establish, maintain and adhere to written policies and procedures that shall be followed for the receipt, security, storage, inventory and distribution of prescription drugs, including policies and procedures for identifying, recording and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. Wholesale drug distributors shall include in their written policies and procedures the following:

1) A procedure in which the oldest approved stock of a prescription drug product is distributed first. The procedure may permit deviation from this requirement if the deviation is temporary and appropriate.

2) A procedure to be followed for handling recalls and withdrawals of prescription drugs. This procedure shall be adequate to deal with recalls and withdrawals due to:

A) Any action initiated at the request of the Food and Drug Administration or other federal, state or local law enforcement or other government agency;

B) Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or

C) Any action undertaken to promote public health and safety by replacing existing merchandise with an improved product or new package design.

3) A procedure to ensure that wholesale drug distributors prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of strike or fire, flood or other natural disaster, or other situations of local, state or national emergency.

4) A procedure to ensure that any outdated prescription drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of outdated prescription drugs. This documentation shall be maintained for 2 years after disposition of the outdated drugs.

h) Responsible Persons. Wholesale drug distributors and third-party logistics providers shall establish and maintain lists of officers, directors, managers and other persons in charge of wholesale drug distribution, storage and handling, including a description of their duties and a summary of their qualifications.

i) Compliance with Federal, State and Local Laws. Wholesale drug distributors and third-party logistics providers shall operate in compliance with applicable federal, state and local laws and regulations.

1) Wholesale drug distributors and third-party logistics providers shall permit drug compliance investigators of the Department and authorized federal, state and local law enforcement officials, at reasonable times, in a reasonable manner, and upon presentation of appropriate identification, to the extent authorized by law, to:

A) enter and inspect their premises and delivery vehicles; and

B) audit their records and written operating procedures.

2) Wholesale drug distributors and third-party logistics providers who deal in controlled substances shall register with the appropriate state-controlled substance authority and with the Drug Enforcement Administration (DEA), and shall comply with all applicable state, local and DEA regulations.

j) Salvaging and Reprocessing. Wholesale drug distributors and third-party logistics providers shall be subject to the provisions of any applicable federal, state or local laws or regulations that relate to prescription drug product salvaging or reprocessing.

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