RULE WORKSHOP AGENDA

Department of Business and Professional Regulation
Division of Drugs, Devices and Cosmetics
May 10, 2018 -10:00 a.m.

Floridays Resort, Orlando-
12562 International Drive, Orlando, FL 32821
321-329-4029

DDC will start the rule workshop on topic #1 at 10:00 a.m. or as soon thereafter as reasonably possible. The rule development workshop on topic #2 will begin at 1:00 p.m. or as soon thereafter as reasonably possible.

1. Exemptions from establishment, security and storage requirements under s. 499.0121, F.S., for prescription drug manufacturer – virtual, non-resident prescription drug manufacturer - virtual, and prescription drug wholesale distributor-broker only permit holders pursuant to section 499.01(2)(a),(c), and (e), Florida Statutes.
   1. Call to Order and Opening Remarks
   2. Public Input on Section 499.01(2)(a),(c) and (e), F.S., regarding Virtual Prescription Drug Manufacturer Permit, Virtual Nonresident Prescription Drug Manufacturer Permit and Prescription Drug Wholesale Distributor-Broker Permit.
   3. Closing Remarks

2. Definition of “solely administrative services” as set forth in section 499.003(48)(t), F.S., and applicable to rule chapters 61N-1 and 61N-2, F.A.C.
   1. Call to Order and Opening Remarks
   2. Public Input on “solely administrative services” as set forth in section 499.003(48)(t), F.S.
   3. Closing Remarks

All interested parties may attend. Participation via teleconference will not be available during the workshop. However, interested parties may view the workshop proceedings via webcast by clicking at the following link at the time indicated in the notices: Click Here to View Meeting.
Notice of Development of Rulemaking

DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION
Drugs, Devices and Cosmetics
RULE NO.: RULE TITLE:
61N-1.0155 Establishment, Security, Storage Exemptions for Virtual Manufacturers and Broker-Only Distributors
PURPOSE AND EFFECT: The purpose of development is create a new rule establishing exemptions from establishment, security and storage requirements under s. 499.0121, F.S., for prescription drug manufacturer-virtual, non-resident prescription drug manufacturer-virtual, and prescription drug wholesale distributor-broker only permit holders pursuant to s. 499.01(2)(a), (c), and (e), F.S.
SUBJECT AREA TO BE ADDRESSED: The subject area to be addressed in this rule is exemptions from establishment, security and storage requirements under s. 499.0121, F.S., for prescription drug manufacturer-virtual, non-resident prescription drug manufacturer-virtual, and prescription drug wholesale distributor-broker only permit holders pursuant to s. 499.01(2)(a), (c), and (e), F.S.
RULEMAKING AUTHORITY: 499.003, 499.01, 499.0121, 499.05(1)(a) FS.
LAW IMPLEMENTED: 499.002, 499.003, 499.01, 499.012, 499.0121, 499.03, 499.05, 499.052 FS.
A RULE DEVELOPMENT WORKSHOP WILL BE HELD AT THE DATE, TIME AND PLACE SHOWN BELOW:
DATE AND TIME: May 10, 2018, 10:00 a.m.
PLACE: Floridays Resort, 12562 International Drive, Orlando, FL 32821 – (407)238-7700
THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE DEVELOPMENT AND A COPY OF THE PRELIMINARY DRAFT, IF AVAILABLE, IS: Dinah Greene, Division of Drugs, Devices and Cosmetics, Department of Business and Professional Regulation, 2601 Blair Stone Road, Tallahassee, Florida 32399-1047; Dinah.Green@myfloridalicense.com; (850)717-1802.
THE PRELIMINARY TEXT OF THE PROPOSED RULE DEVELOPMENT IS NOT AVAILABLE.
Notice of Development of Rulemaking

DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION
Drugs, Devices and Cosmetics
RULE NO.: RULE TITLE:
61N-1.001 General Regulations; Definitions
PURPOSE AND EFFECT: The purpose of the rule development is the adoption of a definition of “solely administrative services” as set forth in s. 499.003(48)(f), F.S., and applicable to Rule Chapters 61N-1 and 61N-2, F.A.C.
SUBJECT AREA TO BE ADDRESSED: The subject area to be addressed in this rule is definitions applicable to chapter 499, F.S., and rule chapters 61N-1 and 61N-2, F.A.C.
RULEMAKING AUTHORITY: 499.003, 499.01, 499.0121, 499.05(1)(a), FS.
LAW IMPLEMENTED: 499.002, 499.003, 499.01, 499.012, 499.0121, 499.03, 499.05, 499.052, FS
A RULE DEVELOPMENT WORKSHOP WILL BE HELD AT THE DATE, TIME AND PLACE SHOWN BELOW:
DATE AND TIME: May 10, 2018, 1:00 p.m.
PLACE: Floridays Resort, Orlando, 12562 International Drive, Orlando, FL 32821 (407)238-7700
THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE DEVELOPMENT AND A COPY OF THE PRELIMINARY DRAFT, IF AVAILABLE, IS: Dinah Greene, Division of Drugs, Devices and Cosmetics, Department of Business and Professional Regulation, 2601 Blair Stone Road, Tallahassee, Florida 32399-1047; Dinah.Greene@myfloridalicense.com; (850)717-1802.
THE PRELIMINARY TEXT OF THE PROPOSED RULE DEVELOPMENT IS NOT AVAILABLE.
The 2017 Florida Statutes

Title XXXIII
REGULATION OF TRADE, COMMERCE, INVESTMENTS, AND SOLICITATIONS

Chapter 499
FLORIDA DRUG AND COSMETIC ACT

499.01 Permits.—

(1) Before operating, a permit is required for each person and establishment that intends to operate as:
(a) A prescription drug manufacturer;
(b) A prescription drug repackager;
(c) A nonresident prescription drug manufacturer;
(d) A nonresident prescription drug repackager;
(e) A prescription drug wholesale distributor;
(f) An out-of-state prescription drug wholesale distributor;
(g) A retail pharmacy drug wholesale distributor;
(h) A restricted prescription drug distributor;
(i) A complimentary drug distributor;
(j) A freight forwarder;
(k) A veterinary prescription drug retail establishment;
(l) A veterinary prescription drug wholesale distributor;
(m) A limited prescription drug veterinary wholesale distributor;
(n) An over-the-counter drug manufacturer;
(o) A device manufacturer;
(p) A cosmetic manufacturer;
(q) A third party logistics provider; or
(r) A health care clinic establishment.

(2) The following permits are established:

(a) Prescription drug manufacturer permit.—A prescription drug manufacturer permit is required for any person that is a manufacturer of a prescription drug and that manufactures or distributes such prescription drugs in this state.

1. A person that operates an establishment permitted as a prescription drug manufacturer may engage in distribution of prescription drugs for which the person is the manufacturer and must comply with s. 499.0121 and all other provisions of this part and rules adopted under this part. The department shall adopt rules for issuing a virtual prescription drug manufacturer permit to a person who engages in the manufacture of prescription drugs but does not make or take physical possession of any prescription drugs. The rules adopted by the department under this section may exempt virtual manufacturers from certain establishment, security, and storage requirements set forth in s. 499.0121.

2. A prescription drug manufacturer must comply with all appropriate state and federal good manufacturing practices.

3. A blood establishment, as defined in s. 381.06014, operating in a manner consistent with the provisions of 21 C.F.R. parts 211 and 600-640, and manufacturing only the prescription drugs described in s. 499.003(48)(j) is not required to be permitted as a prescription drug manufacturer under this paragraph or to register products under s. 499.015.
(b) Prescription drug repackage permit.—A prescription drug repackage permit is required for any person that repackages a prescription drug in this state.
1. A person that operates an establishment permitted as a prescription drug repackage may engage in distribution of prescription drugs repackaged at that establishment and must comply with all of the provisions of this part and the rules adopted under this part that apply to a prescription drug manufacturer.
2. A prescription drug repackage must comply with all appropriate state and federal good manufacturing practices.
(c) Nonresident prescription drug manufacturer permit.—A nonresident prescription drug manufacturer permit is required for any person that is a manufacturer of prescription drugs, unless permitted as a third party logistics provider, located outside of this state or outside the United States and that engages in the distribution in this state of such prescription drugs. Each such manufacturer must be permitted by the department and comply with all of the provisions of a prescription drug manufacturer under this part. The department shall adopt rules for issuing a virtual nonresident prescription drug manufacturer permit to a person who engages in the manufacture of prescription drugs but does not make or take physical possession of any prescription drugs. The rules adopted by the department under this section may exempt virtual nonresident manufacturers from certain establishment, security, and storage requirements set forth in s. 499.0121.
1. A person that distributes prescription drugs for which the person is not the manufacturer must also obtain an out-of-state prescription drug wholesale distributor permit or third party logistics provider permit pursuant to this section to engage in the distribution of such prescription drugs when required by this part. This subparagraph does not apply to a manufacturer that distributes prescription drugs only for the manufacturer of the prescription drugs where both manufacturers are affiliates.
2. Any such person must comply with the licensing or permitting requirements of the jurisdiction in which the establishment is located and the federal act, and any prescription drug distributed into this state must comply with this part. If a person intends to import prescription drugs from a foreign country into this state, the nonresident prescription drug manufacturer must provide to the department a list identifying each prescription drug it intends to import and document approval by the United States Food and Drug Administration for such importation.
(d) Nonresident prescription drug repackage permit.—A nonresident prescription drug repackage permit is required for any person located outside of this state, but within the United States or its territories, that repackages prescription drugs and engages in the distribution of such prescription drugs into this state.
1. A nonresident prescription drug repackage must comply with all of the provisions of this section and the rules adopted under this section that apply to a prescription drug manufacturer.
2. A nonresident prescription drug repackage must be permitted by the department and comply with all appropriate state and federal good manufacturing practices.
3. A nonresident prescription drug repackage must be registered as a drug establishment with the United States Food and Drug Administration.
(e) Prescription drug wholesale distributor permit.—A prescription drug wholesale distributor permit is required for any person who is a wholesale distributor of prescription drugs and that wholesale distributes such prescription drugs in this state. The department may adopt rules for issuing a prescription drug wholesale distributor-broker permit to a person who engages in the wholesale distribution of prescription drugs and does not take physical possession of any prescription drugs.
(f) Out-of-state prescription drug wholesale distributor permit.—An out-of-state prescription drug wholesale distributor permit is required for any person that is a wholesale distributor located outside this state, but within the United States or its territories, which engages in the wholesale distribution of prescription drugs into this state. The out-of-state prescription drug wholesale distributor must maintain at all times a license or permit to engage in the wholesale distribution of prescription drugs in compliance with laws of the state in which it is a resident. If the state from which the wholesale distributor distributes prescription drugs does not require a license to engage in the wholesale distribution of prescription drugs, the distributor must be licensed as a wholesale distributor as required by the federal act.
499.0121 Storage and handling of prescription drugs; recordkeeping.—The department shall adopt rules to implement this section as necessary to protect the public health, safety, and welfare. Such rules shall include, but not be limited to, requirements for the storage and handling of prescription drugs and for the establishment and maintenance of prescription drug distribution records.

1. Establishments.—An establishment at which prescription drugs are stored, warehoused, handled, held, offered, marketed, or displayed must:
   a. Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;
   b. Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;
   c. 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;
   d. Be maintained in a clean and orderly condition; and
   e. Be free from infestation by insects, rodents, birds, or vermin of any kind.

2. Security.—
   a. An establishment that is used for wholesale drug distribution must be secure from unauthorized entry.
      1. Access from outside the premises must be kept to a minimum and be well controlled.
      2. The outside perimeter of the premises must be well lighted.
      3. Entry into areas where prescription drugs are held must be limited to authorized personnel.
   b. An establishment that is used for wholesale drug distribution must be equipped with:
      1. An alarm system to detect entry after hours; however, the department may exempt by rule establishments that only hold a permit as prescription drug wholesale distributor-brokers; and
      2. A security system that will provide suitable protection against theft and diversion. When appropriate, the security system must provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.
   c. Any vehicle that contains prescription drugs must be secure from unauthorized access to the prescription drugs in the vehicle.

3. 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 official compendium.
   a. If no storage requirements are established for a prescription drug, the drug may be held at “controlled” room temperature, as defined in the official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.
   b. Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, or logs must be used to document proper storage of prescription drugs.
   c. The recordkeeping requirements in subsection (6) must be followed for all stored prescription drugs.

4. Examination of materials and records.—
(a) Upon receipt, each outside shipping container must be visually examined for identity and to prevent the acceptance of contaminated prescription drugs that are otherwise unfit for distribution. This examination must be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

(b) Each outgoing shipment must be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have expired or been damaged in storage or held under improper conditions.

(c) The recordkeeping requirements in subsection (6) must be followed for all incoming and outgoing prescription drugs.

(d) Upon receipt, a wholesale distributor must review records required under this section for the acquisition of prescription drugs for accuracy and completeness, considering the total facts and circumstances surrounding the transactions and the wholesale distributors involved.

(5) RETURNED, DAMAGED, OR OUTDATED PRESCRIPTION DRUGS.—

(a)1. Prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated must be quarantined and physically separated from other prescription drugs until they are destroyed or returned to their supplier. A quarantine section must be separate and apart from other sections where prescription drugs are stored so that prescription drugs in this section are not confused with usable prescription drugs.

2. Prescription drugs must be examined at least every 12 months, and drugs for which the expiration date has passed must be removed and quarantined.

(b) Any prescription drugs of which the immediate or sealed outer containers or sealed secondary containers have been opened or used must be identified as such and must be quarantined and physically separated from other prescription drugs until they are destroyed or returned to the supplier.

(c) 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 must 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 distributor must consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the conditions of the drug and its container, carton, or labeling, as a result of storage or shipping.

(d) The recordkeeping requirements in subsection (6) must be followed for all outdated, damaged, deteriorated, misbranded, or adulterated prescription drugs.

(6) RECORDKEEPING.—The department shall adopt rules that require keeping such records of prescription drugs, including active pharmaceutical ingredients, as are necessary for the protection of the public health.

(a) The following persons must maintain business records that include the information specified in paragraph (b):

1. Persons permitted or required to be permitted under this chapter to engage in the manufacture, repackaging, or distribution of active pharmaceutical ingredients or prescription drugs.

2. Persons other than those set forth in subparagraph 1. that engage in the receipt of active pharmaceutical ingredients or prescription drugs.

(b) Business records for persons specified in paragraph (a) must include:

1. The name and address of the seller, and the Florida permit number of the seller if such seller is not exempt from Florida permitting requirements, of the active pharmaceutical ingredient or prescription drug.

2. The address of the location the active pharmaceutical ingredient or prescription drug was shipped from.

3. The distribution date of the active pharmaceutical ingredient or prescription drug.

4. The name, strength, and quantity, and the National Drug Code if such code has been assigned, of the distributed active pharmaceutical ingredient or prescription drug.

5. The name and Florida permit number of the person that purchased the active pharmaceutical ingredient or prescription drug.

6. The financial data, including the unit type and unit price, for the distributions involving active pharmaceutical ingredients or prescription drugs.

7. The date and method of disposition of the active pharmaceutical ingredient or prescription drug.
   (c) Each manufacturer or repackager of medical devices, over-the-counter drugs, or cosmetics must maintain business records that include:
   1. The name and address of the seller or transferor of the product.
   2. The address of the location the product was shipped from.
   3. The date of the sale or distribution of the product.
   4. The name and quantity of the product involved.
   5. The name and address of the person who purchased the product.
   (d) Persons permitted, or required to be permitted, under this chapter to engage in the manufacture, repackaging, or distribution of active pharmaceutical ingredients or prescription drugs; or the manufacture or repackaging of medical devices, over-the-counter drugs, and cosmetics; must establish, maintain, or have the capability to create a current inventory of the active pharmaceutical ingredients, prescription drugs, over-the-counter drugs, cosmetics, and devices at an establishment where activities specified in this paragraph are undertaken and must be able to produce such inventory for inspection by the department within 2 business days.
   (e) Business records required to be kept pursuant to this section, and that are kept at the inspection site or can be immediately retrieved by computer or other electronic means, must be readily available for authorized inspection during the retention period. Records kept at a central location outside of this state which are not electronically retrievable must be made available for inspection within 2 working days after a request by an authorized official of a federal, state, or local law enforcement agency. Records maintained at a central location within this state must be maintained at an establishment that is permitted pursuant to this part, and such records must be readily available for inspection.
   (f) Records required to be kept pursuant to this subsection must be maintained as specified for a period of not less than 6 years from the date of disposition of the active pharmaceutical ingredients, prescription drugs, over-the-counter drugs, medical devices, or cosmetics.
   (g) To the extent that prescription drugs are also products as defined in the federal act, as amended, and the information required by the business records requirements of this section are also included in the tracking and tracing requirements of the federal act, as amended, and departmental rules, the manufacturer, wholesale distributor, repackager, or dispenser must follow both the requirements of the federal act, as amended, and departmental rules.

(7) PRESCRIPTION DRUG PURCHASE LIST.—
   (a) Each wholesale distributor, except for a manufacturer, shall annually provide the department with a written list of all wholesale distributors and manufacturers from whom the wholesale distributor purchases prescription drugs. A wholesale distributor, except a manufacturer, shall notify the department not later than 10 days after any change to either list.
   (b) Such portions of the information required pursuant to this subsection which are a trade secret, as defined in s. 812.081, shall be maintained by the department as trade secret information is required to be maintained under s. 499.051. This paragraph is subject to the Open Government Sunset Review Act in accordance with s. 119.15 and shall stand repealed on October 2, 2021, unless reviewed and saved from repeal through reenactment by the Legislature.

(8) WRITTEN POLICIES AND PROCEDURES.—Wholesale distributors must establish, maintain, and adhere to written policies and procedures, which must 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 distributors must include in their written policies and procedures:
   (a) A procedure whereby 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.
   (b) A procedure to be followed for handling recalls and withdrawals of prescription drugs. Such procedure must be adequate to deal with recalls and withdrawals due to:
1. Any action initiated at the request of the Food and Drug Administration or any other federal, state, or local law enforcement or other government agency, including the department.

2. Any voluntary action by the manufacturer or repackager to remove defective or potentially defective drugs from the market; or

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

(c) A procedure to ensure that wholesale distributors prepare for, protect against, and handle any crisis that affects security or operation of any facility if a strike, fire, flood, or other natural disaster, or a local, state, or national emergency, occurs.

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

9) RESPONSIBLE PERSONS.—Wholesale distributors must establish and maintain lists of officers, directors, managers, designated representatives, and other persons in charge of wholesale drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications.

10) COMPLIANCE WITH FEDERAL, STATE, AND LOCAL LAW.—A wholesale distributor must operate in compliance with applicable federal, state, and local laws and regulations.

(a) A wholesale distributor must allow the department and authorized federal, state, and local officials to enter and inspect its premises and delivery vehicles, and to audit its records and written operating procedures, at reasonable times and in a reasonable manner, to the extent authorized by law.

(b) A wholesale distributor that deals in controlled substances must register with the Drug Enforcement Administration and must comply with all applicable state, local, and federal laws. A wholesale distributor that distributes any substance controlled under chapter 893 must notify the department when registering with the Drug Enforcement Administration pursuant to that chapter and must provide the department with its DEA number.

11) SALVAGING AND REPROCESSING.—A wholesale distributor is subject to any applicable federal, state, or local laws or regulations that relate to prescription drug product salvaging or reprocessing.

12) SHIPPING AND TRANSPORTATION.—The person responsible for shipment and transportation of a prescription drug in a wholesale distribution may use a common carrier; its own vehicle or employee acting within the scope of employment if authorized under s. 499.03 for the possession of prescription drugs in this state; or, in the case of a prescription drug intended for domestic distribution, an independent contractor who must be the agent of the authorized seller or recipient responsible for shipping and transportation as set forth in a written contract between the parties. A person selling a prescription drug for export must obtain documentation, such as a validated airway bill, bill of lading, or other appropriate documentation that the prescription drug was exported. A person responsible for shipping or transporting prescription drugs is not required to maintain documentation from a common carrier that the designated recipient received the prescription drugs; however, the person must obtain such documentation from the common carrier and make it available to the department upon request of the department.

13) DUE DILIGENCE OF SUPPLIERS.—Prior to purchasing any prescription drugs from another wholesale distributor, a prescription drug wholesale distributor, an out-of-state prescription drug wholesale distributor, or a prescription drug repackager must:

(a) Enter an agreement with the selling wholesale distributor by which the selling wholesale distributor will indemnify the purchasing wholesale distributor for any loss caused to the purchasing wholesale distributor related to the purchase of drugs from the selling wholesale distributor which are determined to be counterfeit or to have been distributed in violation of any federal or state law governing the distribution of drugs.

(b) Determine that the selling wholesale distributor has insurance coverage of not less than the greater of 1 percent of the amount of total dollar volume of the prescription drug sales reported to the department under s. 499.012(8)(g) or $500,000; however the coverage need not exceed $2 million.
(c) Obtain information from the selling wholesale distributor, including the length of time the selling wholesale distributor has been licensed in this state, a copy of the selling wholesale distributor’s licenses or permits, and background information concerning the ownership of the selling wholesale distributor, including the experience of the wholesale distributor in the wholesale distribution of prescription drugs.

(d) Verify that the selling wholesale distributor’s Florida permit is valid.

(e) Inspect the selling wholesale distributor’s licensed establishment to document that it has a policies and procedures manual relating to the distribution of drugs, the appropriate temperature controlled environment for drugs requiring temperature control, an alarm system, appropriate access restrictions, and procedures to ensure that records related to the wholesale distribution of prescription drugs are maintained as required by law:

1. Before purchasing any drug from the wholesale distributor, and at least once each subsequent year; or
2. Before purchasing any drug from the wholesale distributor, and each subsequent year obtain a complete copy of the most recent inspection report for the establishment which was prepared by the department or the regulatory authority responsible for wholesale distributors in the state in which the establishment is located.

(14) DISTRIBUTION REPORTING.—Each prescription drug wholesale distributor, out-of-state prescription drug wholesale distributor, retail pharmacy drug wholesale distributor, manufacturer, or repackager that engages in the wholesale distribution of controlled substances as defined in s. 893.02 shall submit a report to the department of its receipts and distributions of controlled substances listed in Schedule II, Schedule III, Schedule IV, or Schedule V as provided in s. 893.03. Wholesale distributor facilities located within this state shall report all transactions involving controlled substances, and wholesale distributor facilities located outside this state shall report all distributions to entities located in this state. If the prescription drug wholesale distributor, out-of-state prescription drug wholesale distributor, retail pharmacy drug wholesale distributor, manufacturer, or repackager does not have any controlled substance distributions for the month, a report shall be sent indicating that no distributions occurred in the period. The report shall be submitted monthly by the 20th of the next month, in the electronic format used for controlled substance reporting to the Automation of Reports and Consolidated Orders System division of the federal Drug Enforcement Administration. Submission of electronic data must be made in a secured Internet environment that allows for manual or automated transmission. Upon successful transmission, an acknowledgment page must be displayed to confirm receipt. The report must contain the following information:

(a) The federal Drug Enforcement Administration registration number of the wholesale distributing location.

(b) The federal Drug Enforcement Administration registration number of the entity to which the drugs are distributed or from which the drugs are received.

(c) The transaction code that indicates the type of transaction.

(d) The National Drug Code identifier of the product and the quantity distributed or received.

(e) The Drug Enforcement Administration Form 222 number or Controlled Substance Ordering System Identifier on all Schedule II transactions.

(f) The date of the transaction.

The department must share the reported data with the Department of Law Enforcement and local law enforcement agencies upon request and must monitor purchasing to identify purchasing levels that are inconsistent with the purchasing entity’s clinical needs. The Department of Law Enforcement shall investigate purchases at levels that are inconsistent with the purchasing entity’s clinical needs to determine whether violations of chapter 893 have occurred.

(15) DUE DILIGENCE OF PURCHASERS.—

(a) Each prescription drug wholesale distributor, out-of-state prescription drug wholesale distributor, and retail pharmacy drug wholesale distributor must establish and maintain policies and procedures to credential physicians licensed under chapter 458, chapter 459, chapter 461, or chapter 466 and pharmacies that purchase or otherwise receive from the wholesale distributor controlled substances listed in Schedule II or Schedule III as provided in s. 893.03. The prescription drug wholesale distributor, out-of-state prescription drug wholesale distributor, or retail pharmacy drug wholesale distributor shall maintain records of such credentialing and make the records available to the department upon request. Such credentialing must, at a minimum, include:
1. A determination of the clinical nature of the receiving entity, including any specialty practice area.
2. A review of the receiving entity's history of Schedule II and Schedule III controlled substance purchasing from the wholesale distributor.
3. A determination that the receiving entity's Schedule II and Schedule III controlled substance purchasing history, if any, is consistent with and reasonable for that entity's clinical business needs.
(b) A wholesale distributor must take reasonable measures to identify its customers, understand the normal and expected transactions conducted by those customers, and identify those transactions that are suspicious in nature. A wholesale distributor must establish internal policies and procedures for identifying suspicious orders and preventing suspicious transactions. A wholesale distributor must assess orders for more than 7,500 unit doses of any one controlled substance in any one month to determine whether the purchase is reasonable. In making such assessments, a wholesale distributor may consider the purchasing entity's clinical business needs, location, and population served, in addition to other factors established in the distributor's policies and procedures. A wholesale distributor must report to the department any regulated transaction involving an extraordinary quantity of a listed chemical, an uncommon method of payment or delivery, or any other circumstance that the regulated person believes may indicate that the listed chemical will be used in violation of the law. The wholesale distributor shall maintain records that document the report submitted to the department in compliance with this paragraph.
(c) A wholesale distributor may not distribute controlled substances to an entity if any criminal history record check for any person associated with that entity shows that the person has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction related to controlled substances, the practice of pharmacy, or the dispensing of medicinal drugs.


Note.—Paragraph (6)(d) former s. 499.013(4).
35) “Permittee” means any person holding a permit issued under this chapter.

36) “Person” means any individual, child, joint venture, syndicate, fiduciary, partnership, corporation, division of a corporation, firm, trust, business trust, company, estate, public or private institution, association, organization, group, city, county, city and county, political subdivision of this state, other governmental agency within this state, and any representative, agent, or agency of any of the foregoing, or any other group or combination of the foregoing.

37) “Pharmacist” means a person licensed under chapter 465.

38) “Pharmacy” means an entity licensed under chapter 465.

39) “Prepackaged drug product” means a drug that originally was in finished packaged form sealed by a manufacturer and that is placed in a properly labeled container by a pharmacy or practitioner authorized to dispense pursuant to chapter 465 for the purpose of dispensing in the establishment in which the prepackaging occurred.

40) “Prescription drug” means a prescription, medicinal, or legend drug, including, but not limited to, finished dosage forms or active pharmaceutical ingredients subject to, defined by, or described by s. 503(b) of the federal act or s. 465.003(8), s. 499.007(13), subsection (31), or subsection (47), except that an active pharmaceutical ingredient is a prescription drug only if substantially all finished dosage forms in which it may be lawfully dispensed or administered in this state are also prescription drugs.

41) “Prescription drug label” means any display of written, printed, or graphic matter upon the immediate container of any prescription drug before it is dispensed to an individual patient pursuant to a prescription of a practitioner authorized by law to prescribe.

42) “Prescription label” means any display of written, printed, or graphic matter upon the immediate container of any prescription drug dispensed pursuant to a prescription of a practitioner authorized by law to prescribe.

43) “Proprietary drug,” or “OTC drug,” means a patent or over-the-counter drug in its unbroken, original package, which drug is sold to the public by, or under the authority of, the manufacturer or primary distributor thereof, is not misbranded under the provisions of this part, and can be purchased without a prescription.

44) “Repackage” includes repacking or otherwise changing the container, wrapper, or labeling to further the distribution of the drug, device, or cosmetic.

45) “Repackager” means a person who repackages. The term excludes pharmacies that are operating in compliance with pharmacy practice standards as defined in chapter 465 and rules adopted under that chapter.

46) “Retail pharmacy” means a community pharmacy licensed under chapter 465 that purchases prescription drugs at fair market prices and provides prescription services to the public.

47) “Veterinary prescription drug” means a prescription drug intended solely for veterinary use. The label of the drug must bear the statement, “Caution: Federal law restricts this drug to sale by or on the order of a licensed veterinarian.”

48) “Wholesale distribution” means the distribution of a prescription drug to a person other than a consumer or patient, or the receipt of a prescription drug by a person other than the consumer or patient, but does not include:

a) Any of the following activities, which is not a violation of s. 499.005(21) if such activity is conducted in accordance with s. 499.01(2)(h):

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

2. The distribution of a prescription drug or an offer to distribute a prescription drug by a charitable organization described in s. 501(c)(3) of the Internal Revenue Code of 1986, as amended and revised, to a nonprofit affiliate of the organization to the extent otherwise permitted by law.

3. The distribution of a prescription drug among hospitals or other health care entities that are under common control. For purposes of this subparagraph, “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, by contract, or otherwise.

4. The distribution of a prescription drug from or for any federal, state, or local government agency or any entity eligible to purchase prescription drugs at public health services prices pursuant to Pub. L. No. 102-585, s. 602 to a contract provider or its subcontractor for eligible patients of the agency or entity under the following conditions:
   a. The agency or entity must obtain written authorization for the distribution of a prescription drug under this subparagraph from the Secretary of Business and Professional Regulation or his or her designee.
   b. The contract provider or subcontractor must be authorized by law to administer or dispense prescription drugs.
   c. In the case of a subcontractor, the agency or entity must be a party to and execute the subcontract.
   d. The contract provider and subcontractor must maintain and produce immediately for inspection all records of movement or transfer of all the prescription drugs belonging to the agency or entity, including, but not limited to, the records of receipt and disposition of prescription drugs. Each contractor and subcontractor dispensing or administering these drugs must maintain and produce records documenting the dispensing or administration. Records that are required to be maintained include, but are not limited to, a perpetual inventory itemizing drugs received and drugs dispensed by prescription number or administered by patient identifier, which must be submitted to the agency or entity quarterly.
   e. The contract provider or subcontractor may administer or dispense the prescription drugs only to the eligible patients of the agency or entity or must return the prescription drugs for or to the agency or entity. The contract provider or subcontractor must require proof from each person seeking to fill a prescription or obtain treatment that the person is an eligible patient of the agency or entity and must, at a minimum, maintain a copy of this proof as part of the records of the contractor or subcontractor required under sub-subparagraph d.
   f. In addition to the departmental inspection authority set forth in s. 499.051, the establishment of the contract provider and subcontractor and all records pertaining to prescription drugs subject to this subparagraph shall be subject to inspection by the agency or entity. All records relating to prescription drugs of a manufacturer under this subparagraph shall be subject to audit by the manufacturer of those drugs, without identifying individual patient information.

   (b) Any of the following activities, which is not a violation of s. 499.005(21) if such activity is conducted in accordance with rules established by the department:
   1. The distribution of a prescription drug among federal, state, or local government health care entities that are under common control and are authorized to purchase such prescription drug.
   2. The distribution of a prescription drug or offer to distribute a prescription drug for emergency medical reasons, which may include transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage. For purposes of this subparagraph, a drug shortage not caused by a public health emergency does not constitute an emergency medical reason.
   3. The distribution of a prescription drug acquired by a medical director on behalf of a licensed emergency medical services provider to that emergency medical services provider and its transport vehicles for use in accordance with the provider’s license under chapter 401.
   4. The donation of a prescription drug by a health care entity to a charitable organization that has been granted an exemption under s. 501(c)(3) of the Internal Revenue Code of 1986, as amended, and that is authorized to possess prescription drugs.
   5. The distribution of a prescription drug by a person authorized to purchase or receive prescription drugs to a person licensed or permitted to handle reverse distributions or destruction under the laws of the jurisdiction in which the person handling the reverse distribution or destruction receives the drug.
   6. The distribution of a prescription drug by a hospital or other health care entity to a person licensed under this part to repackage prescription drugs for the purpose of repackaging the prescription drug for use by that hospital, or other health care entity and other health care entities that are under common control, if ownership of the prescription drugs remains with the hospital or other health care entity at all times. In addition to the
recordkeeping requirements of s. 499.0121(6), the hospital or health care entity that distributes prescription drugs pursuant to this subparagraph must reconcile all drugs distributed and returned and resolve any discrepancies in a timely manner.

c) Intracompany distribution of any drug between members of an affiliate or within a manufacturer.

d) The distribution of a prescription drug by the manufacturer of the prescription drug.

e) The distribution of prescription drug samples by manufacturers' representatives or distributors' representatives conducted in accordance with s. 499.028.

(f) The distribution of a prescription drug by a third-party logistics provider permitted or licensed pursuant to and operating in compliance with the laws of this state and federal law if such third-party logistics provider does not take ownership of the prescription drug.

g) The distribution of a prescription drug, or an offer to distribute a prescription drug by a repackager registered as a drug establishment with the United States Food and Drug Administration that has taken ownership or possession of the prescription drug and repacks it in accordance with this part.

(h) The purchase or other acquisition by a dispenser, hospital, or other health care entity of a prescription drug for use by such dispenser, hospital, or other health care entity.

(i) The distribution of a prescription drug by a hospital or other health care entity, or by a wholesale distributor or manufacturer operating at the direction of the hospital or other health care entity, to a repackager for the purpose of repackaging the prescription drug for use by that hospital, or other health care entity and other health care entities that are under common control, if ownership of the prescription drug remains with the hospital or other health care entity at all times.

(j) The distribution of blood and blood components intended for transfusion. As used in this paragraph, the term “blood” means whole blood collected from a single donor and processed for transfusion or further manufacturing, and the term “blood components” means that part of the blood separated by physical or mechanical means.

(k) The lawful dispensing of a prescription drug in accordance with chapter 465.

(l) The distribution of a prescription drug between pharmacies as a result of a sale, transfer, merger, or consolidation of all or part of the business of the pharmacies from or with another pharmacy, whether accomplished as a purchase and sale of stock or of business assets.

(m) The distribution of minimal quantities of prescription drugs by a licensed retail pharmacy to a licensed practitioner for office use in compliance with chapter 465 and rules adopted thereunder. The department shall adopt rules specifying the quantities of prescription drugs which are considered to be minimal quantities. However, until such rules are adopted, minimal quantities distributed may not exceed 3 percent of the retail pharmacy’s total annual purchases of prescription drugs.

(n) The distribution of an intravenous prescription drug that, by its formulation, is intended for the replenishment of fluids and electrolytes, such as sodium, chloride, and potassium or calories, such as dextrose and amino acids.

(o) The distribution of an intravenous prescription drug used to maintain the equilibrium of water and minerals in the body, such as dialysis solutions.

(p) The distribution of a prescription drug that is intended for irrigation or sterile water, whether intended for such purposes or for injection.

(q) The distribution of an exempt medical convenience kit pursuant to 21 U.S.C. s. 353(e)(4)(M).

(r) A common carrier that transports a prescription drug, if the common carrier does not take ownership of the prescription drug.

(s) Saleable drug returns when conducted by a dispenser.

(t) Facilitating the distribution of a prescription drug by providing solely administrative services, including processing of orders and payments.

(u) The distribution by a charitable organization described in s. 501(c)(3) of the Internal Revenue Code of prescription drugs donated to or supplied at a reduced price to the charitable organization to:
1. A licensed health care practitioner, as defined in s. 456.001, who is authorized under the appropriate practice act to prescribe and administer prescription drugs;

2. A health care clinic establishment permitted pursuant to this chapter; or

3. The Department of Health or the licensed medical director of a government agency health care entity, authorized to possess prescription drugs, for storage and use in the treatment of persons in need of emergency medical services, including controlling communicable diseases or providing protection from unsafe conditions that pose an imminent threat to public health,

if the distributor and the receiving entity receive no direct or indirect financial benefit other than tax benefits related to charitable contributions. Distributions under this section that involve controlled substances must comply with all state and federal regulations pertaining to the handling of controlled substances.

(v) The distribution of medical gas pursuant to part III of this chapter.

(49) “Wholesale distributor” means a person, other than a manufacturer, a manufacturer’s co-licensed partner, a third-party logistics provider, or a repacker, who is engaged in wholesale distribution.


Note.—Subsection (24) former s. 499.029(3)(f); subsection (25) former s. 499.029(3)(h); subsection (26) former s. 499.029(3)(i); subsection (34) former s. 499.029(3)(j); subsection (35) former s. 499.0661(1); subsection (39) former s. 499.029(3)(l); subsection (40) former s. 499.029(3)(m); subsection (46) intro., paragraphs (a), (b) former s. 499.012(1)(d); paragraph (46)(c) former s. 499.012(1)(e); subsection (50) former s. 499.012(1)(c); subsection (51) former s. 499.012(1)(f); subsection (53) former s. 499.012(1)(a); subsection (54) former s. 499.012(1)(b).
61N-1.001 General Regulations; Definitions.

(1) A word or phrase defined in the federal Food, Drug, and Cosmetic Act as defined in paragraph 499.002(1)(b), F.S., shall have the same meaning as in those provisions unless specifically defined otherwise in Chapter 499, F.S., or Rule Chapter 61N-1, F.A.C.

(2) In addition to definitions contained in Sections 499.003, 499.028(1), 499.029(3), and 499.61, F.S., the following definitions apply, to Chapter 499, F.S., and to Rule Chapters 61N-1 and 61N-2, F.A.C.:

(a) “Administer” or “administration” — means the direct application or introduction of a single dose of drugs by a legally authorized person to or into the body of an individual human or animal patient whether by injection, inhalation, ingestion or any other means.

(b) “Authorized absence” — means, for purposes of Section 499.012(16)(d)3., F.S., the physical absence of the designated representative from the permitted establishment, for a cumulative 60 calendar days in any 365 calendar day period for situations such as: the birth of the employee’s child and to care for the newborn child; the placement of a child with the employee for adoption or foster care; the care of a family member (child, spouse, or parent) with a health condition, where the employee is needed to care for the family member; or the employee’s own serious health condition makes the employee unable to perform the functions of the designated representative.

(c) “Authorized recipient” — means a person permitted by or otherwise authorized by Florida law, or by the law of the jurisdiction in which the person receives the prescription drugs, to purchase, own, receive or possess those prescription drugs. The term includes:

1. Any pharmacy licensed pursuant to Chapter 465, F.S., except a Class I Institutional Pharmacy since it is only authorized to possess dispensed prescription drugs and medical oxygen for administration to its patients,

2. Any person who is authorized by the law where the delivery occurs to purchase, own, receive or possess prescription drugs,

3. A licensed ship captain, first officer, or designated medical officer for a vessel engaged in international trade or in trade between ports of the United States or for any merchant vessel belonging to the U.S. Government. The prescription drugs must be intended solely for emergency medical purposes and the wholesale distributor must deliver the prescription drugs directly to the ship or transfer possession to the appropriate ship’s officer as near to the ship as permitted by state and federal law.

(d) “Broker” — means a person participating in the wholesale distribution of a prescription drug by buying, purchasing, or otherwise taking ownership of or title to the prescription drug and selling or transferring, or offering to sell or transfer, ownership of or title to the prescription drug to a person other than the patient or the patient’s agent without taking physical possession of the prescription drug.

(e) “Change in Ownership” — means that there has been a transfer or assignment of a majority of the direct ownership or controlling interest of a permitted establishment or that a lessee of a permitted establishment agrees to or becomes legally liable for the operation of the establishment. A transfer or assignment of a majority of direct ownership or controlling interest of a permitted establishment occurs where an event or other transaction occurs and the result of such event or transaction is that more than 50% of the ownership interest or controlling interest of the permitted establishment resides with a person who prior to the event or transaction did not own or control more than a 50% ownership interest in the permitted establishment. A change in the permitted establishment’s federal identification number or the taxpayer identification number is indicative of a change in ownership, but is not dispositive; a change of ownership could occur where the federal identification number or the taxpayer identification number does not change. For a publicly traded corporation, the changing of officers or directors is not a change in ownership nor is the change in ownership of a parent company provided that such change does not result in more than a 50% change in the ownership or controlling interest of any permitted establishment.

(f) “Chief Executive Officer” — means the owner or the highest ranking official of a corporation, company, or business.

(g) “Electronic signature” — means a method of signing an electronic message that identifies a particular person as the source of the message and indicates the person’s approval of the information contained in the message.

(h) “Established safe and effective indication” — means any indication that has been approved as safe and effective by the FDA, which is generally recognized as safe and effective under conditions established by the FDA, or which is otherwise in compliance with FDA’s regulations.

(i) “FDA” — means the United States Food and Drug Administration.

(j) “Intracompany transfer” — means, pursuant to Section 499.003(34), F.S., a distribution of a specific unit of a prescription
drug between two establishments wholly owned and operated by the same business entity.

(k) “Legend Device or Restricted Device” – means any device which can be dispensed only by the prescription or order of a licensed practitioner and which device on its label bears either the words: “Caution: Federal Law restricts this device to sale by or on the order of a _______,” the blank to be filled with the word “physician,” “dentist,” “veterinarian,” or with the descriptive designation of any practitioner licensed by law to use or prescribe the device; “Caution: Federal Law prohibits dispensing without prescription; “Rx Only;” or “Caution: Florida Law prohibits dispensing without prescription.”

(l) “Minimal quantities” for the purpose of distribution of prescription drugs by a licensed retail pharmacy to a licensed practitioner for office use in compliance with Chapter 465, F.S., pursuant to Section 499.003(48)(m), F.S., means the total annual dollar volume of prescription drugs sold does not exceed five percent of the total dollar volume of that pharmacy’s annual prescription drug sales.

(m) “Point of origin” – means the location from which the manufacturer transfers title, and the location from which the manufacturer transfers possession, if different, of the specific unit of the prescription drug being transferred or sold.

(n) “Practitioner” means a person who is duly licensed and authorized by laws of the state to administer, prescribe, or dispense, as appropriate, a drug or device for medical purposes.

(o) “Principal address” or “principal business address” means the person’s primary place of business.

(p) “Product” – anything produced or made either naturally or artificially.

(q) “Propagation” of a drug – means, as used under the definition of “manufacture” at Section 499.003(29), F.S., for purposes of permitting under Section 499.012, F.S., the holder or holders of a New Drug Application (NDA), an Abbreviated New Drug Application (ANDA), a Biologics License Application (BLA) or a New Animal Drug Application (NADA), provided that such application has become effective or is otherwise approved consistent with Section 499.023, F.S.; a private label distributor for whom the private label distributor’s prescription drugs are originally manufactured and labeled for the distributor and have not been repackaged; or the distribution point for the manufacturer, contract manufacturer or private label distributor whether the establishment is a member of the manufacturer’s affiliated group or is a contract distribution site.

(r) “Provides prescription services to the public” – means, for the purposes of the retail pharmacy wholesaler permit, holding the pharmacy out to the public through prominently displayed pharmacy signs on the exterior of the building and adequate inventory on hand to fill a variety of prescriptions for a variety of medical conditions that would be required by the public generally.

(s) “Readily available” and “readily retrievable” mean that records, either hard copy or computerized, are organized in such a manner that they can be quickly and easily retrieved during an inspection; individual records can be produced within minutes of the request (unless the permitted address is not within the state in which case a 48 hour timeframe is available for producing records). Required records that are kept by automatic data processing systems or other electronic or mechanized recordkeeping systems are kept in such a manner so that they can be separated out from all other records in a reasonable time.

(t) “Regular and systematic supplying of a drug” for the purpose of distributions of prescription drugs between licensed pharmacies operating in end-stage renal dialysis clinics pursuant to Section 499.01(2)(h)5., F.S., means the distribution of that prescription drug where the receiving pharmacy:

1. Has failed to establish a written policy and procedure for forecasting the pharmacy’s prescription drug inventory needs based on the pharmacy’s historical prescription drug dispensing records,

2. Has failed to establish and maintain an inventory of prescription drugs based on historical prescription drug dispensing records; and,

3. Has implemented a business practice where a prescription drug shortage is resolved primarily by obtaining prescription drugs from another pharmacy under common ownership.

(u) “Repackaging or otherwise changing the container, wrapper, or labeling to further the distribution” means:

1. Altering a packaging component that is or may be in direct contact with the drug, device, or cosmetic. For example, repackaging from bottles of 1000 to bottles of 100.

2. Altering a manufacturer’s package for sale under a label different from the manufacturer. For example, a kit that contains an injectable vaccine from manufacturer A; a syringe from manufacturer B; alcohol from manufacturer C; and sterile gauze from manufacturer D packaged together and marketed as an immunization kit under a label of manufacturer Z.

3. Altering a package of multiple-units, which the manufacturer intended to be distributed as one unit, for sale or transfer to a person engaged in the further distribution of the product. This does not include:

   a. Selling or transferring an individual unit which is a fully labeled self-contained package that is shipped by the manufacturer in
multiple units, or

b. Selling or transferring a fully labeled individual unit, by adding the package insert, by a person authorized to distribute prescription drugs to an institutional pharmacy permit, health care practitioner or emergency medical service provider for the purpose of administration and not for dispensing or further distribution.

(v) “Rx” – means prescription.

(w) “Sale” – includes any transfer of title or ownership whether by barter, exchange or gift.

(x) “Separate and distinct cosmetic product” – means a cosmetic product for that establishment which is, or will be sold, distributed, or given away. The adding of color, flavor, or scents does not make a separate and distinct cosmetic product for each variation.

(y) “Separate and distinct device product” – means a device product in its finished form for that manufacturer which is, or will be sold, distributed, or given away. The function or use of the device determines whether a device is separate and distinct.

(z) “Separate and distinct drug product” – means a drug product in the finished form and strength for that manufacturer which is, or will be sold, distributed or given away.

(aa) “Specific unit of a prescription drug” – means the individual saleable unit of a specific prescription drug being transferred or sold, which is capable of being serialized to contain its own serial number, which drug is identified by name, strength, dosage form, container size, and lot number.

(bb) “State Current Good Manufacturing Practices” means current good manufacturing practices and quality system regulations as prescribed as of 6/1/2015 in Title 21 Code of Federal Regulations, Parts 210, 211, 212, 600-610, and 820, and the federal guidelines which are incorporated by reference herein and made a part of this rule, https://www.frlrules.org/Gateway/reference.asp?No=Ref-06161, and the requirements of this chapter. Current good manufacturing practices for cosmetics means the requirements for manufacturing cosmetics as set forth in Rule 61N-1.010, F.A.C.

(cc) “Unapproved new drug” – means any drug which has not been approved or otherwise authorized for use under the federal act, 21 U.S.C. ss. 301 et seq., and the regulations promulgated thereunder or which does not have a Notice of Claimed Investigational Exemption on file with the United States Food and Drug Administration.

(dd) “Usual course of business as carriers” – means for purposes of commercial airlines, the purchase, receipt, distribution and storage of prescription drugs for emergency medical reasons, which includes:

1. The transportation of a prescription drug aboard a commercial aircraft where the drug is required by 14 CFR 121.803 (and appendix A to 14 CFR part 121), to be on board the aircraft as part of an approved emergency medical kit; and,

2. The purchase of the prescription drug by the commercial airline, and receipt of the prescription drug by the commercial airline at an establishment operated by the airline, provided that, the prescription drug is sold and provided to the commercial airline by a person and establishment that is licensed to engage in wholesale distribution of prescription drugs. The recordkeeping requirements of subsections 61N-1.012(1), (2), F.A.C., apply to all distributions of prescription drugs under this sub-sub paragraph.

In all such distributions to commercial airlines, the recipient’s license number shall be the registration number assigned to the carrier by the Federal Aviation Administration.

(ee) “Valid client-veterinarian relationship” – means one in which (1) a veterinarian has assumed the responsibility for making medical judgments regarding the health of an animal and the need for medical treatment, and the client (the owner or other caretaker of the animal or animals) has agreed to follow the instructions of the veterinarian; (2) there is sufficient knowledge of the animal(s) by the veterinarian to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s); and (3) the veterinarian is readily available for follow-up in case of adverse reactions or failure of the regimen of therapy. Such a relationship can exist only when the veterinarian has recently seen and is personally acquainted with the keeping and care of the animal(s) by virtue of examination of the animal(s), and/or by medically appropriate and timely visits to the premises where the animal(s) are kept.

(ff) “Verifiable account” – means a number issued by the manufacturer to a wholesaler when the wholesaler sets up an account with the manufacturer for the purchase of a prescription drug from that manufacturer that uniquely identifies the wholesaler and that is to be used on a recurring basis.

(gg) “Wholesaler” – means a person who engages in the wholesale distribution of a prescription drug.

Rulemaking Authority 499.003(48)(m), 499.024, 499.025(5), 499.012(2), (3), (4), 499.012(16), 499.012(5), 499.012(12), 499.025, 499.03(4), 499.05 FS. Law Implemented 499.003, 499.005, 499.0034, 499.006, 499.007, 499.008, 499.009, 499.01, 499.012, 499.0121, 499.015, 499.023, 499.024, 499.025, 499.028, 499.03, 499.033, 499.035, 499.039, 499.041, 499.05, 499.051, 499.052, 499.06, 499.066, 499.067, 499.61, 499.62, 499.63,
61N-1.028 Product Tracking and Tracing – Definitions.

The following definitions apply to the product tracking and tracing requirements set forth in Rules 61N-1.029, 61N-1.030, 61N-1.031 and 61N-1.032, F.A.C.

(1) “AFFILIATE” means a business entity that has a relationship with a second business entity if, directly or indirectly:
   (a) One business entity controls, or has the power to control, the other business entity; or
   (b) A third party controls, or has the power to control, both of the business entities.

(2) “AUTHORIZED” means:
   (a) A manufacturer or repackager, registered as a drug establishment with the FDA;
   (b) A wholesale distributor, having a valid license under Florida law or federal law, and complying with the licensure reporting requirements under 21 U.S.C. s. 353(e), (as of 12/1/15) which is incorporated by reference herein, http://www.flrules.org/Gateway/reference.asp?No=Ref-06713;
   (c) A third-party logistics provider, having a valid license under Florida law or federal law, and complying with the licensure reporting requirements under 21 U.S.C. s. 360eee-3(b) (as of 12/1/15) which is incorporated by reference herein, http://www.flrules.org/Gateway/reference.asp?No=Ref-06714; and,
   (d) A dispenser, having a valid license under Florida law.

(3) “DISPENSER” means a retail pharmacy, hospital pharmacy, a group of chain pharmacies under common ownership and control that do not act as a wholesale distributor, or any other person authorized by law to dispense or administer prescription drugs, and the affiliated warehouses or distribution centers of such entities under common ownership and control that do not act as a wholesale distributor. Dispenser does not include a person who dispenses only products to be used in animals when the product is dispensed on the lawful written or oral order of a licensed veterinarian within the context of a veterinarian-client-patient relationship.

(4) “DISPOSITION” means, with respect to a product within the possession or control of an entity, the removal of such product from the pharmaceutical distribution supply chain, which may include disposal or return of the product for disposal or other handling or actions, such as retaining a sample of the product for further additional physical examination or laboratory analysis of the product by a manufacturer or regulatory or law enforcement agency.

(5) “DISTRIBUTE” or “DISTRIBUTION” means to sell, purchase, trade, deliver, handle, store, or receive a product. The term does not mean to administer or dispense and does not include the billing and invoicing activities that commonly follow a wholesale distribution transaction.

(6) “EXCLUSIVE DISTRIBUTOR” means the wholesale distributor that directly purchased the product from the manufacturer and is the sole distributor of that manufacturer’s product to a subsequent repackager, wholesale distributor, or dispenser.

(7) “GRANDFATHERED” means, with respect to a product, a product that is not labeled with a product identifier and that entered the pharmaceutical distribution supply chain on or before March 1, 2016.

(8) “HOMOGENOUS CASE” means a sealed case containing only product that has a single National Drug Code number belonging to a single lot.

(9) “ILLEGITIMATE PRODUCT” means a product that:
   (a) Is counterfeit, diverted, or stolen;
   (b) Is intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;
   (c) Is the subject of a fraudulent transaction; or
   (d) Appears unfit for distribution such that the product would likely result in serious adverse health consequences or death to humans.

(10) “LICENSED” means having a valid license in accordance with Florida law. For the purposes of Rules 61N-1.028, 61N-1.029, 61N-1.030, 61N-1.031 and 61N-1.032, F.A.C., a dispenser is considered “licensed” if the dispenser has a valid license under Florida law.

(11) “MANUFACTURER” means:
   (a) A person that holds an application approved under 21 U.S.C. 355 (as of 12/1/15) which is incorporated by reference herein, http://www.flrules.org/Gateway/reference.asp?No=Ref-06715, or a license issued under section 351 of the Public Health Service Act (42 U.S.C. s. 262) (as of 12/1/15) which is incorporated by reference herein, http://www.flrules.org/Gateway/reference.asp?No=Ref-06716, for such product, or if such product is not the subject of an approved application or license, the person who manufactured the product;
(b) A co-licensed partner or affiliate of a person described in paragraph 61N-1.028(11)(a), F.A.C., that obtains the product directly from a person described in this paragraph or paragraph 61N-1.028(11)(a) or 61N-1.028(11)(e), F.A.C.; or

c) An affiliate of a person described in paragraph 61N-1.028(11)(a) or 61N-1.028(11)(b), F.A.C., that receives the product directly from a person described in this paragraph or paragraph 61N-1.028(11)(a) or 61N-1.028(11)(b), F.A.C.

(12) “MEDICAL CONVENIENCE KIT” means packages or units that contain combination products as defined in 21 C.F.R. s. 3.2(e)(2) (as of 12/1/15) which is incorporated by reference herein, http://www.flnrules.org/Gateway/reference.asp?No=Ref-06712. A “medical convenience kit” is considered an “exempt medical convenience kit” if it is a collection of finished medical devices, which may include a product or biological product, assembled in kit form strictly for the convenience of the purchaser or user, and:

(a) The kit is assembled in an establishment that is registered with the Food and Drug Administration as a device manufacturer in accordance with 21 U.S.C. s. 360(b)(2) (as of 12/1/15) which is incorporated by reference herein, http://www.flnrules.org/Gateway/reference.asp?No=Ref-06717;


(c) If the kit includes a product:

1. The person that manufactures the kit purchased the product directly from the pharmaceutical manufacturer or from a wholesale distributor that purchased the product directly from the pharmaceutical manufacturer and did not alter the primary container or label of the product as purchased from the manufacturer or wholesale distributor; and,

2. The product is:

a. An intravenous solution intended for the replenishment of fluids and electrolytes;

b. A product intended to maintain the equilibrium of water and minerals in the body;

c. A product intended for irrigation or reconstitution;

d. An anesthetic;

e. An anticoagulant;

f. A vasoconstrictor or

g. A sympathomimetic.

(13) “PACKAGE” means the smallest individual saleable unit of product for distribution by a manufacturer or repackager that is intended by the manufacturer for ultimate sale to the dispenser of such product. For purposes of this paragraph, an “individual saleable unit” is the smallest container of product introduced into commerce by the manufacturer or repackager that is intended by the manufacturer or repackager for individual sale to a dispenser.


(15) “PRODUCT IDENTIFIER” means a standardized graphic that includes, in both human readable form and on a machine-readable data carrier, the standardized numerical identifier, lot number, and expiration date of the product. Unless authorized by the department, the applicable data shall be included in a 2-dimensional data matrix barcode when affixed to, or imprinted upon a package and homogeneous case.

(16) “QUARANTINE” means the storage or identification of a product, to prevent distribution or transfer of the product, in a physically separate area clearly identified for such use.
(17) “REPACKAGER” means a person who owns or operates an establishment that repacks and relabels a product or package for further sale or distribution without a further transaction.

(18) “RETURN” means providing product to the authorized immediate trading partner from which such product was purchased or received, or to a returns processor or reverse logistics provider for handling of such product.

(19) “RETURNS PROCESSOR or REVERSE LOGISTICS PROVIDER” means a person who owns or operates an establishment that dispositions or otherwise processes saleable or nonsaleable product received from an authorized trading partner such that the product may be processed for credit to the purchaser, manufacturer, or seller or disposed of for no further distribution.

(20) “SPECIFIC PATIENT NEED” refers to the transfer of a product from one pharmacy to another to fill a prescription for an identified patient. Such term does not include the transfer of a product from one pharmacy to another for the purpose of increasing or replenishing stock in anticipation of a potential need.

(21) “STANDARDIZED NUMERICAL IDENTIFIER” means a set of numbers or characters used to uniquely identify each package or homogenous case that is composed of the National Drug Code that corresponds to the specific product (including the particular package configuration) combined with a unique alphanumeric serial number of up to 20 characters.

(22) “SUSPECT PRODUCT” means a product for which there is reason to believe that such product:

(a) Is potentially counterfeit, diverted, or stolen;
(b) Is potentially intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;
(c) Is potentially the subject of a fraudulent transaction; or
(d) Appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans.

(23) “THIRD PARTY LOGISTICS PROVIDER” means an entity that provides or coordinates warehousing, or other logistics services of a product in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of a product, but does not take ownership of the product, nor have responsibility to direct the sale or disposition of the product.

(24) “TRADING PARTNER” means:

(a) A manufacturer, repacker, wholesale distributor, or dispenser from whom a manufacturer, repacker, wholesale distributor, or dispenser accepts direct ownership of a product or to whom a manufacturer, repacker, wholesale distributor, or dispenser transfers direct ownership of a product; or

(b) A third-party logistics provider from whom a manufacturer, repacker, wholesale distributor, or dispenser accepts direct possession of a product or to whom a manufacturer, repacker, wholesale distributor, or dispenser transfers direct possession of a product.

(25) “TRANSACTION”.

(a) The term “transaction” means the transfer of product between persons in which a change of ownership occurs.

(b) EXEMPTIONS. The term “transaction” does not include:

1. Intracompany distribution of any product between members of an affiliate or within a manufacturer;
2. The distribution of a product among hospitals or other health care entities that are under common control;
3. The distribution of a product for emergency medical reasons including a public health emergency declaration pursuant to section 319 of the Public Health Service Act (42 U.S.C. s. 247d) (as of 12/1/15) which is incorporated by reference herein, http://www.frlrules.org/Gateway/reference.asp?No=Ref-06724, except that a drug shortage not caused by a public health emergency shall not constitute an emergency medical reason;
5. The distribution of product samples by a manufacturer or a licensed wholesale distributor in accordance with 21 U.S.C. s. 353(d) (as of 12/1/15) which is incorporated by reference herein, http://www.frlrules.org/Gateway/reference.asp?No=Ref-06726;
6. The distribution of blood or blood components intended for transfusion;
7. The distribution of minimal quantities of product by a licensed retail pharmacy to a licensed practitioner for office use;
8. The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization described in 26 U.S.C. s. 501(c)(3) (Internal Revenue Code) (as of 12/1/15) which is incorporated by reference herein, http://www.frlrules.org/Gateway/reference.asp?No=Ref-06727, to a nonprofit affiliate of the organization to the extent otherwise permitted by law;
9. The distribution of a product pursuant to the sale or merger of a pharmacy or pharmacies or a wholesale distributor or wholesale distributors, except that any records required to be maintained for the product shall be transferred to the new owner of the pharmacy or pharmacies or wholesale distributor or wholesale distributors;


11. Products transferred to or from any facility that is licensed by the Nuclear Regulatory Commission or by a State pursuant to an agreement with such Commission under section 274 of the Atomic Energy Act of 1954 (42 U.S.C. s. 2021) (as of 12/1/15) which is incorporated by reference herein, http://www.flrules.org/Gateway/reference.asp?No=Ref-06720.


   a. A product comprised of a device and 1 or more other regulated components (such as a drug/device, biologic/device, or drug/device/biologic) that are physically, chemically, or otherwise combined or mixed and produced as a single entity;
   b. 2 or more separate products packaged together in a single package or as a unit and comprised of a drug and device or device and biological product; or
   c. 2 or more finished medical devices plus one or more drug or biological products that are packaged together in a “medical convenience kit”;

13. The distribution of an “exempt medical convenieent kit” as set forth in subsection 61N-1.028(12), F.A.C.;

14. The distribution of an intravenous product that, by its formulation, is intended for the replenishment of fluids and electrolytes (such as sodium, chloride, and potassium) or calories (such as dextrose and amino acids);

15. The distribution of an intravenous product used to maintain the equilibrium of water and minerals in the body, such as dialysis solutions;

16. The distribution of a product that is intended for irrigation, or sterile water, whether intended for such purposes or for injection;

17. The distribution of a medical gas (as defined in 21 U.S.C. s. 360ddd) (as of 12/1/15) which is incorporated by reference herein, http://www.flrules.org/Gateway/reference.asp?No=Ref-06721; or


(26) “TRANSACTION HISTORY” means a statement in paper or electronic form, including the transaction information for each prior transaction going back to the manufacturer of the product. The transaction history for a grandfathered product begins with the owner of the product on January 1, 2015.

(27) “TRANSACTION INFORMATION” means:

   a. The proprietary or established name or names of the product;
   b. The strength and dosage form of the product;
   c. The National Drug Code number of the product;
   d. The container size;
   e. The number of containers;
   f. The lot number of the product;
   g. The date of the transaction;
   h. The date of the shipment, if more than 24 hours after the date of the transaction;
   i. The business name and address of the person from whom ownership is being transferred; and,
   j. The business name and address of the person to whom ownership is being transferred.

(28) “TRANSACTION STATEMENT” means a statement, in paper or electronic form, that the entity transferring ownership in a transaction:

   a. Is authorized as required under this chapter;
   b. Received the product from a person that is authorized as defined in subsection 61N-1.028(2), F.A.C.;
(c) Received transaction information and a transaction statement from the prior owner of the product, as required under Rules 61N-1.028, 61N-1.029, 61N-1.030, 61N-1.031 and 61N-1.032, F.A.C.;

(d) Did not knowingly ship a suspect or illegitimate product;

(e) Had systems and processes in place to comply with verification requirements under Rules 61N-1.028, 61N-1.029, 61N-1.030, 61N-1.031 and 61N-1.032, F.A.C.;

(f) Did not knowingly provide false transaction information; and,

(g) Did not knowingly alter the transaction history.

The owner of a grandfathered product is exempt from asserting receipt of transaction information and transaction statement from the prior owner.

(29) “VERIFICATION” or “VERIFY” means determining whether the product identifier affixed to, or imprinted upon, a package or homogeneous case corresponds to the standardized numerical identifier or lot number and expiration date assigned to the product by the manufacturer or the repackager.

(30) “WHOLESALE DISTRIBUTION” means the distribution of a drug subject to 21 U.S.C. s. 353(b) (as of 12/1/15) which is incorporated by reference herein, http://www.frules.org/Gateway/reference.asp?No=Ref-06723, to a person other than a consumer or patient, or receipt of a drug subject to 21 U.S.C. s. 353(b) (as of 12/1/15) which is incorporated by reference herein, http://www.frules.org/Gateway/reference.asp?No=Ref-06723, by a person other than the consumer or patient, but does not include:

(a) Intracompany distribution of any drug between members of an affiliate or within a manufacturer;

(b) The distribution of a drug, or an offer to distribute a drug among hospitals or other health care entities which are under common control;

(c) The distribution of a drug or an offer to distribute a drug for emergency medical reasons, including a public health emergency declaration pursuant to 42 U.S.C. s. 247d (section 319 of the Public Health Service Act) (as of 12/1/15) which is incorporated by reference herein, http://www.frules.org/Gateway/reference.asp?No=Ref-06724, except that, for purposes of this paragraph, a drug shortage not caused by a public health emergency shall not constitute an emergency medical reason;

(d) The dispensing of a drug pursuant to a prescription executed in accordance with 21 U.S.C. s. 353(b)(1) (as of 12/1/15) which is incorporated by reference herein, http://www.frules.org/Gateway/reference.asp?No=Ref-06725;

(e) The distribution of minimal quantities of drug by a licensed community pharmacy that is a retail pharmacy to a licensed practitioner for office use;

(f) The distribution of a drug or an offer to distribute a drug by a charitable organization to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(g) The purchase or other acquisition by a dispenser, hospital, or other health care entity of a drug for use by such dispenser, hospital, or other health care entity;

(h) The distribution of a drug by the manufacturer of such drug;

(i) The receipt or transfer of a drug by an authorized third-party logistics provider provided that such third-party logistics provider does not take ownership of the drug;

(j) A common carrier that transports a drug, provided that the common carrier does not take ownership of the drug;

(k) The distribution of a drug, or an offer to distribute a drug by an authorized repackager that has taken ownership or possession of the drug and repacks it in accordance with 21 U.S.C. s. 360eee-1(e) (as of 12/1/15) which is incorporated by reference herein, http://www.frules.org/Gateway/reference.asp?No=Ref-06732.

(l) Saleable drug returns when conducted by a dispenser;

(m) The distribution of an “exempt medical convenience kit” as set forth in subsection 61N-1.028(12), F.A.C.;

(n) The distribution of an intravenous drug that, by its formulation, is intended for the replenishment of fluids and electrolytes (such as sodium, chloride, and potassium) or calories (such as dextrose and amino acids);

(o) The distribution of an intravenous drug used to maintain the equilibrium of water and minerals in the body, such as dialysis solutions;

(p) The distribution of a drug that is intended for irrigation, or sterile water, whether intended for such purposes or for injection;


(r) Facilitating the distribution of a product by providing solely administrative services, including processing of orders and payments; or
(3) The transfer of a product by a hospital or other health care entity, or by a wholesale distributor or manufacturer operating at the direction of the hospital or other health care entity, to a repackager described in 21 U.S.C. s. 360eee(16)(B) (as of 12/1/15) which is incorporated by reference herein, http://www.frlrules.org/Gateway/reference.asp?No=Ref-06732, and registered under 21 U.S.C. s. 360 (as of 12/1/15) which is incorporated by reference herein, http://www.frlrules.org/Gateway/reference.asp?No=Ref-06731, for the purpose of repackaging the drug for use by that hospital, or other health care entity and other health care entities that are under common control, if ownership of the drug remains with the hospital or other health care entity at all times.

(31) "WHOLESALE DISTRIBUTOR" means a person (other than a manufacturer, a manufacturer's co-licensed partner, a third-party logistics provider, or repackager) engaged in wholesale distribution.

Rulemaking Authority 499.0121, 499.05 FS. Law Implemented 499.002, 499.0121, 499.05, 499.052 FS. History--New 5-16-16.