NOTICE OF PROPOSED AMENDMENTS

The Department of Financial and Professional Regulation is posting these proposed amendments in an effort to make the public aware of possible changes that may have an impact on the industry/profession.

The general public may submit written comments to the Department during the first 45-day public comment period. Any suggested changes will be considered by the Department and (if applicable) the appropriate Board.

These proposed amendments were published in the November 15, 2019 Illinois Register. The 45-day comment period will end December 30, 2019.

Please submit written comments to Craig Cellini as stated in the attached notice.

THESE PROPOSED CHANGES ARE NOT IN EFFECT AT THIS TIME AND THE ADOPTED RULES MAY DIFFER FROM THOSE ORIGINALLY PUBLISHED.

1) Heading of the Part: Wholesale Drug Distribution Licensing Act

2) Code Citation: 68 Ill. Adm. Code 1510

3) Section Numbers: Proposed Actions:
   1510.10 Amendment
   1510.15 New Section
   1510.20 Repealed
   1510.30 Repealed
   1510.50 Repealed
   1510.60 Amendment
   1510.65 Amendment
   1510.70 Amendment
   1510.80 New Section
   1510.85 New Section
   1510.90 New Section
   1510.100 New Section
   1510.110 New Section
   1510.120 New Section

4) Statutory Authority: Implementing and authorized by the Wholesale Drug Distribution Licensing Act [225 ILCS 120]
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5) **A Complete Description of the Subjects and Issues Involved:** This proposed rulemaking implements the statutory change made to Wholesale Drug Distribution Licensing Act in Public Act 101-0420, which creates a license for third-party logistics providers. The changes include the setting forth of licensure requirements for third-party logistics providers, fingerprints and liability insurance requirements, storage and record keeping requirements, and defining change of ownership. This rulemaking also includes technical changes to maintain consistency with Department Acts.

6) **Any published studies or reports, along with the sources of underlying data, that were used when comprising this rulemaking, in accordance with 1 Ill. Adm. Code 100.355:** None

7) **Will this rulemaking replace any emergency rule currently in effect?** No

8) **Does this rulemaking contain an automatic repeal date?** No

9) **Does this rulemaking contain incorporations by reference?** No

10) **Are there any other proposed rulemakings pending on this Part?** No

11) **Statement of Statewide Policy Objectives:** This rulemaking will not require a local government to establish, expand or modify its activities in such a way as to necessitate additional expenditures from local revenues.

12) **Time, Place, and Manner in which interested persons may comment on this proposed rulemaking:** Persons who wish to comment on this proposed rulemaking may submit written comments no later than 45 days after the publication of this Notice to:

    Department of Financial and Professional Regulation  
    Attention: Craig Cellini  
    320 West Washington, 2nd Floor  
    Springfield, IL 62786

    Phone: 217/785-0813  
    Fax: 217/557-4451

    All written comments received within 45 days after this issue of the Illinois Register will be considered.

13) **Initial Regulatory Flexibility Analysis:**
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A) **Types of small businesses, small municipalities and not for profit corporations affected:** Licensed wholesale drug distributors and applicants, as well as newly-eligible third-party logistics providers regulated under the Act may be affected.

B) **Reporting, bookkeeping or other procedures required for compliance:** Each applicant for license as a wholesale drug distributor or a third-party logistics provider shall maintain minimum liability insurance for the duration of the license. Additionally, each wholesale drug distributor and third-party logistics provider shall submit a bond or other equivalent means of security in the amount of one hundred thousand dollars ($100,000.00).

C) **Types of professional skills necessary for compliance:** The education, training and experience necessary to safely and lawfully engage in the wholesale distribution of drugs is necessary for all persons employed by a licensed wholesale distributor.

14) **Small Business Impact Analysis:**

A) **Types of businesses subject to the proposed rule:**
54 – professional, scientific and technical services

B) **Categories that the agency reasonably believes the rulemaking will impact, including:**
ii – regulatory requirements

15) **Regulatory Agenda on which this rulemaking was summarized:** July 2019

The full text of the Proposed Amendments begins on the next page:
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TITLE 68: PROFESSIONS AND OCCUPATIONS
CHAPTER VII: DEPARTMENT OF PROFESSIONAL REGULATION
SUBCHAPTER b: PROFESSIONS AND OCCUPATIONS

PART 1510
WHOLESALE DRUG DISTRIBUTION LICENSING ACT

SUBPART A: GENERAL PROVISIONS

Section 1510.10 Definitions
1510.15 Liability Insurance Requirements
1510.20 Application for Licensure (Repealed)
1510.30 Personnel (Repealed)
1510.40 Violations and Penalties
1510.50 Minimum Requirements for the Storage and Handling of Prescription Drugs and for the Establishment and Maintenance of Prescription Drug Distribution Records (Repealed)
1510.60 Renewals
1510.65 Fees
1510.70 Granting Variances

SUBPART B: WHOLESALE DISTRIBUTOR

Section 1510.80 Application for Licensure
1510.85 Personnel
1510.90 Change of Ownership for a Wholesale Drug Distributor

SUBPART C: THIRD-PARTY LOGISTICS PROVIDER

Section 1510.100 Application for Licensure
1510.110 Change of Ownership of a Third-party Logistics Provider

SUBPART D: STORAGE AND RECORDKEEPING REQUIREMENTS

Section 1510.120 Minimum Requirements for the Storage and Handling of Prescription Drugs and for the Establishment and Maintenance of Prescription Drug Distribution Records
AUTHORITY: Implementing the Wholesale Drug Distribution Licensing Act [225 ILCS 120] and authorized by Section 2105-15(7) of the Civil Administrative Code of Illinois [20 ILCS 2105].


SUBPART A: GENERAL PROVISIONS

Section 1510.10 Definitions

"Act" means the Wholesale Drug Distribution Licensing Act [225 ILCS 120].

"Blood" means whole blood collected from a single donor and processed either for transfusion or further manufacturing.

"Blood component" means that part of blood separated by physical or mechanical means.

"Board" means the State Board of Pharmacy.

"Department" means the Illinois Department of Financial and Professional Regulation.

"Director" means the Director of the Division of Professional Regulation.

"Drug sample" means a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug.

"Manufacturer" means anyone who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging or labeling a prescription drug.

"Prescription drug" means any human drug required by federal law or...
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regulation to be dispensed only by a prescription, including finished dosage forms and active ingredients subject to section 503(b) of the Federal Food, Drug and Cosmetic Act, (21 U.S.C. 301 et seq. (1976)).

"Third-party logistics provider" means anyone who contracts with a prescription drug manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of a manufacturer, but does not take title to the prescription drug or have general responsibility to direct the prescription drug's sale or disposition.

"Wholesale distribution" or "wholesale distributions" means distribution of prescription drugs to a person other than a consumer or patient, but does not include:

Intracompany sales, defined as any transaction or transfer between any division, subsidiary, parent and/or affiliated or related company under the common ownership and control of a corporate entity;

The purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a drug for its own use from the group purchasing organization or from other hospitals or health care entities that are members of those organizations;

The sale, purchase or trade of a drug or an offer to sell, purchase or trade a drug by a charitable organization described in section 501(c)(3) of the Internal Revenue Code of 1954 (26 USC 501(c)(3)) to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

The sale, purchase or trade of a drug or an offer to sell, purchase or trade a drug among hospitals or other health care entities that are under common control (for purposes of this Section, "common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, by voting rights, or by contract, or otherwise);

The sale, purchase or trade of a drug or an offer to sell, purchase or trade a drug for emergency medical reasons (for purposes of this Section "emergency medical reasons" includes transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage);
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The sale, purchase or trade of a drug; an offer to sell, purchase or trade a drug; or the dispensing of a drug pursuant to a prescription;

The lawful distribution of drug samples by manufacturers' representatives or distributors' representatives;

The sale, purchase or trade of blood and blood components intended for transfusion; or

The sale of prescription drugs by a pharmacy to practitioners (i.e., licensed physicians, dentists, veterinarians or podiatrists), providing the sales do not exceed 5% of the annual dollar purchases of prescription drugs by the pharmacy and providing the pharmacy maintains a log of sales to practitioners that includes date of sale; practitioner's name and address; drug and strength; size of package; and quantity sold.

"Wholesale distributor" means anyone engaged in wholesale distribution of prescription drugs, including, but not limited to, manufacturers; repackers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies that conduct wholesale distributions.

(Source: Amended at 44 Ill. Reg. ______, effective ____________)

Section 1510.15 Liability Insurance Requirements

a) Each applicant for license as a wholesale drug distributor or a third-party logistics provider shall maintain, for the duration of that license, minimum liability insurance.

b) Each wholesale drug distributor shall submit a bond or other equivalent means of security, as approved by the Department, in the amount of $100,000.

c) Each third-party logistics provider shall submit a bond or other equivalent means of security, as approved by the Department, in the amount of $100,000.

(Source: Added at 44 Ill. Reg. ______, effective ____________)
Section 1510.20 Application for Licensure (Repealed)

Every wholesale distributor, wherever located, who engages in wholesale distribution into, out of, or within Illinois shall be licensed by the Department in accordance with the Act and this Part before engaging in wholesale distribution of prescription drugs.

a) The applicant for a license as a wholesale drug distributor shall file with the Department an application which includes the following:

1) The name, full business address and telephone number of the applicant;

2) All trade or business names used by the applicant;

3) Addresses, telephone numbers and the names of contact persons at all facilities used by the applicant for the storage, handling and distribution of prescription drugs;

4) The type of ownership or operation (i.e., partnership, corporation or sole proprietorship). If a corporation, a copy of the Articles of Incorporation; and

5) The names of the owner and/or operator of the entity, including:

A) The name of the person, if a person;

B) The name of each partner and the name of the partnership, if a partnership;

C) The name and title of each corporate officer and director, the corporate names, the name of the state where incorporated and the name of the parent company, if any, if a corporation; or

D) The full name of the sole proprietor and the name of the business entity, if a sole proprietorship; and

6) The fee set forth in Section 1510.65.

b) The Department shall consider the following factors in determining eligibility for licensure of persons who engage in the wholesale distribution of prescription drugs.
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drugs:

1) Any conviction of the applicant under any federal, state or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances;

2) Any felony conviction of the applicant under federal, state or local laws;

3) The applicant’s past experience in the manufacture or distribution of prescription drugs, including controlled substances;

4) The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution;

5) Suspension or revocation by federal, state or local government of any license currently or previously held by the applicant for the manufacture or distribution of any drugs, including controlled substances;

6) Compliance with licensing requirements under previously granted licenses, if any;

7) Compliance with the requirements to maintain and/or make available to the state licensing authority or to federal, state or local law enforcement officials those records required to be maintained by wholesale drug distributors; and

8) Any other factors or qualifications the Department considers relevant to and consistent with public health and safety.

e) A separate license is required for each facility directly or indirectly owned or operated by the same business that distributes prescription drugs.

d) When the address or name of a facility is changed, the licensee shall be required to apply for a new license and pay a $100 fee. If the facility is relocated, the licensee shall also cause the facility to pass an inspection, meeting all requirements of the Act and this Section.

e) Changes in any information in this Section shall be submitted to the Department within 45 days after such change.
The Department reserves the right to deny a license to an applicant if it determines that the granting of such a license would not be in the public interest.

The applicant shall retain on premises a copy of the application and check to the Department to serve as a temporary license prior to the issuance of a certificate of registration as a Wholesale Drug Distributor. This is valid for 90 days.

(Source: Repealed at 44 Ill. Reg. ______, effective ____________)

Section 1510.30 Personnel (Repealed)

The licensed wholesale distributor shall employ personnel with the education, training and experience necessary to safely and lawfully engage in the wholesale distribution of drugs. As a condition for receiving and retaining a wholesale drug distributor license, the licensee shall require each person employed in any prescription drug wholesale distribution activity to have education, training and experience, or any combination thereof, sufficient for that person to perform the assigned functions in such a manner as to provide assurance that the drug product quality, safety and security will at all times be maintained as required by law.

(Source: Repealed at 44 Ill. Reg. ______, effective ____________)

Section 1510.50 Minimum Requirements for the Storage and Handling of Prescription Drugs and for the Establishment and Maintenance of Prescription Drug Distribution Records (Repealed)

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 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, 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 such drugs, or with requirements in the current edition of an official compendium.

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.
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3) The recordkeeping requirements in subsection (f) of this Section 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) of this Section 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 as such, 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, then 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, identity, strength, quality or purity, the wholesale drug distributor shall consider, among other things, the conditions under which the drug has been held, stored or shipped before or during its return and
the condition of the drug and its container, carton or labeling, as a result of
storage or shipping.

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

f) Recordkeeping:

1) Wholesale drug distributors 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 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 inspection and
photocopying by drug compliance investigators or any authorized official
of any governmental agency charged with enforcement of this Part for a
period of 2 years following disposition of the drugs.

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 of 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 shall establish,
maintain and adhere to written policies and procedures, which 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 whereby the oldest approved stock of a prescription drug product is distributed first. The procedure may permit deviation from this requirement if such deviation is temporary and appropriate.

2) A procedure to be followed for handling recalls and withdrawals of prescription drugs. Such 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, including the Department;

   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 of 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, 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 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.
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i) Compliance with federal, state, and local laws. Wholesale drug distributors shall operate in compliance with applicable federal, state and local laws and regulations.

1) Wholesale drug distributors shall permit drug compliance investigators of the Department and authorized federal, state and local law enforcement officials to enter and inspect upon presentation of appropriate identification, their premises and delivery vehicles, and to audit their records and written operating procedures, at reasonable times and in a reasonable manner, to the extent authorized by law.

2) Wholesale drug distributors 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 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.

(Source: Repealed at 44 Ill. Reg. _______, effective ____________)

Section 1510.60 Renewals

a) The first renewal period for registration issued under the Act shall be December 31 of even-numbered years. The holder of a certificate of registration may renew that registration 60 days prior to the expiration date by filing an application with the Department and paying the required fee set forth in Section 1510.65.

b) It is the responsibility of each registrant to notify the Department of any change of mailing address. Failure to receive a renewal notice from the Department shall not constitute an excuse for failure to pay the renewal fee or to renew a certificate of one's registration.

(Source: Amended at 44 Ill. Reg. _______, effective ____________)

Section 1510.65 Fees

The following fees shall be paid to the Department for the administration of the Act and are not refundable:
a) Application Fees

1) The fee for application for a certificate of registration as a wholesale drug distributor is $200.

2) The fee for application for a certificate of registration as a third-party logistics provider is $200.

b) Renewal Fees

1) The fee for the renewal of a certificate of registration shall be $200 per year.

2) The fee for renewal for a certificate of registration as a third-party logistics provider is $200.

c) General Fees

1) The fee for change of ownership of a wholesale drug distributor certificate of registration is $200, the issuance of a duplicate license, for the issuance of a replacement license for a license that has been lost or destroyed or for the issuance of a license with a change of name or address, other than during the renewal period, is $20. No fee is required for name and address changes on Department records when no duplicate license is issued.

2) The fee for change of ownership of a third-party logistics provider certificate of registration is $200, a certification of a licensee’s record for any purpose is $20.

3) The fee for the change of designated representative/person responsible for drugs is $50.

4) The fee for change of location is $100, a wall certificate showing licensure shall be the actual cost of producing the certificate.

5) The fee for a facility or business name change is $100, roster of persons licensed as a wholesale drug distributor in this State shall be the actual cost of producing the roster.
Section 1510.70 Granting Variances

a) The Director of the Department may grant variances from these rules in individual cases when he/she finds that:

a1) The provision from which the variance is granted is not statutorily mandated;

b2) No party will be injured by the granting of the variance; and

c3) The rule from which the variance is granted would, in the particular case, be unreasonable or unnecessarily burdensome.

b) The Director shall notify the Board of the granting of such variance, and the reasons therefor, at the next meeting of the Board.

Section 1510.80 Application for Licensure

Each wholesale distributor, wherever located, who engages in wholesale distribution into, out of, or within Illinois shall be licensed by the Department in accordance with the Act and this Part before engaging in wholesale distribution of prescription drugs.

a) The applicant shall file with the Department an application that includes the following:

1) The name, full business address, and telephone number of the applicant;

2) All trade or business names used by the applicant;

3) Addresses, telephone numbers and names of contact persons at all facilities used by the applicant for the storage, handling and distribution of prescription drugs;

4) The type of ownership or operation (i.e., partnership, corporation or sole proprietorship). If a corporation, a copy of the Articles of Incorporation;
5) The names of the owner and/or operator of the entity, including:
   A) The name of the person, if a person;
   B) The name of each partner and the name of the partnership, if a partnership;
   C) The name and title of each corporate officer and director, the corporate names, the name of the state where incorporated, and the name of the parent company, if any, if a corporation; or
   D) The full name of the sole proprietor and the name of the business entity, if a sole proprietorship;

6) A list of all licenses and permits issued to the applicant by any other state that authorizes the applicant to purchase or possess prescription drugs;

7) The name of the designated representative for the wholesale drug distributor, together with the personal information statement and fingerprints required by Section 25(b)(7) of the Act;

8) Minimum liability insurance set forth in Section 1510.15;

9) Each wholesale drug distributor must designate an individual representative to serve as the contact person for the Department. This representative must provide the Department with all the information required under the Act;

10) The fee set forth in Section 1510.65; and

11) Any additional information required by the Department.

b) The Department will consider the following factors in determining eligibility for licensure of persons who engage in the wholesale distribution of prescription drugs:

1) Any conviction of the applicant under any federal, state or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances;
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2) Any felony conviction of the applicant under federal, state or local laws;

3) The applicant's past experience in the manufacture or distribution of prescription drugs, including controlled substances;

4) The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution;

5) Suspension or revocation by federal, state or local government of any license currently or previously held by the applicant for the manufacture or distribution of any drugs, including controlled substances;

6) Compliance with licensing requirements under previously granted licenses, if any;

7) Compliance with the requirements to maintain and/or make available to the state licensing authority or to federal, state or local law enforcement officials those records required to be maintained by wholesale drug distributors; and

8) Any other factors or qualifications the Department considers relevant to, and consistent with, public health and safety.

c) A separate license is required for each facility, directly or indirectly owned or operated by the same business, that distributes prescription drugs.

d) The Department reserves the right to deny a license to an applicant if it determines that the granting of that a license would not be in the public interest.

(Source: Added at 44 Ill. Reg. _____, effective ____________)

Section 1510.85 Personnel

The licensed wholesale distributor shall employ personnel with the education, training and experience necessary to safely and lawfully engage in the wholesale distribution of drugs. As a condition for receiving and retaining a wholesale drug distributor license, the licensee shall require each person employed in any prescription drug wholesale distribution activity to have education, training and experience, or any combination of these, sufficient for that person to perform the assigned functions in a manner that provides assurance that the drug product quality, safety and security will at all times be maintained as required by law.
Section 1510.90 Change of Ownership of a Wholesale Drug Distributor

a) When the address or name of a facility is changed, the licensee shall be required to apply for a new license and pay a $100 fee. If the facility is relocated, the facility shall pass an inspection, meeting all requirements of the Act and this Section.

b) A new wholesale drug distributor application must be filed whenever:

1) The address or name of a facility is changed;

2) 50% or more of the ownership of the business, other than a publicly traded business, to which the wholesale drug distributor license was issued is sold or otherwise transferred to a person or entity that does not hold any interest in the business issued the wholesale drug distributor license prior to the sale or transfer; or

3) A change occurs in more than half the board of directors or executive officers of a business issued a wholesale drug distributor license.

c) Any change of ownership or change in location requires an inspection.

d) Conversion of a business entity to a different type of business entity is considered a change of ownership.

e) Any change of ownership of a parent company that owns a wholesale drug distributor shall not be considered a change of ownership of the wholesale drug distributor.

f) Any change in information required by the Department shall be submitted to the Department 60 days prior to that change, except for changes in information of nonresident licensees. A nonresident licensee shall submit any change in information required by the Department within 30 days after a change of the resident state license.
Section 1510.100 Application for Licensure

Each resident and nonresident third-party logistics provider must be licensed by the Department, in accordance with the Act, prior to shipping a prescription drug into this State.

a) The applicant shall file with the Department an application that includes the following:

1) The name, full business address, and telephone number of the applicant;
2) All trade or business names used by the applicant;
3) Addresses, telephone numbers, and names of contact persons for all facilities used by the applicant for the storage, handling and distribution of prescription drugs;
4) The type of ownership or operation, such as a partnership, corporation or sole proprietorship;
5) The name of the owner or operator of the applicant, including:
   A) if a natural person, the name of the natural person;
   B) if a partnership, the name of each partner and the name of the partnership;
   C) if a corporation, the name and title of each corporate officer and director, the corporate names, and the name of the state of incorporation; and
   D) if a sole proprietorship, the full name of the sole proprietor and the name of the business entity;
6) A list of all licenses and permits issued to the applicant by any other state that authorizes the applicant to purchase or possess prescription drugs;
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7) The name of the designated representative for the applicant, together with the personal information statement and fingerprints required by Section 25(b)(7) of the Act;

8) Minimum liability insurance set forth in Section 1510.20;

9) Each applicant must designate an individual representative to serve as the contact person for the Department. This representative must provide the Department with all the information required under the Act;

10) The fee set forth in Section 1510.65; and

11) Any additional information required by the Department.

b) The Department will consider the following factors in determining eligibility for licensure as a third-party logistics provider:

1) Any conviction of the applicant under any federal, state or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances;

2) Any felony conviction of the applicant under federal, state or local laws;

3) The applicant's past experience in the manufacture or distribution of prescription drugs, including controlled substances;

4) The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution;

5) Suspension or revocation by federal, state or local government of any license currently or previously held by the applicant for the manufacture or distribution of any drugs, including controlled substances;

6) Compliance with licensing requirements under previously granted licenses, if any;

7) Compliance with the requirements to maintain and/or make available to the state licensing authority or to federal, state or local law enforcement officials those records required to be maintained by wholesale drug distributors; and
8) Any other factors or qualifications the Department considers relevant to, and consistent with, public health and safety.

c) A separate license is required for each facility, directly or indirectly owned or operated by the same business, that distributes prescription drugs.

d) The Department reserves the right to deny a license to an applicant if it determines that the granting of that license would not be in the public interest.

(Source: Added at 44 Ill. Reg. ______, effective ____________)

Section 1510.110 Change of Ownership of a Third-Party Logistics Provider

a) When the address or name of a facility is changed, the licensee shall be required to apply for a new license and pay a $100 fee. If the facility is relocated, the facility shall pass an inspection, meeting all requirements of the Act and this Part.

b) A new third-party logistics provider application must be filed whenever:

1) The address or name of a facility is changed;

2) 50% or more of the ownership of the business, other than a publicly traded business, to which the third-party logistics provider license was issued is sold or otherwise transferred to a person or entity that does not hold any interest in the business issued the wholesale drug distributor license prior to the sale or transfer; or

3) A change occurs in more than half the board of directors or executive officers of a business issued a third-party logistics provider license.

c) Any change of ownership or change in location requires an inspection.

d) Conversion of a business entity to a different type of business entity is considered a change of ownership.

e) Any change of ownership of a parent company that owns a third-party logistics provider shall not be considered a change of ownership of the third-party logistics provider.
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f) Any change in information required by the Department shall be submitted to the Department 60 days prior to that change, except for changes in information of nonresident licensees. A nonresident licensee shall submit any change in information required by the Department within 30 days after a change of the resident state license.

(Source: Added at 44 Ill. Reg. ______, effective ____________)

SUBPART D: STORAGE AND RECORDKEEPING REQUIREMENTS

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 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.

(Source: Added at 44 Ill. Reg. ______, effective ____________ )