Boards and Commissions

Board of Pharmacy

(Amendment)

201 KAR 2:105. Requirements for wholesalers, medical gas wholesalers, wholesale distributors, and virtual wholesale distributors.

RELATES TO: KRS 315.010, 315.121, 315.350, 315.400, 315.402, 315.404, 315.406, 315.408, 315.410, 315.412

STATUTORY AUTHORITY: KRS 315.010, 315.191(1)(a), 315.350, 315.402, 315.406

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1)(a) authorizes the board to promulgate administrative regulations to regulate and control all matters set forth in KRS Chapter 315. KRS 315.350, 315.402 and 315.406 require the board to promulgate administrative regulations to regulate wholesalers, medical gas wholesalers, wholesale distributors, and virtual wholesale distributors of prescription drugs and drug-related devices. This administrative regulation establishes the requirements for the regulation of wholesalers, medical gas wholesalers, wholesale distributors, and virtual wholesale distributors.

Section 1. Definitions.

(1) "Component" means any raw material, ingredient, or article intended for use in the manufacture of a drug and drug-related device.

(2) "Distribution" or "distribute" is defined by KRS 315.400(5).

(3) "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.

(4) "Illegitimate Product" is defined by KRS 315.400(11).

(5) "Medical gas wholesaler" is defined by KRS 315.400(13).

(6) "Product" means a prescription drug in a finished dosage form for administration to a patient without substantial further manufacturing, such as capsules, tablets, and lyophilized products before reconstitution.

(7) "Suspect product" means a component, prescription drug, or drug-related device for which there is reason to believe that such component, prescription drug, or drug-related device:

(a) Is potentially counterfeit, diverted, or stolen;

(b) Is potentially intentionally adulterated such that the component, prescription drug, or drug-related device would result in serious adverse health consequences or death to humans or animals;

(c) Is potentially the subject of a fraudulent transaction; or

(d) Appears otherwise unfit for distribution such that the component, prescription drug, or drug-related device would result in serious adverse health consequences or death to humans or animals.

(8) "Wholesale distribution" is defined by KRS 315.400(20).

(9) "Wholesale distributor" is defined by KRS 315.400(21).

(10) "Wholesaler" is defined by KRS 315.010(28), and includes medical gas wholesalers, wholesale distributors, and virtual wholesale distributors.

(11) "Virtual wholesale distributor" has the same meaning given in KRS 315.400(21).

Section 2. Requirements.

(1) A wholesaler engaged in wholesale distribution in the Commonwealth shall apply for a license from the Board of Pharmacy in accordance with KRS 315.350, 315.402, 315.406, and this administrative regulation.

(2) A surety bond is required of not less than $25,000, or other equivalent means of security acceptable to the Board of Pharmacy or a third party recognized by the Board of Pharmacy such as insurance, an irrevocable letter of credit, or funds deposited in a trust account or financial institution. This shall be used to secure payment of any administrative penalties imposed by the Board of Pharmacy and any fees or costs incurred by the Board of Pharmacy regarding that licensee if those penalties, fees, or costs are authorized under state law, and the licensee fails to pay thirty (30) days after the penalty, fee, or costs becomes final. A separate surety bond or other equivalent means of security is not required for each company's separate locations or for affiliated companies or groups if separate locations or affiliated companies orgroups are required to apply for or renew their wholesaler license with the Board of Pharmacy. The Board of Pharmacy may make a claim against the bond or other equivalent means of security until one (1) year after the wholesaler's license closes, lapses or expires, or until sixty (60) days after any administrative or legal proceeding before or on behalf of the Board of Pharmacy that involves the wholesaler is concluded, including any appeal, whichever occurs later. The Board of Pharmacy may waive the bond requirement, if the wholesaler:

(a) Has previously obtained a comparable surety bond or other equivalent means of security for the purpose of licensure in another state, where the wholesaler possesses a valid license in good standing;

(b) Is a publicly held company;

(c) Is a medical gas wholesaler; or

(d) Has a license for the sole purpose of distribution within a health care entity under common ownership.

(3) A separate license shall be required for each wholesaler's facility that engages in wholesale distribution within the Commonwealth regardless of whether joint ownership or control exists.

(4) An agent or employee of a licensee shall not be required to obtain a license under this section if the agent or employee is acting in the usual course of business or employment.

(5) A license shall not be issued or renewed unless the applicant demonstrates or continues to demonstrate acceptable operational procedures, including:

(a) Adequate operational, maintenance, and storage conditions to ensure proper lighting, ventilation, temperature and humidity control, sanitation, space, and security as per label requirements or official United States Pharmacopoeia (USP) compendium requirements, USP Chapter 659, Packaging and Storage Requirements. Appropriate manual, electromechanical or electronic temperature and humidity recording equipment, devices, or logs shall be utilized to document proper storage of prescription drugs and drug-related devices;

(b) Separation and quarantine of deteriorated, damaged, outdated, misbranded, adulterated or otherwise recalled prescription drugs and drug-related devices until they are destroyed or returned;

(c) Providing accurate and precise records of all prescription drugs and drug-related devices sold, purchased, traded, delivered, handled, stored, or received and any other information pertinent to the distribution or disposition; and

(d) Providing proof of registration with the U.S. Drug Enforcement Administration (DEA) and shall comply with all DEA regulations, if applicable.

(6) Wholesale distributors and virtual wholesale distributors shall comply with all requirements outlined in the Drug Supply Chain Security Act (DSCSA), 21 U.S.C. 360eee-360eee-4.

(7) Wholesalers shall establish a system to:

(a) Quarantine and investigate suspect product to determine if it is illegitimate; and

(b) Notify U.S. Food and Drug Administration (FDA), if applicable, the Board of Pharmacy and recipient(s) of illegitimate product, if illegitimate product is found.

(8) A virtual wholesale distributer shall be exempt from the following, subsection 2(5)(a) and (b) of this Section, and Section 5(1)(a) and (b), and (2)(a) and (b) of this administrative regulation.

Section 3. Qualifications for License.

(1) The Board of Pharmacy shall consider, at a minimum, the following factors in reviewing the qualifications of persons who engage in wholesale distribution of prescription drugs and drug-related devices within the Commonwealth:

(a) Any convictions of the applicant under any federal, state, or local laws relating to drugs, including drug samples and controlled substances;

(b) Any felony convictions of the applicant under federal, state, or local laws;

(c) The applicant's past experience in the distribution of prescription drugs and drug-related devices, including drug samples and controlled substances;

(d) The furnishing by the applicant of false or fraudulent material in any application made in connection with the distribution of prescription drugs and drug-related devices;

(e) Suspension or revocation by federal, state, or local government of any license or permit currently or previously held by the applicant for distribution of any prescription drugs and drug-related devices, including drug samples and controlled substances;

(f) Compliance with the requirements under any previously granted license or permit, if any; and

(g) Compliance with requirements to maintain or make available to the Board of Pharmacy or to federal, state, or local law enforcement officials those records required under this administrative regulation.

(2) The Board of Pharmacy shall have 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 based on health and safety considerations.

(3) A license shall not be issued pursuant to this administrative regulation unless the applicant has furnished proof satisfactory to the Board of Pharmacy:

(a) That the applicant is in compliance with all applicable federal, state, and local laws and regulations relating to drugs; and

(b) That the applicant is equipped as to land, buildings, and security to properly carry on the business described in the application.

(4) A license issued pursuant to this administrative regulation failing to comply with the provisions of KRS 315.350, 315.400, 315.402, 315.404, 315.406596, 315.408, 315.410, 315.412, or this administrative regulation may result in action under KRS 315.121.

Section 4. Application, Fees, Renewals.

(1) An application for a license shall be submitted to the Board of Pharmacy on the Application for a License to Operate as a Wholesaler.

(2) An application shall be accompanied by the annual fee set forth in 201 KAR 2:050.

(3) An application shall include:

(a) The name, full business address, and telephone number of the licensee;

(b) All trade or business names used by the licensee;

(c) Addresses, telephone numbers, and the names of contract persons for all facilities used by the licensee for the storage, handling, and distribution of prescription drugs and drug-related devices;

(d) The type of ownership or operation (i.e. partnership, corporation, or sole proprietorship);

(e) The name(s) of the owner and operator of the licensee, including;

1. If a person, the name and Social Security number of the person;

2. If a partnership, the name and Social Security number of each partner, and the name of the partnership;

3. If a corporation, the name, Social Security number and title of each corporate officer and director, the corporate names, and the name of the state of incorporation; and

4. If a sole proprietorship, the full name and Social Security number of the sole proprietor and the name of the business entity;

(f) 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 and drug-related devices; and

(g) Proof of surety bond or equivalent.

(4) All licenses shall:

(a) Expire on September 30 following date of issuance; and

(b) Be renewable annually thereafter upon submission of the Renewal Application to Operate as a Wholesaler accompanied by the renewal fee set forth in 201 KAR 2:050 and shall be nontransferable.

Section 5. Standards.

(1) Facilities.

(a) All facilities in which prescription drugs and drug-related devices are held for wholesale distribution, stored, sold, offered for sale, exposed for sale, or kept for sale shall be of suitable size, construction, and location to facilitate cleaning, maintenance, and proper operations.

(b) All facilities shall meet all applicable federal, state, and local standards. The facility shall quarantine prescription drugs and drug-related devices that are outdated, damaged, deteriorated, misbranded, recalled, or adulterated, or that are in immediate or sealed secondary containers that have been opened.

(c) A facility shall not be located in a residence.

(d) A facility shall be located apart and separate from a pharmacy permitted by the Board of Pharmacy, with the exception of a medical gas wholesaler.

(2) Security.

(a) A wholesaler shall be equipped with an alarm system to detect entry after hours.

(b) A wholesaler shall ensure that access from outside their premises is well controlled and reduced to a minimum. This includes the installation of adequate lighting at the outside perimeter of the premises.

(c) Internal security policies shall be developed to provide reasonable protection against theft and diversion by limiting access to areas where prescription drugs and drug-related devices are held to authorized personnel. These policies shall provide protection against tampering with computers or electronic records.

(d) A licensee shall employ adequate personnel with the education and experience necessary to safely and lawfully engage in the wholesale distribution of prescription drugs and drug-related devices.

(3) Recordkeeping requirements for companies handling prescription drugs and drug-related devices exempt from the DSCSA.

(a) Inventories and other records regarding the receipt and distribution or disposition of prescription drugs and drug-related devices shall be maintained and readily available for inspection or photocopying by the Board of Pharmacy and authorized law enforcement officials for a period of six (6) years). These records shall include:

1. The proprietary and established name of the prescription drug and related device, if applicable;

2. The dosage, if applicable;

3. The size of the container, if applicable;

4. The number of containers;

5. The lot number or control number of the prescription drug and related device, if applicable;

6. The business name and address of all parties involved in each receipt and distribution or disposition of the prescription drug and related device, starting with the manufacturer; and

7. The date of each receipt and distribution or disposition of the prescription drug and related device.

(b) Records described in this section that are kept at the inspection site or that can be readily retrievable within forty-eight (48) hours 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 two (2) working days of a request by the Board of Pharmacy or an authorized official of a federal, state, or local law enforcement agency.

(c) Wholesalers shall maintain an ongoing list of verified persons or businesses with whom they do business.

(d) A wholesaler may sell or distribute prescription drugs and drug-related devices only to the following, except as provided in KRS 315.0351(2) and 315.404:

1. A currently licensed wholesaler;

2. A currently licensed third party logistics provider;

3. A currently permitted pharmacy;

4. A currently licensed outsourcing facility;

5. A currently licensed practitioner;

6. A currently permitted repackager;

7. A currently licensed hospital, but only for use by or in that hospital pursuant to KRS 217.182(1);

8. A person in charge of a laboratory, but only for use in that laboratory for scientific and medical research purposes pursuant to KRS 217.182(1); or

9. Any other appropriately licensed or permitted facility in the jurisdiction in which it is located.

(e) A wholesaler may acquire prescription drugs and drug-related devices only from the following, except as provided in KRS 315.404:

1. A currently permitted manufacturer;

2. A currently permitted repackager;

3. A currently licensed wholesaler; or

4. A currently licensed third-party logistics provider.

(f) Wholesalers shall maintain a system for the mandatory reporting of any theft, suspected theft, diversion, or other significant loss of any prescription drug and related device to the Board of Pharmacy, and if applicable, the FDA and DEA.

(4) Written policies and procedures, requirements for companies handling prescription drugs and drug-related devices exempt from the DSCSA.

(a) A wholesaler shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, distribution, and disposition of prescription drugs and drug-related devices

(b) There shall be written policies and procedures for identifying, recording, and reporting losses or thefts.

(c) There shall be written policies and procedures to assure that the wholesaler prepares for, protects against, and handles crisis situations that affect the security or operation of the facility.

These crises shall include fires, floods, or other natural disasters, and situations of local, state, or national emergency.

(d) There shall be written policies and procedures for managing and correcting all errors or inaccuracies in inventories.

(e) There shall be written policies and procedures to assure that any outdated stock or any stock with an expiration date that, in the wholesaler's view, does not allow sufficient time for repacking or resale shall be segregated from other stock and shall be prepared for return to the manufacturer or otherwise destroyed, and this shall be documented.

(f) There shall be written policies and procedures by which the wholesaler exercises control over the shipping and receiving of all stock within the operation.

(g) There shall be written policies and procedures for investigating suspect product and reporting illegitimate product to the Board of Pharmacy and the FDA pursuant to the DSCSA, if applicable.

(5) Returned, damaged, and outdated prescription drugs and drug-related devices. A wholesaler shall maintain and follow a written policy and procedure to assure the proper handling and disposal of returned goods. If conditions under which a prescription drug or related device has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, then the drug or related device shall be destroyed, or returned, unless examination, testing, or other investigation proves that the drug or drug-related device meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a prescription drug or related device has been returned cast doubt on the drug's or related device's safety, identity, strength, quality, or purity, the wholesaler shall consider, among other things, the conditions under which the drug or related device has been held, stored, or shipped before or during its return and the condition of the drug or related device and its container, carton, or labeling, as a result of storage or shipping.

(6) Handling recalls. A wholesaler shall establish, maintain, and adhere to a written policy and procedure for handling recalls and withdrawals of prescription drugs and drug-related devices. The policy and procedure shall cover all recalls and withdrawals of drugs and drug-related devices due to:

(a) Any voluntary action on the part of the manufacturer;

(b) The direction of the FDA, or any other federal, state, or local government agency; and

(c) Replacement of existing.

(7) Procedures

(a) A visual examination of all materials received or shipped shall be made to guarantee product identity and to reasonably guard against acceptance or delivery of damaged, contaminated, tampered, or otherwise unfit stock.

(b) Procedures for distribution of approved stock shall provide for a rotation whereby the expiration date is taken into consideration when distributing inventory.

(c) A wholesaler shall be subject to the provisions of any applicable federal, state, or local laws or regulations that relate to prescription drug and related device salvaging or reprocessing.

Section 6. Violations.

(1) A wholesaler shall not distribute prescription drugs and drug-related devices directly to a consumer or a patient, except as provided in KRS 315.0351(2).

(2) A wholesaler shall not operate in a manner that endangers the public health.

(3) Violations of any of these provisions shall be grounds for action under KRS 315.121.

Section 7. Incorporation by Reference.

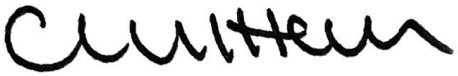
(1) The following material is incorporated by reference:

(a) "Application for a License to Operate as a Wholesaler", June 2023 [~~May 2020~~];

(b) "Renewal Application to Operate as a Wholesaler", June 2023 [~~May 2020~~]; and

(c) "USP Chapter 659 Packaging and Storage Requirements", April 1, 2021 [~~November 1, 2020~~].

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Board of Pharmacy, State Office Building Annex, Suite 300, 125 Holmes Street, Frankfort, Kentucky 40601-8024. Monday through Friday, 8 a.m. to 4:30 p.m. or on the Board's website at https://pharmacy.ky.gov/Businesses/Pages/Wholesale-Distributors.aspx.



June 7, 2023

Christopher Harlow, Pharm.D.
Executive Director
Board of Pharmacy

Date

PUBLIC HEARING AND PUBLIC COMMENT PERIOD:

A public hearing on this administrative regulation shall be held on August 30, 2023, at 10:00 a.m. Eastern Time via zoom teleconference. Individuals interested in being heard at this hearing shall notify this agency in writing by five workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. This hearing is open to the public. Any person who wishes to be heard will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on the proposed administrative regulation. Written comments shall be accepted through August 31, 2023. Send written notification of intent to be heard at the public hearing or written comments on the proposed administrative regulation to the contact person.

Contact person: Christopher Harlow, Executive Director, Kentucky Board of Pharmacy, 125 Holmes Street, Suite 300, State Office Building Annex, Frankfort, Kentucky 40601, phone (502) 564-7910, fax (502) 696-3806, email Christopher.harlow@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

201 KAR 2:105. Licensing and drug distribution requirements for wholesale distributors.
Contact person: Christopher Harlow
Contact Phone No.: 502-564-7910
Contact email: Christopher.harlow@ky.gov

(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation establishes the requirements for the regulation of wholesalers, medical gas wholesalers, wholesale distributors and virtual wholesale distributors.

(b) The necessity of this administrative regulation: KRS 315.191(1)(a) authorizes the Board of Pharmacy to promulgate administrative regulations with minimum requirements for the permitting of those entities that provide pharmacy services. This administrative regulation establishes the requirements for the regulation of wholesalers, medical gas wholesalers, wholesale distributors and virtual wholesale distributors.

(c) How this administrative regulation conforms to the content of the authorizing statues: This administrative regulation establishes the requirements for the regulation of wholesalers, medical gas wholesalers, wholesale distributors and virtual wholesale distributors.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: Retitle this regulation and cleanup language to be consistent with Federal Regulations.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of: How the amendment will change this existing administrative regulation: This amendment only amends the application and fee listed there.

(a) The necessity of the amendment to this administrative regulation: The criteria needed to be updated.(b) How the amendment conforms to the content of the authorizing statutes: KRS 315.191(1)(a) authorizes the board to promulgate administrative regulations pertaining to pharmacists and pharmacies. The amendment ensures that the appropriate amount is listed in the applications.

(b) How the amendment will assist in the effective administration of the statutes: The amendment will further promote, preserve, and protect public health through effective the correct fee amount being listed in the application.

(c) How the amendment conforms to the content of the authorizing statutes: The amendment is only to the applications, and the amendment is required to align with proposed changes to 201 KAR 2:050.

(d) How the amendment will assist in the effective administration of the statutes? The amendment is necessary to ensure that the regulation is aligned with the Board's fee regulation, 201 KAR 2:050.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: The board anticipates pharmacies and pharmacists will be affected minimally by this regulation amendment. Wholesalers will be impacted.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: Pharmacies and pharmacists will have to familiarize themselves with amended language. The board will help to educate regulated entities about these changes.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): Due to the amendment to the fee amount in the form pursuant to 201 KAR 2:050, it will cost wholesalers an additional $25 per year in their licensing fee.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): This amendment will ensure robust regulation and quick administrative turn-around. .

(5) Provide an estimate of how much it will cost to implement this administrative Regulation:
(a) Initially: There will be no costs incurred.
(b) On a continuing basis: There will be no costs incurred.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: Board revenues from pre-existing fees provide the funding to enforce the regulation.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: The fee for wholesale distributor permit will be increased by $25.00 in 201 KAR 2:050.

(8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees: This administrative regulation does not establish fees directly, but references in the forms a fee increase from 201 KAR 2:050.

(9) TIERING: Is tiering applied? Tiering is not applied because the regulation is applicable to all entities wishing to distribute pharmaceuticals in Kentucky.

FISCAL NOTE

201 KAR 2:105. Licensing and drug distribution requirements for wholesale distributors.
Contact Person: Christopher Harlow
Contact Phone No.: 502-564-7910
Contact email: Christopher.harlow@ky.gov

1. What units, parts, or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation?
The Kentucky Board of Pharmacy will be the only entity impacted by this administrative regulation.
2. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 315.191(1)(a).
3. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.
a. How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? It is estimated this administrative regulation will generate an annual increase in revenue in the amount of $106,800.00 for the Board in the first year. This regulation does not directly create a fee, but the application incorporated by reference does include a fee, as authorized in 201 KAR 2:050.
b. How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? It is estimated this administrative regulation will generate an annual increase in revenue in the amount of $106,800.00 for the Board in the first year. This regulation does not directly create a fee, but the application incorporated by reference does include a fee, as authorized in 201 KAR 2:050.
c. How much will it cost to administer this program for the first year? The administrative costs to administer this program include application processing, inspections, and general regulatory inquiries.
d. How much will it cost to administer this program for subsequent years? The administrative costs to administer this program include application processing, inspections, and general regulatory inquiries.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation. N/A

Revenues (+/-): proposed amendment will provide an annual $106,800 increase in revenue

Expenditures (+/-): -$106,800, cost of ensuring compliance of license holder.

Other Explanation: n/a

(4) Estimate the effect of this administrative regulation on the expenditures and cost savings of regulated entities for the first full year the administrative regulation is to be in effect.
(a) How much cost savings will this administrative regulation generate for the regulated entities for the first year? None
(b) How much cost savings will this administrative regulation generate for the regulated entities for subsequent years? None.

(c) How much will it cost the regulated entities for the first year? $150 annually.
(d) How much will it cost the regulated entities for subsequent years? $150 annually.
Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.
Cost Savings (+/-): 0
Expenditures (+/-): -$150 annually
Other Explanation: This is the cost of the annual permit.
(5) Explain whether this administrative regulation will have a major economic impact, as defined below. "Major economic impact" means an overall negative or adverse economic impact from an administrative regulation of five hundred thousand dollars ($500,000) or more on state or local government or regulated entities, in aggregate, as determined by the promulgating administrative bodies. [KRS 13A.010(13)] This regulation does not have major economic impact.

Summary of Material Incorporated by Reference

The “Application for License to Operate as a Wholesaler”, June 2023 form is an 12-page form to be utilized by applicants for an initial license.

The “Renewal Application to Operate as a Wholesaler”, June 2023 form is an 10-page form to be utilized by applicants for annual license renewal.

“USP Chapter 659”, April 1, 2021 is a 6-page document that sets the standards for packaging and storage of drugs.

Summary of Changes to Material Incorporated by Reference

Both the “Application for License to Operate as a Wholesaler” and “Renewal Application to Operate as a Wholesaler” were amended to ask for the website address, how the entity is registered with the Kentucky Secretary of State, and to include changes to formatting, the exclusion of content that is no longer relevant and the inclusion of content that is relevant in assessing if a license should be issued or renewed.

KENTUCKY BOARD OF PHARMACY
State Office Building Annex, Suite 300
125 Holmes Street
Frankfort KY 40601
Phone (502) 564-7910 Fax (502) 696-3806

Application for License to Operate as a Wholesaler

Please print legibly. Make check or money order payable to 'Kentucky State Treasurer' and. Mail to the above address. Payment can also be made online at https://secure.kentucky.gov/formservices/Pharmacy/VirtualTerminal. All applicable entries must be completed. Incomplete applications will be returned. Each license expires September 30th following the date of issuance.

1. Name of Facility

_____

Physical Address of Facility

_____
(Street and Number)

City _____ State _____

County _____ Zip_____

Phone Number _____ Fax Number _____

Email Address _____

Website Address _____

Mailing Address of Facility

_____
(Street and Number)

City _____State _____Zip _____

Check and complete one of the following and attach proper fee:

☐ New Wholesaler .. . .
$150.00 ~~125.00~~

Proposed date of Opening _____
(Filed with Board 30 days in advance of Opening)

☐ Change of Ownership . . . . . .
$150.00~~75.00~~

Date of Proposed Acquisition _____
Name of Previous Owner(s) _____
(Confirmation statement of previous owner must be attached)

☐ Change of Address/Location . . . . . .
$150.00~~75.00~~

Date of Proposed Relocation _____
Previous Address _____

☐ Name Change . . . . . .
NO CHARGE

Previous Name _____

2. Type of wholesaler:

◯ Wholesale Distributor
◯ Virtual Wholesale Distributor
◯ Medical Gas Wholesale Distributor
◯ Other Wholesaler _____

3. DEA Number: _____ Exp. Date: _____/_____/_____

4. Name, ~~and~~ title, phone and email of the facility contact person:

Name: _____ Phone: _____

Title: _____ Email: _____

5. Has applicant, or any owner [s], partner [s], officer [s], agent or employee of the applicant, ever been convicted of any felony under federal, state, and/or local laws?

☐ Yes, attach explanation ☐ No

Has applicant, or any owner [s], partner [s], officer [s], agent or employee of the applicant, ever had a license or permit related to drugs revoked or suspended by any federal, state, or local government?

☐ Yes, attach explanation ☐ No

Has applicant, or any owner [s], partner [s], officer [s], agent or employee of the applicant, ever been convicted under federal, state and/or local drug laws, including drug samples and wholesale or retail drug distribution of controlled substances?

☐ Yes, attach explanation ☐ No

6. Schedule of Hours:

Monday . . . . _____ A.M. to _____ P.M.
Tuesday . . . _____ A.M. to _____ P.M.
Wednesday ._____ A.M. to _____ P.M.
Thursday . . . _____ A.M. to _____ P.M.
Friday . . . _____ A.M. to _____ P.M.
Saturday . _____ A.M. to _____ P.M.
Sunday . . ._____ A.M. to _____ P.M.

7. How is the facility registered with the Secretary of State? ~~Ownership~~: ☐ Sole Proprietor ☐ Partnership ☐ Unincorporated Business ☐ Incorporated Business ☐ Other

Pursuant to 201 KAR 2:105, Section 4, on a separate sheet of paper, please provide the following information for each owner/officer, including professional designation (e.g. Pres. John Jones, M.D.):

- Name and Title
- Address (Business and Home)
- Phone Number (Business and Home)
- Social Security Number
- Date of Birth

8. Proof of surety bond or equivalent pursuant to 201 KAR 2:105, Section 2. ☐ Yes ☐ No

9. Does ~~Is~~ this facility have a Digital Distributor Accreditation ~~VAWD accredited~~?_____ Yes, please provide number _____ _____ No

10. List of other states, districts, or territories in which licensed/permitted:
_____

11. Has the facility undergone any third-party inspections?____yes ____no (If yes, please include inspection report).

12. REQUIRED DOCUMENTATION FOR NON-RESIDENT FACILITIES MUST BE ENCLOSED:

Completed application	Copy of DEA Registration
Copy of Resident Permit/License	Completed Attached License Verification Form
Copy of Last Inspection Report	Ownership information as described in Section 7
Copy of Surety Bond or other Security	Third-Party Inspection Report (if applicable)

The Board may refuse to issue or renew a license, or suspend, temporarily suspend, revoke, fine or reasonably restrict any license holder for knowingly making or causing to be made, any false, fraudulent or forged statement in connection with an application for a license. KRS 315.121.

I hereby certify that the foregoing is true and correct to the best of my knowledge. If the registration herein applied for is granted, I certify that this business will be conducted in full compliance with all applicable federal and state laws and that I will make available any or all records required by law to the extent authorized by law.

_____ _____/_____/_____
(Signature of Owner/Officer and Title) (Date)

I hereby certify that the above Application for Wholesaler was signed, subscribed and sworn to before me this____day of _____, 20____.

My Commission Expires_____State of_____

Signature_____

~~REQUIRED DOCUMENTATION FOR NON-RESIDENT FACILITIES MUST BE ENCLOSED:~~

~~Completed application~~	~~Copy of DEA Registration~~
~~Copy of Resident Permit/License~~	~~Completed Attached License Verification Form~~
~~Copy of Last Inspection Report~~	~~Ownership information as described in Section~~

KENTUCKY BOARD OF PHARMACY
State Office Building Annex,Suite 300
125 Holmes Street
Frankfort KY 40601
Phone:(502) 564-7910
Fax:(502) 696-3806
Email: pharmacy.board@ky.gov
http://pharmacy.ky.gov

Application for License to Operate as Wholesaler

Please print legibly. Make check or money order payable to 'Kentucky State Treasurer' and: Mail to the above address. Payment can also be made online at https://secure.kentucky.gov/formservices/Pharmacy/VirtualTerminal. All applicable entries must be completed. Incomplete applications will be returned. Each license expires September 30th following the date of issuance.

I. Facility Information:

Name of Facility:			
Physical Address of Facility:			
CITY:	STATE:	COUNTY:	ZIP:
Mailing Address of Facility:			
CITY:	STATE:	COUNTY:	ZIP:
Email:			

Phone Number:	
Fax Number:	
DEA Number:	Exp. Date:

II. Check and complete one of the following and attach proper fee:

☐ **New Wholesaler** → **$150.00**

Proposed date of Opening:

(Filed with board 30 days in advance of opening)

☐ **Change of Ownership** → **$150.00**

Proposed date of Acquisition:
Name of Previous Owner(s):

(Confirmation statement of previous owner must be attached)

☐ **Change of Address/Location** → **$150.00**

Date of Proposed Relocation:
Previous Address:

☐ **Name Change** → **NO CHARGE**

Previous Name:

III. Type of Wholesaler

☐ **Wholesale Distributor**	☐ **Virtual Wholesale Distributor**
☐ **Medical Gas Wholesale Distributor**	☐ **Other Wholesaler:** _____ .

IV. Name, title, phone and email of the facility contact person:

Name:
Title:
Phone number:
Email:

V. Qualifying Questions:

1. **Has applicant, or any owner[s], partner[s], officer[s], agent or employee of the applicant, ever been convicted of any felony under federal, state, and/or local laws?**

☐ **YES***	☐ **NO**

If yes: please provide explanation below:

Explanation:

2. **Has applicant, or any owner [s], partner [s], officer [s], agent or employee of the applicant, ever had a license or permit related to drugs revoked or suspended by any federal, state, or local government?**

☐ **YES***	☐ **NO**

If yes: please provide explanation below:

Explanation:

3. **Has applicant, or any owner [s], partner [s], officer [s], agent or employee of the applicant, ever been convicted under federal, state and/or local drug laws, including drug samples and wholesale or retail drug distribution of controlled substances?**

☐ **YES***	☐ **NO**

If yes: please provide explanation below:

Explanation:

VI. Schedule of Hours:

MONDAY	**TUESDAY**	**WEDNESDAY**	**THURSDAY**	**FRIDAY**	**SATURDAY**	**SUNDAY**
OPEN:	OPEN:	OPEN:	OPEN:	OPEN:	OPEN:	OPEN:

CLOSE:	CLOSE:	CLOSE:	CLOSE:	CLOSE:	CLOSE:	CLOSE:

VII. Ownership:

How is the facility registered with the Secretary of State?

- ☐ Sole Proprietor
- ☐ Partnership
- ☐ LLC
- ☐ Corporation
- ☐ Other

★★Pursuant to 201 KAR 2:105, Section 4, please provide the following information for each owner/officer/member, including professional designation (e.g. Pres. John Jones, M.D.):

1.

Name:	Title:
Phone number(Business):	
Phone number(Home):	
Social Security Number:	Date of Birth:
Address(Home):	

CITY:	STATE:	COUNTY:	ZIP:

Address(Business):			
CITY:	STATE:	COUNTY:	ZIP:

2.

Name:	Title:

Phone number(Business):

Phone number(Home):

Social Security Number:	Date of Birth:

Address(Home):			
CITY:	STATE:	COUNTY:	ZIP:

Address(Business):			
CITY:	STATE:	COUNTY:	ZIP:

3.

Name:	Title:

Phone number(Business):	
Phone number(Home):	
Social Security Number:	Date of Birth:
Address(Home):	
CITY: STATE: COUNTY: ZIP:	
Address(Business):	
CITY: STATE: COUNTY: ZIP:	

4.

Name:	Title:
Phone number(Business):	
Phone number(Home):	
Social Security Number:	Date of Birth:
Address(Home):	
CITY: STATE: COUNTY: ZIP:	

Address(Business):			
CITY:	STATE:	COUNTY:	ZIP:

5.

Name:	Title:
Phone number(Business):	
Phone number(Home):	
Social Security Number:	Date of Birth:

Address(Home):			
CITY:	STATE:	COUNTY:	ZIP:

Address(Business):			
CITY:	STATE:	COUNTY:	ZIP:

(Use supplemental information page if necessary)

VIII. Proof of surety bond or equivalent pursuant to 201 KAR 2:105, Section 2.

☐ **YES**	☐ **NO**

IX. Does this facility have a Digital Distributor Accreditation ?

☐ YES*	☐ NO

If yes: please provide the number below

:

X. List of other states, districts, or territories in which licensed/permitted:

:

XI. Has this facility undergone any third-party inspections?

☐ YES*	☐ NO

If yes: please include inspection report

REQUIRED DOCUMENTATION FOR NON-RESIDENT FACILITIES MUST BE ENCLOSED:

☐ Completed application

☐ Copy of Resident Permit/License

☐ Copy of Last Inspection Report

☐ Copy of DEA Registration

☐ Completed Attached License Verification Form

☐ Copy of Surety Bond or other Security

☐ Third-Party Inspection Report (if applicable)

Supplemental Information Page:

Form 6/2023

The Board may refuse to issue or renew a license, or suspend, temporarily suspend, revoke, fine or reasonably restrict any license holder for knowingly making or causing to be made, any false, fraudulent or forged statement in connection with an application for a license. KRS 315.121.

I hereby certify that the foregoing is true and correct to the best of my knowledge. If the registration herein applied for is granted, I certify that this business will be conducted in full compliance with all applicable federal and state laws and that I will make available any or all records required by law to the extent authorized by law.

Signature of Owner/Officer and Title: **Date:**

I hereby certify that the above Application for Wholesaler was signed, subscribed and sworn to

before me this _____day of _____, 20_____.

By: _____

Signature: _____

My Commission Expires _____ State of

Form 6/2023

KENTUCKY BOARD OF PHARMACY
State Office Building Annex, Suite 300
125 Holmes Street
Frankfort KY 40601
Phone (502) 564-7910 Fax (502) 696-3806

RENEWAL APPLICATION TO OPERATE AS A WHOLESALER

All permits expire September 30 and are not transferable. Please print legibly and submit each application with a check or money order in the amount of $150.00~~125.00~~ made payable to the "KENTUCKY STATE TREASURER". Mail to the above address. Payment can also be made online at https://secure.kentucky.gov/formservices/Pharmacy/VirtualTerminal.
Incomplete applications will be returned.

TYPE: □ Wholesale Distributor □ Virtual Wholesale Distributor

□ Medical Gas Wholesale Distributor □ Other_____

LICENSE NUMBER: _____

NAME OF FACILITY:
_____

PHYSICAL ADDRESS:
_____

CITY: _____ STATE: _____COUNTY _____ ZIP _____

PHONE NUMBER: _____FAX NUMBER: _____

EMAIL ADDRESS: _____
Website: _____

DEA NUMBER: _____ EXPIRATION DATE: _____

MAILING ADDRESS:
_____
_____

_____
_____

1. Name, ~~and~~ title, phone and email of the facility contact person:

Name: _____ Phone: _____

Title: _____ Email: _____

2. How is the facility registered with the Secretary of State? ~~Ownership~~:

☐ Sole Proprietor ☐ Partnership ☐ Unincorporated Business ☐ Incorporated Business ☐ Other

Pursuant to 201 KAR 2:105, Section 4, on a separate sheet of paper, please provide the following

information for each owner/officer, including professional designation (e.g. Pres. John Jones, M.D.):

- **Name and Title**
- **Address (Business and Home)**
- **Phone Number (Business and Home)**
- **Social Security Number[XXX-XX-____]**
- **Date of Birth[Month and Year only]**

3. Has applicant, or any owner [s], partner [s], officer [s], agent or employee of the applicant, ever been convicted of any felony under federal, state, and/or local laws not previously reported to the Board?

◯ Yes, attach explanation ◯No

Has applicant, or any owner [s], partner [s], officer [s], agent or employee of the applicant, ever had a license or permit related to drugs revoked or suspended by any federal, state, or local government not previously reported to the Board?

◯ Yes, attach explanation ◯No

Has applicant, or any owner [s], partner [s], officer [s], agent or employee of the applicant, ever been convicted under federal, state and/or local drug laws, including drug samples and wholesale or retail drug distribution of controlled substances not previously reported to the Board?

◯ Yes, attach explanation ◯No

4. Schedule of Hours:

Monday: _____ A.M. to _____ P.M. Friday: _____ A.M. to _____ P.M.

Tuesday: _____ A.M. to _____ P.M. Saturday: _____ A.M. to _____ P.M.

Wednesday: _____ A.M. to _____ P.M. Sunday: _____ A.M. to _____ P.M.

Thursday: _____ A.M. to _____ P.M.

5. Does this facility have a Digital Distributor Accreditation ~~Is this facility VAWD accredited~~?

____ Yes ____ No

6. List of other state, districts, or territories in which licensed/permitted:

_____

7. Has the facility undergone any third-party inspections? ____yes ____no (If yes, please include inspection report).

The Board may refuse to issue or renew a license/permit or suspend, temporarily suspend, revoke, fine or reasonably restrict the license/permit holder for knowingly making or causing to be made any false, fraudulent or forged statement in connection with an application for a permit. See KRS 315.121.

I hereby certify that the foregoing is true and correct to the best of my knowledge. If the registration herein applied for is granted, I certify that this business will be conducted in full compliance with all applicable federal and state laws and that I will make available any or all records required by law to the extent

authorized by law.

_____ _____

Signature and Title of Owner / Manager Date

I hereby certify that the above Renewal Application for Wholesaler was signed, subscribed and sworn to before me this____day of _____, 20____.

My Commission Expires_____State of_____

Signature_____

Changes in the above information must be submitted in writing with the appropriate application fee to the Board office within thirty (30) days.

KENTUCKY BOARD OF PHARMACY
State Office Building Annex,Suite 300
125 Holmes Street
Frankfort KY 40601
Phone: (502) 564-7910
Fax: (502) 696-3806
Email: pharmacy.board@ky.gov
http://pharmacy.ky.gov

Renewal Application to Operate as a Wholesaler

All permits expire September 30 and are not transferable. Please print legibly and submit each application with a check or money order in the amount of $150.00 made payable to the "KENTUCKY STATE TREASURER". Mail to the above address. Payment can also be made online at https://secure.kentucky.gov/formservices/Pharmacy/VirtualTerminal.

Incomplete applications will be returned.

Type:

☐ **Wholesale Distributor**	☐ **Virtual Wholesale Distributor**
☐ **Medical Gas Wholesale Distributor**	☐ **Other:** _____.

I. Facility Information:

Name of Facility:
License Number:

Physical Address of Facility:			
CITY:	STATE:	COUNTY:	ZIP:
Email:			
Phone number:			
Fax number:			
DEA Registration No.:		Exp. Date:	

II. Name, title, phone and email of the facility contact person:

Name:
Title:
Phone number:
Email:

III. Ownership:

How is the facility registered with the Secretary of State?

☐ Sole Proprietor

☐ Partnership
☐ LLC
☐ Corporation
☐ Other

★★Pursuant to 201 KAR 2:105, Section 4, please provide the following information for each owner/officer/member, including professional designation (e.g. Pres. John Jones, M.D.):

1.

Name:	Title:
Phone number(Business):	
Phone number(Home):	
Social Security Number:	Date of Birth:
Address(Home):	
CITY: STATE: COUNTY: ZIP:	
Address(Business):	
CITY: STATE: COUNTY: ZIP:	

2.

Name:	Title:

Phone number(Business):	
Phone number(Home):	
Social Security Number:	Date of Birth:
Address(Home):	
CITY: STATE: COUNTY: ZIP:	
Address(Business):	
CITY: STATE: COUNTY: ZIP:	

3.

Name:	Title:
Phone number(Business):	
Phone number(Home):	
Social Security Number:	Date of Birth:
Address(Home):	
CITY: STATE: COUNTY: ZIP:	

Address(Business):			
CITY:	STATE:	COUNTY:	ZIP:

4.

Name:	Title:
Phone number(Business):	
Phone number(Home):	
Social Security Number:	Date of Birth:

Address(Home):			
CITY:	STATE:	COUNTY:	ZIP:
Address(Business):			
CITY:	STATE:	COUNTY:	ZIP:

5.

Name:	Title:
Phone number(Business):	

Phone number(Home):			
Social Security Number:		Date of Birth:	
Address(Home):			
CITY:	STATE:	COUNTY:	ZIP:
Address(Business):			
CITY:	STATE:	COUNTY:	ZIP:

(Use supplemental information page if necessary)

IV. Qualifying Questions:

1. **Has applicant, or any owner [s], partner [s], officer [s], agent or employee of the applicant, ever been convicted of any felony under federal, state, and/or local laws not previously reported to the Board?**

☐ **YES***	☐ **NO**

If yes: please provide explanation below:

Explanation:

2. **Has applicant, or any owner[s], partner[s], officer[s], agent or employee of the applicant, ever had a license or permit related to drugs revoked or suspended by any federal, state, or local government not previously reported to the Board?**

☐ YES*	☐ NO

*If yes: please provide explanation below:

Explanation:

3. **Has applicant, or any owner[s], partner[s], officer[s], agent or employee of the applicant, ever been convicted under federal, state and/or local drug laws, including drug samples and wholesale or retail drug distribution of controlled substances not previously reported to the Board?**

☐ YES*	☐ NO

*If yes: please provide explanation below:

Explanation:

V. Schedule of Hours:

MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY	SUNDAY
OPEN:	OPEN:	OPEN:	OPEN:	OPEN:	OPEN:	OPEN:
CLOSE:	CLOSE:	CLOSE:	CLOSE:	CLOSE:	CLOSE:	CLOSE:

VI. Does this facility have a Digital Distributor Accreditation?

☐ **YES**	☐ **NO**

VII. List of other states, districts, or territories in which licensed/permitted:

:

VIII. Has this facility undergone any third-party inspections?

☐ **YES***	☐ **NO**

If yes: please include inspection report

Supplemental Information Page:

Form 6/2023

The Board may refuse to issue or renew a license/permit or suspend, temporarily suspend, revoke, fine or reasonably restrict the license/permit holder for knowingly making or causing to be made any false, fraudulent or forged statement in connection with an application for a permit. See KRS 315.121.

I hereby certify that the foregoing is true and correct to the best of my knowledge. If the registration herein applied for is granted, I certify that this business will be conducted in full compliance with all applicable federal and state laws and that I will make available any or all records required by law to the extent authorized by law.

Signature and Title of Owner/ Manager: _____ **Date:** _____

I hereby certify that the above Renewal Application for Wholesaler was signed, subscribed and sworn to before me this _____day of _____, 20_____.

By: _____

Signature: _____

My Commission Expires _____ State of

Changes in the above information must be submitted in writing with the appropriate application fee to the Board office within thirty (30) days.

⟨659⟩ PACKAGING AND STORAGE REQUIREMENTS

(A portion of the *Packaging* section of this chapter will become official on December 1, 2025 as indicated. Early adoption of the requirements in this chapter and *Plastic Materials of Construction* ⟨661.1⟩ and *Plastic Packaging Systems for Pharmaceutical Use* ⟨661.2⟩ is permitted by USP.)

INTRODUCTION

The purpose of this chapter is to provide packaging definitions, auxiliary packaging information, and storage condition definitions relevant to the storage and distribution of active ingredients, excipients, and medical products, such as pharmaceuticals, combination products, and,when labeled as being USP compliant, dietary supplements.

Change to read:

PACKAGING

Packaging materials must not interact physically or chemically with a packaged article in a manner that causes its safety, identity, strength, quality, or purity to fail to conform to established requirements. ▲Any plastic material used to construct a *Packaging system* must meet the applicable requirements of *Plastic Materials of Construction* ⟨661.1⟩.▲ (Official 1-Dec-2025) All *Packaging systems* must meet the applicable requirements specified in *Containers—Glass* ⟨660⟩, *Plastic Packaging Systems and Their Materials of Construction* ⟨661⟩, ▲*Plastic Packaging Systems for Pharmaceutical Use* ⟨661.2⟩,▲ (Official 1-Dec-2025) and *Auxiliary Packaging Components* ⟨670⟩. All elastomeric closures must meet the applicable requirements in *Elastomeric Components in Injectable Pharmaceutical Product Packaging/Delivery Systems* ⟨381⟩.

Every monograph in *USP–NF* must have packaging and storage requirements. For the packaging portion of the statement, the choice of containers is provided in this chapter. For active pharmaceutical ingredients (APIs), the choice would be a tight or well-closed container (as specified in the monograph), and, where needed, a light-resistant container. For excipients, given their typical presentation as large-volume commodity items (*Packaging systems* ranging from drums to tank cars), a well-closed container is an appropriate default requirement. Articles must be protected from moisture, freezing, and excessive heat (see *General Definitions*) when no specific directions or limitations are provided.

The compendial requirements for the use of specified containers apply also to articles packaged by *Dispensers*, *Repackagers*, or other individuals, unless otherwise indicated in the individual drug product monograph.

POISON PREVENTION PACKAGING ACT

This act, which is administered by the US Consumer Product Safety Commission (CPSC), requires special packaging for most human oral prescription drugs, oral controlled drugs, certain non-oral prescription drugs, certain dietary supplements, and many over-the-counter (OTC) drug preparations, to protect the public from personal injury or illness from misuse of these preparations [16 Code of Federal Regulations (CFR) §1700].

The primary packaging of substances regulated under the Poison Prevention Packaging Act (PPPA) must comply with the special packaging standards. These apply to all packaging types, including reclosable, non-reclosable, and unit-dose types.

Special packaging is not required for drugs dispensed within a hospital setting for inpatient administration. Also, special packaging does not need to be used by manufacturers and packagers of bulk-packaged prescription drugs that will be repackaged by the pharmacist. PPPA-regulated prescription drugs may be dispensed in non-*Child-resistant packaging* upon the request of the purchaser or when directed in a legitimate prescription.

Manufacturers or packagers of PPPA-regulated OTC preparations are allowed to package one size in non-*Child-resistant packaging* as long as popular-size, special packages are also supplied. The non-*Child-resistant packaging* requires special labeling.

TEMPERATURE AND STORAGE

Specific directions are stated in some monographs with respect to storage conditions (e.g., the temperature or humidity) at which an article must be stored and shipped. Storage and shipping directions apply except where the label on the article or its prescribing information has different storage conditions that are based on stability studies. Where no specific directions or limitations are provided in the article's labeling or prescribing information, articles must be protected from moisture, freezing, and excessive heat, and, where necessary, from light during shipping and distribution; drug substances are exempt from this requirement.

Change to read:

GENERAL DEFINITIONS

Packaging Definitions

Packaging system (also referred to as a Container–closure system)**:** The sum of *Packaging components* and materials that together contain and protect the article. This includes *Primary packaging components* as well as *Secondary packaging components* when such components are required to provide additional protection.

Container: A receptacle that holds an intermediate compound, API, excipient, or dosage form, and is in direct contact with the article (e.g., ampules, vials, bottles, syringes, and pen injectors).

Closure: A material that seals an otherwise open space of a *Container* and provides protection for the contents. It also provides access to the contents of the *Container* (e.g., screw caps and stoppers).

Packaging component: Any single part of the *Package* or *Container–closure system,* including: the *Container*; *Closures*; ferrules and overseals; *Closure* liners; *Container* liners (e.g., tube cartridge liners); inner seals; administration ports; overwraps; administration accessories; labels; cardboard boxes; and shrink wrap.

Primary packaging component: A *Packaging component* that is in direct contact with or may come into direct contact with the article.

Secondary packaging component: A *Packaging component* that is in direct contact with a *Primary packaging component* and may provide additional protection for the article.

Tertiary packaging component: A *Packaging component* that is in direct contact with a *Secondary packaging component* and may provide additional protection for the article during transportation and/or storage.

Ancillary component: A component or entity that may come into contact with a *Tertiary packaging component* during the distribution, storage, and/or transportation of the packaged article (e.g., pallets, skids, and shrink wrap).

Associated component: A *Packaging component* that is typically intended to deliver the drug article to the patient but is not stored in contact with the article for its entire shelf life (e.g., spoons, *Dosing cups*, and dosing syringes).

Materials of construction: The materials (e.g., glass, plastic, elastomers, and metal) of which a *Packaging component* consists.

Small-volume injection (also referred to as Small-volume parenteral)**:** An injectable dosage form that is packaged in *Containers* labeled as containing 100 mL or less.

Large-volume injection (also referred to as Large-volume parenteral)**:** An injectable dosage form that is packaged in *Containers* labeled as containing more than 100 mL.

Child-resistant packaging: A *Packaging system* designed or constructed to meet CPSC standards pertaining to opening by children (16 CFR §1700.20 et seq. and 16 CFR §1700.15).

Senior-friendly packaging: A *Packaging system* designed or constructed to meet CPSC standards pertaining to opening by senior adults (16 CFR §1700.15 and 16 CFR §1700.20).

Restricted delivery system: A *Packaging system* designed or constructed to restrict (control) the amount of the drug product that may be delivered in order to limit unintended access by children and other similarly vulnerable populations. *Restricted delivery systems* should meet and may exceed CPSC standards for special packaging [*Child-resistant* and *Senior-friendly packaging* (16 CFR §1700.15 et seq.)]. For oral medicinal liquids, surface and flow characteristics vary. It is the responsibility of the manufacturer to ensure that all components of the *Restricted delivery system* provide the intended safety protection. One component of the *Restricted delivery system* is the flow restrictor, which is a *Packaging component* that restricts the flow of liquid. The flow restrictor may be used as part of a *Restricted delivery system* or as an adapter to facilitate use of a measuring device for oral medicinal liquids. A flow restrictor should not compromise CPSC standards for special packaging [*Child-resistant* and *Senior-friendly packaging* (16 CFR §1700.15 et seq.)].

Tamper-evident packaging: A *Packaging system* that may not be accessed without obvious destruction of the seal or some portion of the *Packaging system*. *Tamper-evident packaging* must be used for sterile drug products intended for ophthalmic or otic use, except where extemporaneously compounded for immediate dispensing on prescription. Drug products intended for sale without prescription are also required to comply with the *Tamper-evident packaging* and labeling requirements of the FDA where applicable (21 CFR §211.132). Preferably, the immediate *Container* and/or the outer *Container* or protective packaging used by a manufacturer or distributor for all dosage forms that are not specifically exempt is designed to show evidence of any tampering with the contents.

Reclosable packaging: A package that after it has been initially opened is capable of being reclosed with a similar degree of security and is capable of being used a sufficient number of times to dispense the total contents without loss of security. *Reclosable packaging* may incorporate child-resistance capabilities.

Non-reclosable packaging: A package or part of a package that cannot be closed again after all or part of the contents have been removed. Examples of *Non-reclosable packaging* are blisters, sachets, strips, and other *Single-unit containers*. *Non-reclosable packaging* may include cold-formed foil blisters, foil strip packs, and polyvinyl chloride (PVC)/Aclar combining multilayer materials that are thermo-formed or cold-formed foil blisters. *Non-reclosable packaging* may be child resistant depending on the intended use and place of use. Household non-reclosables are subject to the PPPA as defined in 16 CFR §1700.14.

Hermetic container: A *Container–closure system* that is impervious to air or any other gas under the ordinary or customary conditions of handling, shipment, storage, and distribution.

Tight container: A *Container–closure system* that protects the contents from contamination by extraneous liquids, solids, or vapors; from loss of the article; and from efflorescence, deliquescence, or evaporation under the ordinary or customary conditions of handling, shipment, storage, and distribution, and is capable of tight reclosure. Where a tight container is specified, it may be replaced by a hermetic container for a single dose of an article. [NOTE—Where packaging and storage in a tight container or well-closed container is specified in the individual monograph, the container used for an article when dispensed on prescription meets the requirements in *Containers—Performance Testing* ⟨671⟩.]

Well-closed container: A *Container–closure system* that protects the contents from contamination by extraneous solids and from loss of the article under the ordinary or customary conditions of handling, shipment, storage, and distribution. See ⟨671⟩.

Light-resistant container: A *Container–closure system* that protects the contents from the effects of light by virtue of the specific properties of the material of which it is composed, including any coating applied to it. A clear and colorless or a translucent container may be made light-resistant by means of an opaque covering or by use of secondary packaging, in which case the label of the container bears a statement that the opaque covering or secondary packaging is needed until the articles are to be used or administered. Where it is directed to "protect from light" in an individual monograph, preservation in a light-resistant container is intended. See ⟨671⟩, *Spectral Transmission* ▲*for Light-Resistant Packaging Components or Systems*▲ (ERR 1-Apr-2021) or ⟨661.2⟩, *Functionality* ▲*Test Method,*▲ (ERR 1-Dec-2025) *Spectral Transmission Requirements for Light-Resistant Components and Systems*.

Equivalent container–closure system: A *Container–closure system* that is as protective as or more protective than the original manufacturer's *Packaging system* in terms of moisture vapor transmission rate, oxygen transmission, light transmission, and compatibility. System equivalency extends to any special protective materials, such as those for seals or desiccants associated with the original *Packaging system*.

Table 1. Packaging Systems Definitions: Injection versus Noninjection

Injection	Noninjection
Multiple-dose	Multiple-unit
Single-dose	Single-unit
—	Unit-dose
—	Unit-of-use
Pharmacy bulk package	—
Imaging bulk package	—

Injection Packaging Systems

Multiple-dose container (also referred to as Multi-dose)**:** A *Container–closure system* that holds a sterile medication for parenteral administration (injection or infusion) that has met antimicrobial effectiveness testing requirements, or is excluded from such testing requirements by FDA regulation. A *Multiple-dose container* is intended to contain more than one dose of a drug product. When space permits, a *Multiple-dose container* is labeled as such. *Multiple-dose containers* are generally expected to contain 30 mL or less of medications. The beyond-use date for an opened or entered (e.g., needle-punctured) *Multiple-dose container* is 28 days unless otherwise specified by the manufacturer on the label. An example of a *Multiple-dose container* is a vial.

Single-dose container: A *Container–closure system* that holds a sterile medication for parenteral administration (injection or infusion) that is not required to meet the antimicrobial effectiveness testing requirements. A *Single-dose container* is designed for use with a single patient as a single injection/infusion.[1] When space permits, a *Single-dose container* is labeled as such and should include on the label appropriate discard statements. Examples of *Single-dose containers* are vials, ampules, and prefilled syringes.

Pharmacy bulk package: A *Container–closure system* of a sterile preparation for parenteral use that contains many single doses. The contents are intended for use in a pharmacy admixture program and are restricted to the preparation of admixtures for infusion or, through a sterile transfer device, for the filling of empty sterile syringes. The *Closure* must be penetrated only one time after constitution, if necessary, with a suitable sterile transfer device or dispensing set that allows measured dispensing of the contents. The *Pharmacy bulk package* is to be used only in a suitable work area such as a laminar flow hood (or an equivalent clean-air compounding area). Designation as a *Pharmacy bulk package* is limited to injection, for injection, or injectable emulsion dosage forms as defined in *Nomenclature* ⟨1121⟩, *General Nomenclature Forms*.

Pharmacy bulk packages, although containing more than one single dose, are exempt from the *Multiple-dose container* volume limit of 30 mL and the requirement that they contain a substance or suitable mixture of substances to prevent the growth of microorganisms. See *Labeling* ⟨7⟩ for labeling requirements.

Imaging bulk package: A container of a sterile preparation for parenteral use that contains many single doses of a contrast agent (medical imaging drug product) for use with a medical imaging device. The contents are restricted to use in direct conjunction with a device with features to mitigate the risk of cross-contamination (i.e., an automated contrast injection system, contrast management system, or contrast media transfer set approved or cleared for use with an *Imaging bulk package*). The sterility assurance of the *Imaging bulk package* contents in part is dependent upon the automated contrast injection system, the contrast management system, or the contrast media transfer set.

The *Imaging bulk package* is to be used only in a room designated for radiological procedures that involve intravascular administration of a contrast agent. Using aseptic technique, the *Imaging bulk package* closure must be penetrated only one time with a suitable sterile component of the automated contrast injection system, the contrast management system,or the contrast media transfer set. If the integrity of the *Imaging bulk package* and the delivery system cannot be assured through direct continuous supervision, the *Imaging bulk package* and all associated disposables for the automated contrast injection system, the contrast management system, or the contrast media transfer set should be discarded.

Designation as an *Imaging bulk package* is limited to injection, for injection, or injectable emulsion dosage forms as defined in ⟨1121⟩, *General Nomenclature Forms*. *Imaging bulk packages*, although containing more than one single dose, are exempt from the multiple-dose container volume limit of 30 mL. The contents of the *Imaging bulk package* must have demonstrated the ability to limit the growth of microorganisms over the labeled period of use.

[1] Exceptions may be considered only under conditions described in *Pharmaceutical Compounding—Sterile Preparations* ⟨797⟩.

Where a container is offered as an *Imaging bulk package*, the label must: 1) state prominently "Imaging Bulk Package" and, in juxtaposition with this statement, include the following use statement: "For use only with an automated contrast injection system, contrast management system, or contrast media transfer set approved or cleared for use with this contrast agent in this Imaging Bulk Package"; 2) bear a statement limiting the time frame in which the container may be used once it has been entered, provided it is held under the labeled storage conditions; and 3) bear the statement, "See drug and device labeling for information on devices indicated for use with this Imaging Bulk Package and techniques to help assure safe use".

Noninjection Packaging Systems

Multiple-unit container: A *Container–closure system* that permits withdrawal of successive portions of a noninjection article without changing the safety, strength, quality, or purity of the remaining portion (e.g., bottle of capsules, tablets, oral or topical liquids, and semisolids).

Single-unit container: A *Container–closure system* that holds a quantity of a noninjection article intended for administration as a single dose or a single finished device intended for use promptly after the *Packaging system* is opened.

Unit-dose container: A single-unit *Container–closure system* for an article intended for administration by other than the parenteral route as a single dose.

Unit-of-use container: A *Container–closure system* that contains a specific quantity of an article that is intended to be dispensed as such without further modification except for the addition of appropriate labeling (see ⟨7⟩). It is not permitted to repackage *Unit-of-use containers* for sale.

Miscellaneous

Repackaging: The act of removing a drug product from the original manufacturer's *Packaging system* and placing it into another *Packaging system*, usually one of smaller size.

Repackager: A firm that repackages drug products for distribution (e.g., for resale to distributors, hospitals, or pharmacies). For drug products, this applies to a function that is beyond the regular practice of a pharmacy. The distribution is not patient-specific, in that there are no prescriptions.

Contract packager/contract repackager: A firm that is contracted by another organization, such as a manufacturer, to package bulk into a marketed *Container* of a drug product. A *Contract packager* does not take ownership from the manufacturer and generally receives the assigned expiration date from the manufacturer.

Dispenser: A licensed or registered practitioner who is legally responsible for providing the patient with a preparation that is in compliance with a prescription or a medication order and contains a specific patient label. In addition, dispensers may prepare limited quantities in anticipation of a prescription or medication order from a physician. *Dispensers* are governed by the board of pharmacy of the individual state. The terms "dispenser" and "pharmacy" are used interchangeably.

Beyond-use date: See ⟨7⟩.

Expiration date: See ⟨7⟩.

Black closure system or black bands: The use of a *Black closure system* on a vial (e.g., a black cap overseal and a black ferrule to hold the elastomeric closure) or the use of a *Black band* or series of bands above the constriction on an ampule is prohibited, except for ⟨7⟩, *Labels and Labeling for Injectable Products, Potassium Chloride for Injection Concentrate*.

INJECTION PACKAGING

Packaging for sterile products intended for injection must be validated as meeting the containment, protection, and compatibility requirements that are essential for maintaining the article's strength, quality, and purity. Refer to *Package Integrity Evaluation—Sterile Products* ⟨1207⟩, *Package Integrity Testing in the Product Life Cycle—Test Method Selection and Validation* ⟨1207.1⟩, *Package Integrity Leak Test Technologies* ⟨1207.2⟩, and *Package Seal Quality Test Technologies* ⟨1207.3⟩ for further information regarding sterile product container–closure integrity testing and validation. *Closures* for *Multiple-dose containers* permit the withdrawal of the contents without removal or destruction of the *Closure*. The *Closure* permits penetration by a needle and, upon withdrawal of the needle, closes at once, protecting the contents against contamination. Refer to ⟨381⟩ for *Closure* reseal tests that are useful for screening multiple-dose *Closures* for their reseal properties. Additional testing may be needed to ensure that the specific *Closure* selected for a product package is able to prevent loss of product contents and microbial contamination under anticipated conditions of multiple entry and use. Piggyback *Packaging systems* are usually intravenous infusion *Container–closure systems* that are used to administer a second infusion through a connector of some type or an injection port on the administration set of the first fluid, thereby avoiding the need for another injection site on the patient's body. Piggyback *Packaging systems* also are known as secondary infusion containers.

The volume of injection in a *Single-dose container* provides the amount specified for one-time parenteral administration, and in no case is more than sufficient to permit the withdrawal and administration of 1 L. Preparations intended for intraspinal, intracisternal, or peridural administration are packaged in *Single-dose containers* only. Unless otherwise specified in the individual monograph, a *Multiple-dose container* contains a volume of injection sufficient to permit the withdrawal of NMT 30 mL.

The following injections are exempt from the 1-L restriction of the foregoing requirements relating to packaging:

- Injections packaged for extravascular use as irrigation solutions or peritoneal dialysis solutions
- Injections packaged for intravascular use as parenteral nutrition or as replacement or substitution fluid to be administered continuously during hemofiltration

Injections packaged for intravascular use that may be used for intermittent, continuous, or bolus replacement fluid administration during hemodialysis or other procedures, unless excepted above, must conform to the 1-L restriction. Injections labeled for veterinary use are exempt from the packaging and storage requirements concerning the limitation to single-dose *Packaging systems* and the limitation on the volume of *Multiple-dose containers*.

Packaging for Constitution

Containers, including the *Closures*, for dry solids intended for injection must not interact physically or chemically with the preparation in any manner that alters the strength, quality, or purity beyond the official requirements under the ordinary or customary conditions of handling, shipment, storage, sale, and use. A *Packaging system* for a sterile solid permits the addition of a suitable solvent and withdrawal of portions of the resulting solution or suspension in such manner that the sterility of the product is maintained. Where the assay in a monograph provides a procedure for the sample solution, in which the total withdrawable contents are to be withdrawn from a *Single-dose container* with a hypodermic needle and syringe, the contents are to be withdrawn as completely as possible into a dry hypodermic syringe of a rated capacity not exceeding 3 times the volume to be withdrawn and fitted with a 21-gauge needle NLT 2.5 cm (1 inch) in length. Care must be taken to expel any air bubbles, and the contents are then discharged into a *Container* for dilution and assay.

MEDICAL GAS PACKAGING

Gas cylinder: A metallic *Packaging system* constructed of steel or aluminum and designed to hold medical gases under pressure; these gases may include: *Carbon Dioxide USP*, *Helium USP*, *Medical Air USP*, *Nitrogen NF*, and *Oxygen USP*. As a safety measure, for carbon dioxide, helium, medical air, nitrous oxide, and oxygen, the Pin Index Safety System of matched fittings is recommended for cylinders of Size E or smaller.

ASSOCIATED COMPONENTS

Many *Associated Components* are graduated for measurement and dose administration. *Associated Components* can be packaged with the drug product or sold and purchased separately. It is the responsibility of the manufacturer to ensure that the appropriate measurement and dosing component is provided or that a general purpose component, such as those described in this section, is specified for delivering the appropriate amount/dose with the intended accuracy. Liquid preparations have unique surface and flow characteristics. Consequently, the volume delivered from a measurement/dosing component may vary for each preparation.

The graduated *Associated Components* described in this section are for general use and should be composed of safe materials. Graduated markings should be legible and indelible, and on an extraoral surface that does not contact the product.

The markings on associated components must be in metric units only and limited to a single measurement scale that corresponds with the dosing instructions on the OTC or prescription container label (see *Prescription Container Labeling* ⟨17⟩). Under expected conditions of use, the volume error incurred in measuring an individual dose by means of such graduated components should be NMT 10% of the indicated amount of the preparation with which the graduated component will be used.

Dosing cup: A measuring device consisting of a small cup that may be packaged with oral liquid articles.

Dosing spoon: A measuring device consisting of a bowl and handle that may be packaged with oral liquid articles. The handle may be a graduated tube.

Medicine dropper: A measuring device consisting of a transparent or translucent barrel or tube that is generally fitted with a collapsible bulb. It may be packaged with liquid articles.

Oral syringe: A measuring device consisting of a plunger and barrel made of transparent or translucent plastic material and a seal on the end. It may be packaged with oral liquid articles. The syringe should deliver a measured amount of a liquid drug product.

TEMPERATURE AND STORAGE DEFINITIONS

Freezer: A place in which the temperature is controlled between –25° and –10° (–13° and 14° F). It is noted that, in some instances, articles may have a recommended storage condition below –20° (–4° F). In such cases, the temperature of the storage location should be controlled to ±10° of the recommended storage condition.

Refrigerator: A cold place in which the temperature is controlled between 2° and 8° (36° and 46° F).

Cold: Any temperature not exceeding 8° (46° F).

Cool: Any temperature between 8° and 15° (46° and 59° F). [NOTE—An article for which storage in a cool place is directed may, alternatively, be stored and shipped as refrigerated, unless otherwise specified by the individual monograph.]

Room temperature (also referred to as Ambient temperature)**:** The temperature prevailing in a working environment.

Controlled cold temperature: The temperature maintained thermostatically between 2° and 8° (36° and 46° F), which allows for temperature excursions between 2° and 15° (36° and 59° F) that may be experienced during storage, shipping, and distribution, but not to exceed 24 h, such that the allowable calculated mean kinetic temperature (MKT) is NMT 8° (46° F) with no excursions below 2° (36° F) or above 15° (59° F). These limits (time and temperature) and the calculated MKT must be documented (see *Mean Kinetic Temperature in the Evaluation of Temperature Excursions During Storage and Transportation of Drug Products* ⟨1079.2⟩). Additionally, controlled cold excursions may only occur one time during the possession of the product within the supply chain unless directed otherwise by the manufacturer. The length of time the product is held at 2° and 15° (36° and 59° F) should be supported by stability data. Other limits may be permitted if the manufacturer so instructs as supported by the manufacturer's stability data and/or thermal cycling studies.

Controlled room temperature: The temperature maintained thermostatically that encompasses the usual and customary working environment of 20°–25° (68°–77° F).

MKT may be used during an excursion provided: 1) MKT does not exceed 25° (77° F); 2) excursion between 15° and 30° (59° and 86° F); 3) transient excursions are NMT 40° (104° F); and 4) excursion time is NMT 24 h.[2] These limits (time and temperature) and the calculated MKT must be documented.

[2] Anderson C, Seevers R, Hunt D. The use of mean kinetic temperature to aid evaluation of temperature excursions: proper and improper application. *Pharm Forum.* 2018;44(4). www.usppf.com/pf/pub/index.html.

Articles may be labeled for storage at "controlled room temperature" or at "20°–25°", or other wording based on the same MKT. (See ⟨1079.2⟩.)

An article for which storage at *Controlled room temperature* is directed may, alternatively, be stored and shipped in a cool place or refrigerated, unless otherwise specified in the individual monograph or on the label. Storage time in controlled cold or cool place cannot be used to calculate excursion temperature outside of controlled room temperature ranges.

Warm: Any temperature between 30° and 40° (86° and 104° F).

Excessive heat: Any temperature above 40° (104° F).

Dry place: A place that does not exceed 40% average relative humidity at 20° (68° F) or the equivalent water vapor pressure at other temperatures. The determination may be made by direct measurement at the place. Determination is based on NLT 12 equally spaced measurements that encompass either a season, a year, or, where recorded data demonstrate, the storage period of the article. There may be values of up to 45% relative humidity provided that the average value does not exceed 40% relative humidity. Storage in a *Container* validated to protect the article from moisture vapor, including storage in bulk, is considered a *Dry place*.

Do not refrigerate: The *Container* label will bear an appropriate instruction to protect the article from refrigeration in cases where refrigeration exposes the article to loss of strength or potency or destructive alteration of its characteristics (e.g., precipitation, cloudiness). These risks are increased when a drug product with the storage temperature of 20°–25° (68°–77° F) is formulated at near-maximum solubility.

Protect from freezing: The *Container* label will bear an appropriate instruction to protect the article from freezing in cases where freezing exposes an article to loss of strength or potency or to destructive alteration of its characteristics. These risks are present in addition to the risk that the *Container* may break if exposed to freezing temperatures.

Protect from light: Where light subjects an article to loss of strength or potency or to destructive alteration of its characteristics, the *Container* label bears an appropriate instruction to protect the article from light. The article must be packaged in a light-resistant *Container*.