

**AGENDA**  
**Department of Business and Professional Regulation**  
**Drug Wholesale Distributor Advisory Council**  
**Professions Board Room**  
**1940 N. Monroe Street**  
**Tallahassee, FL 32399**

**Conference Call Number 888-670-3525**  
**Conference Code 9259887749**

**August 6, 2015**  
**9:30 a.m.**

Council Members:

Gary Cacciatore, Pharm.D., J.D., Chair,  
Primary Prescription Drug Wholesalers  
Mike Ayotte, Vice Chair, Retail Pharmacy  
Steve Mays, Primary Prescription Drug Wholesalers  
Scott Brock, Pharmaceutical Manufacturers  
Jenn Ungru, Agency for Health Care Administration  
Dean Ellis, Secondary Prescription Drug Wholesalers  
William Mahoney, Primary Prescription Drug Wholesalers  
Patrick Barnes, Hospital Pharmacist  
Michelle Renae Mendez, DO, Physician  
Jeenu Phillips -Board of Pharmacy  
Peter Hart – Airgas Inc.

DBPR Staff:

Reggie Dixon, Division Director  
Division of Drugs, Devices and Cosmetics Program  
Ken Lawson, Secretary  
Tim Vaccaro, Deputy Secretary  
Renee Alsobrook, Compliance Manager  
Dinah Greene, Controlled Substance Reporting  
Rebecca Burnett, Regulatory Supervisor  
Amy Bennett, Office Manager

**Call to Order: Gary Cacciatore, PharmD.,J.D., Chair**

**TAB 1: Approval of Minutes –May 14, 2015**

**TAB 2: Chair's Report – Gary Cacciatore, PharmD, JD**

1. Florida Board of Pharmacy Controlled Substances Standards Committee.
2. The Drug Supply Chain Security Act Overview Update  
Heather Zenk, VP, Secure Supply Chain

**TAB 3: Division Director's Report – Reginald Dixon**

1. DDC Rules Report
2. 2016 DDC Potential Legislative Proposals

**TAB 4: Other Business**

2016 Meeting Dates

## Notice of Meeting/Workshop Hearing

### **DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION**

#### **Drugs, Devices and Cosmetics**

The Division of Drugs, Devices and Cosmetics announces a public meeting to which all persons are invited.

DATE AND TIME: August 6, 2015, 9:30 a.m.

PLACE: Department of Business and Professional Regulation, Professions Board Room, 1940 N. Monroe Street, Tallahassee, FL 32399,

Conference call: number: 1(888)670-3525, conference code: 9259887749

GENERAL SUBJECT MATTER TO BE CONSIDERED: General Business

A copy of the agenda may be obtained by contacting: Dinah Greene, Division of Drugs, Devices and Cosmetics, 1940 N. Monroe Street, Suite 26A, Tallahassee, FL 32399, (850)717-1800.

Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the agency at least 10 days before the workshop/meeting by contacting: Dinah Greene, Division of Drugs, Devices and Cosmetics, 1940 N. Monroe Street, Suite 26A, Tallahassee, FL 32399, (850)717-1800. If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770 (Voice).

If any person decides to appeal any decision made by the Board with respect to any matter considered at this meeting or hearing, he/she will need to ensure that a verbatim record of the proceeding is made, which record includes the testimony and evidence from which the appeal is to be issued.

For more information, you may contact: Dinah Greene, Division of Drugs, Devices and Cosmetics, 1940 N. Monroe Street, Suite 26A, Tallahassee, FL 32399, (850)717-1800.

**TAB 1: APPROVAL OF MINUTES – MAY 14, 2015**

**DRUG WHOLESALE DISTRIBUTOR ADVISORY COUNCIL**  
**Draft Meeting Minutes**  
**May 14, 2015**  
**9:30 a.m.**

**9:30 a.m. Call to Order by Gary Cacciatore, Chair**

The meeting was called to order by the Chair.

**The following members were present:**

Steve Mays, Scott Brock, Dean Ellis, Bill Mahoney, Patrick Barnes, Gary Cacciatore, Jenn Ungru, Jeenu Philip, Mr. Hart and Mike Ayotte. Dr. Mendez was absent.

**TAB 1: Approval of February 19, 2015, Meeting Minutes**

**Motion by:** Mr. Barnes made a motion to approve, Seconded by: Mr. Brock.  
Motion Carried

**TAB 2: Chair's Report – Gary Cacciatore, PharmD, JD**

**1. Board of Pharmacy**

Mr. Cacciatore informed the council that the Board of Pharmacy has formed a committee to address the ability for patients to obtain controlled substances. Mr. Cacciatore stated he will be a member of the committee.

The Board of Pharmacy will be holding a meeting on June 9, 2015 in Orlando if you are interested in attending.

Mr. Phillips stated he will also be a part of the committee and some of the key points for discussion will be what pharmacies use as "red flags" when filling prescriptions.

Mr. Barnes asked Mr. Cacciatore if he will provide updates to the council.

Mr. Cacciatore stated that he would update on any progress.

**TAB 3: Executive Director's Report – Reginald Dixon**

**1. DDC Rules**

Mr. Dixon gave a briefing on the rules report and what will be the next step in the process.

**2. DDC Limited Quantities Workshop Results**

Mr. Dixon gave a briefing on the results of the workshop. Mr. Dixon advised the council that the Division has been provided some language from the workshop.

The division will be hosting two workshops on June 10, 2015.

The first one is to further clarify the language for Limited Quantities and the second to gather language for 61N-1.027 Distribution of Emergency Use Oxygen.

**TAB 4: Other Business**

Mr. Cacciatore encouraged the council and audience to submit any topics they would like to discuss for the next meeting.

Mr. Cacciatore stated with no other business, I will entertain a motion to adjourn.

Mr. Hart made a motion to adjourn, seconded by Mr. Brock. Meeting Adjourned

## **TAB 2: CHAIR'S REPORT – GARY CACCIATOR**

- 1. FLORIDA BOARD OF PHARMACY  
CONTROLLED SUBSTANCES STANDARDS COMMITTEE**

(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 greater than 5,000 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.

**TAB 2: CHAIR'S REPORT – GARY CACCIATORE**

**2. THE DRUG SUPPLY CHAIN SECURITY ACT OVERVIEW UPDATE  
HEATHER ZENK, VP, SECURE SUPPLY CHAIN**



# The Drug Supply Chain Security Act (DSCSA) Update

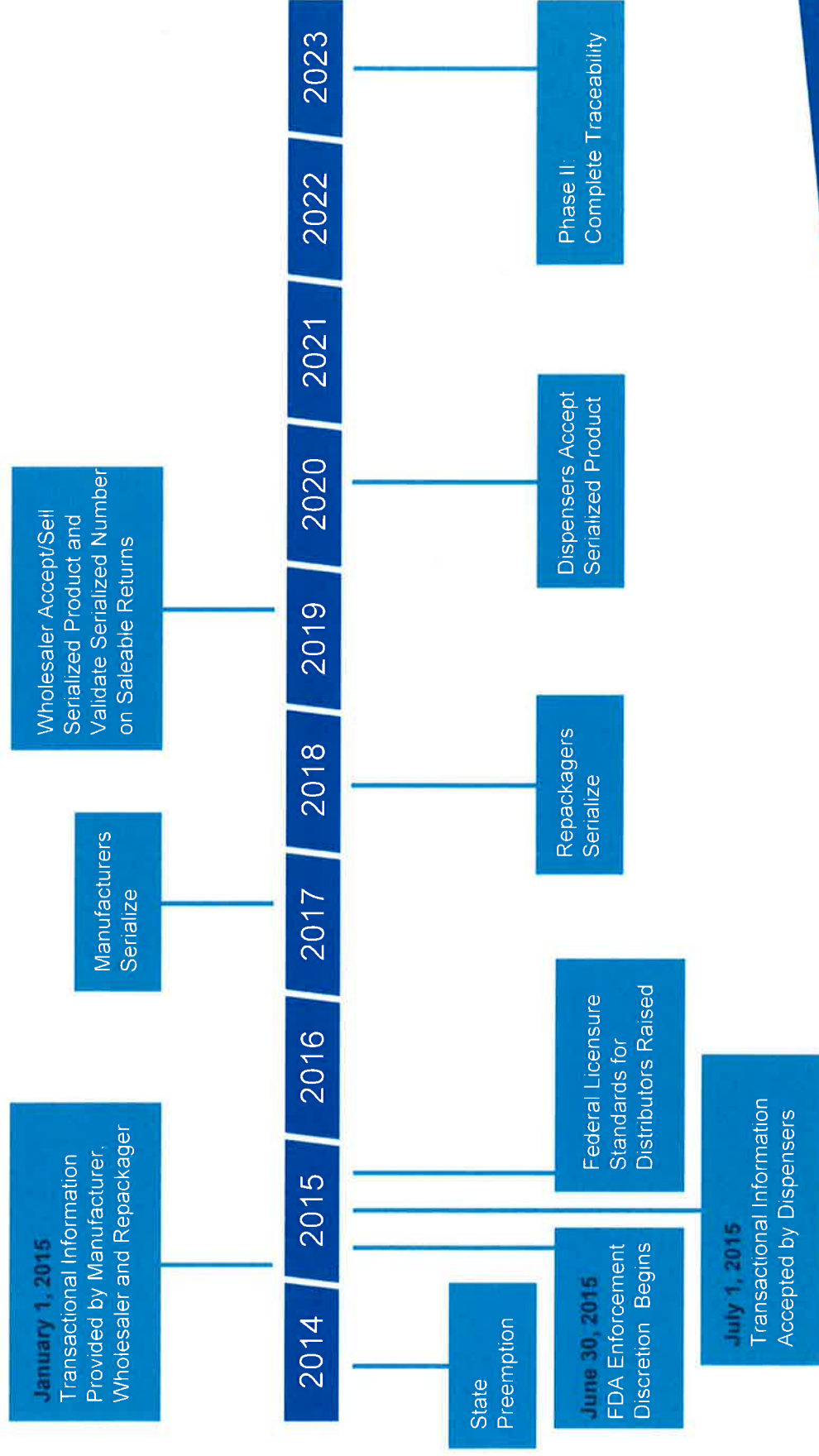
Heather Zenk, VP, Secure Supply Chain

Regulatory details courtesy of the FDA and HDMA



AmerisourceBergen®

# Timeline of the Drug Supply Chain Security Act



# The Drug Quality and Security Act

What is currently in place

- As of **January 1, 2015**, manufacturers, re-packagers and wholesale drug distribution companies are required to provide any entity or enterprise that receives pharmaceutical products with a single document that includes transaction information, transaction history, and transaction statement (TI, TH, and TS).
  - Pharmacies will also need a process to capture and investigate suspect, illegitimate or counterfeit products.
  - Trading partners must be “authorized trading partners” only.

# The Drug Quality and Security Act

What is currently in place and what is coming up

- On **July 1, 2015**, pharmacies and dispensers will be required to accept and maintain the TI, TH, TS data and hold it for a six-year period.
- On **June 30, 2015**, the FDA announced Enforcement Discretion until **November 1, 2015** in reference to the Drug Supply Chain Security Act (DSCSA) and transactional data requirements for dispensers and pharmacies.
- **What you need to know:** This means that the law will go into effect on July 1, 2015, but regulatory agencies do not intend to take action against you on the regulatory requirements until November 1, 2015. This provides you the opportunity to refine your processes and establish best practices.
- **Section IV of the document:** [T]his compliance policy does not extend to transactions in which dispensers must provide the subsequent owner with product tracing information, including transaction history, as required by section 582(d)(1)(A)(ii)... This compliance policy does not extend to other requirements of the FD&C Act...
- The enforcement discretion document is located on the [FDA website](#).



# What are the transactional details (TI, TH, TS)

Transaction information required for the July 1, 2015 DSCSA Deadline

- **Transaction Information (TI)**
  - Name of the product
  - Strength and dosage form of the product
  - NDC
  - Container size
  - Number of containers
  - Lot number\*\*
  - Transaction date\*\*
  - Shipment date
  - Name & Address of the businesses previous and subsequent owner
- **Transaction Statement (TS)**
  - Paper or electronic attestation by the entity transferring ownership of the product that it:
    - > Is authorized under the Act
    - > Received the product from an authorized party
    - > Received TI & TS from the previous seller
    - > Did not knowingly ship suspect or illegitimate product
    - > Systems and processes in place to perform verification
    - > Did not knowingly provide false transaction information and did not alter the transaction history
- **Transaction History (TH)**
  - Paper or electronic statement
  - Includes the transaction information for each prior transaction back to the manufacturer

\*\* Wholesalers that purchase directly from a manufacturer, an exclusive distributor of the manufacturer, or re-packager that purchased directly from manufacturer -- are exempt from passing the above (\*\*) data elements.



AmerisourceBergen®

January 1, 2015

# Preemption

What does it mean

## ■ States

- Immediate preemption of all state laws, regulations, and requirements for tracing products through the supply chain, including recordkeeping and pedigree requirements went into effect upon enactment of the law on November 27, 2013.

## ■ Licensure

- Preemption of state activity regarding wholesale distributor and 3PL licensure that are inconsistent with, less stringent than, directly related to, or covered by the standards established by the Act.
- States cannot alter the standards established by the Federal law, but they may continue to regulate wholesale distributors and 3PLs in areas that are not covered by the and not directly related to the licensing standards in the Act.



AmerisourceBergen®

## ■ Products not impacted by DSCSA

- Over the counter (OTC) products;
- Blood and blood components intended for transfusion;
- Radioactive drugs and radioactive biologics;
- Imaging drug;
- Intravenous products;
- Medical gas;
- Compounded drugs;
- Dispensing drugs pursuant to a prescription;
- Medical convenience kits and combination products;
- Sterile water and products intended for irrigation.



## January 1, 2015 requirements

- Trading partners must be “authorized trading partners” only.
- Must have a method to verify suspect and illegitimate product.
- Must have a “system” in place to quarantine, investigate, notify on suspect and illegitimate products.



## ■ What defines an authorized trading partner

- Authorized trading partner as defined by the FDA
  - Manufacturers/re-packagers must have a valid FDA registration.
  - Wholesalers/3PLs must have a valid State or Federal license.
  - Dispensers must carry a valid State license.

## What is a suspect product

- Suspect Product is a product for which there is reason to believe that such product:
  - Is potentially counterfeit, diverted, or stolen.
  - Is potentially intentionally adulterated such that the product would result in serious adverse health consequences or death to humans.
  - Is potentially the subject of a fraudulent transaction.
  - Appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans.

## What determines an illegitimate product

- Illegitimate product – a product for which credible evidence shows that the product:
  - Is counterfeit, diverted, or stolen.
  - Is intentionally adulterated such that the product would result in serious adverse health consequences or death to humans.
  - Is the subject of a fraudulent transaction.
  - Appears otherwise unfit for distribution such that the product would be reasonably likely to result in serious adverse health consequences or death to humans.

# FDA 3911 draft guidance on suspect and illegitimate

## Contains Nonbinding Recommendations\*

Draft — Not for Implementation

### ATTACHMENT A: FORM FDA 3911

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration		Form Approved OMB No. xxx-xxxx Expiration Date: XXXXX.XX.201X See PRA Statement on page 2
<b>Drug Notification</b>		
1. Type of Report (Select one) <input type="checkbox"/> Initial Notification <input type="checkbox"/> Follow-Up Notification <input type="checkbox"/> Request for Termination		
2. Date of Initial Notification (mm/dd/yyyy) 3. Date Illegitimate Product Was Determined by Company (mm/dd/yyyy) 4. Classification of Notification (Select from list)		
<b>Description of Illegitimate Product</b>		
5. Generic Name		
6. Trade Name (if applicable)		
7. Drug Use (Select from list) 8. Drug Description (Select from list) 9. Strength of Drug 10. Dosage Form (Select from list)		
11. Quantity of Drug (Number and Unit) 12. NDC Number (if applicable) 13. Serial Number (if applicable)		
14. Lot Number(s)		
15. Expiration Dates		
16. For Notification Description of event/issue		

- Guidance for the Industry Drug Supply Chain Security Act
  - Details on identification of suspect product and notification
  - Link to the [draft guidance](#) on the FDA website.

July 1, 2015

## July 1, 2015 requirements

- Pharmacies and dispensers will be required to accept and maintain the TI, TH, TS data and hold it for a six-year period.
- Enforcement discretion was provided by the FDA on June 30, 2015
  - This means that the law will go into effect on July 1, 2015, but regulatory agencies do not intend to take action against you on the regulatory requirements until November 1, 2015.
  - This provides you the opportunity to refine your processes and establish best practices

# Example: Transactional data document

Drug Supply Chain Security Act Transaction Information, History* & Statement			
<b>SELLER</b> AMERISOURCEBERGEN CORP 1400 MORRIS DRIVE CHESTERBROOK PA 19087 US		<b>BUYER</b> BUYER NAME BUYER STREET ADDRESS BUYER CITY STATE ZIP	
<b>SHIPPED FROM</b> SHIPPED FROM NAME SHIPPED FROM STREET ADDRESS SHIPPED FROM CITY STATE ZIP		<b>Shipped To</b> SHIPPED TO NAME SHIPPED TO STREET ADDRESS SHIPPED TO CITY STATE ZIP	
Ref #	Product Description (Name, Strength, Dosage form, Container size)	# Of Container	NDC #
<b>Manufacturers Name: ACTAVIS, INC.</b> <b>Manufacturers Address : 605 TRI STATE PKWY, EURNEL IL 600315277</b>			
15135728	PILOCARPINE 5MG Shipment Date: 11/26/14	36	00228280111
<b>Manufacturers Name: APOTEX CORP</b> <b>Manufacturers Address : 2400 N COMMERCE PKWY STE 400, WESTON, FL 33326-3253</b>			
15135728	LAMIVUDINE/ZIDOV'150/300MG AUR 60 Shipment Date: 11/26/14 / Transaction Date: 11/26/14	48	65862059760
<b>Transaction Statement: AmersourceBergen has complied with each applicable subsection of FDCA Sec 581 (27) (A)-(G)</b>			
15135728	AMLODIATORVA 10MG/80MG RANB 30 Shipment Date: 11/26/14 / Transaction Date: 11/26/14	12	63304060330

Direct Purchase Statement: This wholesale distributor, or a member of the affiliate of such wholesale distributor, purchased the product directly from the manufacturer, exclusive distributor of the manufacturer, or repackaged that purchased the product directly from the manufacturer.

\* Wherever applicable



## ■ Current Hot Topics

- Industry and FDA
  - Drop shipments
  - 340B transactions
  - Borrowing and loaning of pharmaceutical products between hospital entities
- Upcoming Industry and FDA Activities in 2015
  - Serialization pilots
  - 3PL federal licensure
  - Wholesaler federal licensure

# Questions



AmerisourceBergen®

Where knowledge,  
reach and partnership  
shape healthcare delivery.

## **TAB 3: DIVISION DIRECTOR'S REPORT - REGGIE DIXON**

### **1. RULES REPORT**

Ken Lawson, Secretary

Rick Scott, Governor

## RULES REPORT

To: Drug Wholesale Distributor Advisory Council

From: Reginald D. Dixon, Director

Date: July 22, 2015

Re: Division Rulemaking (rev. 7/22/15)

The following chart is a summary of the Division's current rulemaking efforts.

Rule #	Title	Purpose	Status	Next Action
61N-1.001	General Regulations; Definitions	Clear up the definitions of certain terms, as well as to define "limited quantities" as used in ss. 499.01(3) & (4), F.S.	6/10/15 – Rules workshop held.	Notice proposed rule language based on industry input.
61N-1.010	Guidelines for Manufacturing Cosmetics	The rule adopts the federal guidelines for cosmetic manufacturing; the rule is necessary to bring Florida requirements in line with the federal guidelines.	Effective – 7/5/15	
61N-1.012	Records of Drugs, Cosmetics and Devices	Set forth recordkeeping requirements for Florida manufacturers engaging in "limited quantities" of Rx drugs obtained from non-Florida licensed entities.	6/10/15 – Rules workshop held.	Notice proposed rule language based on industry input.
61N-1.013	Prescription Drugs; Receipt, Storage and Security.	Set forth Rx drug storage requirements for Florida manufacturers engaging in "limited quantities" of Rx drugs obtained from non-Florida licensed entities.	6/10/15 – Rules workshop held.	Notice proposed rule language based on industry input.
61N-1.015	Licensing, Application, Permitting	Add language to incorporate updated licensing applications and to incorporate the application for the Restricted RX Drug Distributor-Blood Establishment permit.	2/20/14 – Notice of development published.	Draft language, including revised application forms, then file notice of proposed rule
61N-1.016	Product Registration	Incorporate revised product registration applications.	Effective – 8/2/15	
61N-1.018	Fees	Specify fee for restricted Rx drug distributor – blood establishment permit;	Effective – 6/3/15	
N-1.020	Forms	Repeal of unnecessary rule.	Effective – 6/30/15	

	Drug Distributor Permits; Special Provisions	drug distributor permit; identify Rx drugs these permits can distribute per s. 499.01(2)(g)1.c., F.S.	Development filed	Draft language and file notice of proposed rulemaking
61N-1.027	Distribution of Emergency Use Medical Oxygen	Set forth parameters for distribution of emergency use medical oxygen by 499, Part III, permittees.	4/9/15 – Notice of development published.	Draft language and file notice of proposed rulemaking.
61N-1.028	Product Tracking and Tracing – Definitions	To adopt federal requirements pertaining to the tracking and tracing for entities that engage in the manufacture, repackaging, wholesale distribution, and dispensing of specific prescription drug products falling under Title II, Drug Supply Chain Security Act, of the federal Drug Quality and Security Act.	6/30/15 – Notice of development published.	Draft language and file notice of proposed rulemaking.
61N-1.029	Product Tracking and Tracing – Manufacturer Requirements			
61N-1.030	Product Tracking and Tracing – Wholesale Distributor Requirements			
61N-1.031	Product Tracking and Tracing – Dispenser Requirements			
61N-1.032	Product Tracking and Tracing – Repackager Requirements			



### 61N-1.001 General Regulations; Definitions.

(1) A word or phrase defined in 21 U.S.C. ss. 301 et seq. or federal regulations promulgated thereunder in Title 21 Code of Federal Regulations (C.F.R.), (as of 6/1/15 10/1/03) which are incorporated by reference herein, 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, 499.012(1), 499.012(6), 499.012(1), 499.028(1), 499.029(3), and 499.61, F.S., the following definitions apply, to Chapter 499, F.S. and to Rule Chapter 61N-1, F.A.C.:

(a) "Administer" or "administration" – means the direct application or introduction ~~obtaining and giving~~ of a single dose of drugs by a legally authorized person to or into the body of an individual human or animal a patient whether by injection, inhalation, ingestion or any other means for his consumption.

(b) "Affiliated group" – means the definition set forth in Section 1504 of the Internal Revenue Code, (as of 6/1/2015 April 24, 2003) which is incorporated by reference herein, ~~which is composed of chain drug entities, including at least 50 retail pharmacies, warehouses, or repackagers, which are members of the same affiliated group, if the affiliated group:~~

1. ~~Discloses to the department the names of all its members; and~~

2. ~~Agrees in writing to provide records on prescription drug purchases by members of the affiliated group not later than 48 hours after the department requests such records, regardless of the location where the records are stored.~~

~~For an affiliated group to qualify under Section 499.012(6)(f)1, F.S., such affiliated group must also meet all the conditions specified by Section 499.012(6)(f), F.S.~~

(c) "Authorized absence" – means, for purposes of Section 499.012(16)(d)3.(11)(d), F.S., ~~the management or owner of a permitted wholesale establishment has approved in writing in a document that is available for inspection under Section 499.051, F.S., at the time of the inspection, the physical absence of the designated representative from the permitted establishment, for a cumulative period not to exceed 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~~ a family member ~~(child, spouse or parent) with a serious health condition~~; or the employee's own serious health condition makes the employee unable to perform the functions of the designated representative.

(d) "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, Chapter 499, F.S., to purchase, own, receive or possess those prescription drugs. The term includes:

1. Any a pharmacy licensed pursuant to by 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 a practitioner licensed by Florida law to purchase and receive prescription drugs; or a person who is authorized by the law where the delivery occurs to purchase, own, receive or possess prescription drugs; or -

3. A licensed ship captain, ~~or first officer, or designated medical officer~~ for a vessel engaged in international trade or in trade between ports of the United States or for and any merchant vessel belonging to the U.S. Government. ~~is an authorized recipient for~~ The prescription drugs must be intended solely for emergency medical purposes, and the wholesale distributor must deliver provided the prescription drugs are delivered by the wholesaler 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.

(e) "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 that buys and sells the drug but does not take physical possession such that the drug is "sold to" the broker and "shipped to" a third party.

(f) "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 a majority (more than 50%) of the ownership or controlling interest changes. A change in ownership occurs when there has been any change in a partnership amounting to more than 50% of the ownership or controlling interest. 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.~~

(g) No change.

(h) "Directly from the manufacturer" – means, for purposes other than set forth in Section 499.003(46), F.S., :

~~1. For the purposes of pedigree as defined by Section 499.003(37)(31)(b), F.S., the manufacturer of the specific unit of the prescription drug invoiced and sent that specific unit of the prescription drug directly to the purchasing wholesale distributor, or shipped~~

~~2. For the purposes of Section 499.0121 499.0121(6)(d)5., F.S., the manufacturer of the prescription drug ships the specific unit of the prescription drug directly to an the person authorized recipient by Section 499.0121(6)(d)5., F.S., to receive the specific unit of the prescription drug.~~

(i) through (k) No change.

(l) "Intracompany transfer" – means, pursuant to Section 499.003(34)(31)(b), F.S., a distribution of a specific unit of a prescription drug between two establishments wholly owned and operated by the same business entity.

(m) No change.

(n) "Limited quantities" pursuant to Section 499.01(3) and (4)(b), F.S., means the number of transactions necessary for research and development purposes, the number of transactions necessary for research and development purposes to obtain a final FDA approval, or the number of transactions necessary for research and development purposes to obtain a final approval from a foreign regulatory authority; all transactions must be based on requirements set forth in the acquiring entity's research and development records created contemporaneously with the research and development activities.

(o) "Pedigree" – means a document that satisfies the requirements of Section 499.003(37)(31)(a) ~~or (b)~~, F.S., as applicable, and the applicable rule requirements of subsection 61N-1.012(3), F.A.C., and any forms adopted therein.

(p)(~~e~~) No change.

(q)(~~p~~) No change.

(r)(~~e~~) "Principal address" or "principal business address" means the person's primary place of business.

(s) "Product" – anything produced or made either naturally or artificially.

(t)(~~e~~) "Propagation" of a drug – means, as used under the definition of "manufacture" at Section 499.003(29)(27), F.S., for purposes of permitting under Section 499.012 ~~499.013~~, 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.

(s) through (v) renumbered (u) through (x) No change.

(y)(~~w~~) "Sale" – includes any transfer of title or ownership whether by barter, exchange or gift.

(x) through (aa) renumbered (z) through (cc) No change.

~~(bb) "Specified drug" means all dosage forms, strengths and container sizes of the following prescription drugs:~~

~~1. Bextra (valdecoxib);~~

~~2. Celebrex (celecoxib);~~

~~3. Combivir (lamivudine/zidovudine);~~

~~4. Crixivan (indinavir sulfate);~~

~~5. Diflucan (fluconazole);~~

~~6. Epivir (lamivudine);~~

~~7. Epogen (epoetin alfa);~~

~~8. Gamimune (globulin, immune);~~

~~9. Gammagard (globulin, immune);~~

10. Immune globulin;
11. Lamisil (terbinafine);
12. Lipitor (atorvastatin calcium);
13. Lupron (leuprolide acetate);
14. Neupogen (filgrastim);
15. Nutropin AQ (somatropin, e coli derived);
16. Panglobulin (globulin, immune);
17. Procrit (epoetin alfa);
18. Retrovir (zidovudine);
19. Risperdal (risperidone);
20. Rocephin (ceftriaxone sodium);
21. Serostim (somatropin, mammalian-derived);
22. Sustiva (efavirenz);
23. Trizivir (abacavir sulfate/lamivudine/zidovudine);
24. Venoglobulin (globulin, immune);
25. Viagra (sildenafil citrate);
26. Videx (didanosine);
27. Viracept (nelfinavir mesylate);
28. Viramune (nevirapine);
29. Zerit (stavudine);
30. Ziagen (abacavir sulfate);
31. Zocor (simvastatin);
32. Zofran (ondansetron);
33. Zoladex (goserelin acetate); and
34. Zyprexa (olanzapine).

(dd)(ee) "State Current Good Manufacturing Practices" means current good manufacturing practices and quality system regulations as prescribed as of 6/1/2015 1/1/01 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, and the requirements of this chapter. Current good manufacturing practices for cosmetics means the guidelines for manufacturing cosmetics as set forth in Rule 61N-1.010, F.A.C.

(dd) through (gg) are renumbered (ee) through (hh) No change.

~~(hh) "Wholesale distribution" means distribution of prescription drugs to persons other than a consumer or patient as set forth in Section 499.012(1)(a), F.S.~~

(ii) No change.

~~(jj) "Written agreement" means any type of written correspondence or documentation to establish an account for ongoing sales of prescription drugs by the manufacturer to that wholesaler.~~

*Rulemaking Authority 499.003(31), 499.024, 499.025(5), 499.01(2), 499.01(4), 499.01(6), 499.0121(6), 499.0122(2), 499.012(5), 499.012(12), 499.013(3), 499.014(5), 499.025, 499.03(4), 499.05 FS. Law Implemented 499.003, ~~499.004~~, 499.005, 499.0054, ~~499.0057~~, 499.006, 499.007, 499.008, 499.009, 499.01, 499.012, 499.0121, ~~499.0122~~, ~~499.013~~, ~~499.014~~, 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, ~~499.069~~, 499.61, 499.62, 499.63, 499.64, 499.65, 499.66, 499.67, 499.71, 499.75 FS. History—New 1-1-77, Amended 12-12-82, 1-30-85, Formerly 10D-45.31, Amended 11-26-86, 2-4-93, 7-1-96, Formerly 10D-45.031, Amended 1-26-99, 4-17-01, 6-30-03, 10-7-03, 1-1-04, 1-29-04, 5-29-05, 1-19-06, 2-14-06, 8-6-06, 12-27-07, Formerly 64F-12.001.*



#### **61N-1.010 Requirements for Manufacturing Cosmetics.**

(1) All persons who manufacture or relabel cosmetics in Florida must follow the minimum requirements for manufacturing contained in this section to help assure product safety and quality. If a person does not engage in all phases of cosmetic manufacturing, that person need only comply with paragraphs applicable to those operations in which the person is engaged.

(a) As used in this section, "good manufacturing practice" means that part of quality assurance aimed at ensuring that products are consistently manufactured to a quality appropriate to their intended use. It is thus concerned with both manufacturing and quality control procedures.

(b) As used in this paragraph, "internal audit" means a systematic and independent examination made by competent personnel inside the company, the aim of which is to determine whether activities covered by these rules and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable for achieving objectives.

(c) As used in this paragraph, "standard operating procedure" means instructions on how to perform tasks and descriptions of the approved or required procedures for accomplishing specific quality assurance objectives.

##### **(2) Buildings and facilities requirements.**

Buildings and facilities used for manufacture, processing, packaging, or relabeling of cosmetics must:

(a) Be constructed and maintained in a clean and orderly manner to prevent selection errors (i.e., mix-ups) or cross contamination between consumables, raw materials, intermediate formulations (i.e., in-process materials), and finished products (this applies to containers, closures, labels and labeling materials as well);

(b) Be free of filth and infestation by rodents, birds, insects, and other vermin;

(c) Have a designated quarantine area for the storage of products that are suspected of being contaminated, adulterated, or otherwise potentially injurious to users;

(d) Have floors, walls, and ceilings constructed of smooth, easily cleanable surfaces;

(e) Have adequate lighting and ventilation, and, if necessary for control purposes, screening, filtering, dust, humidity, temperature, and bacteriological controls;

(f) Have washing, cleaning, plumbing, toilet, and locker facilities to allow for:

1. Sanitary operation;

2. Cleaning of facilities, equipment and utensils; and,

3. Personal cleanliness; and,

(g) Have fixtures, ducts, pipes, and drainages installed to prevent condensate or drip contamination.

##### **(3) Equipment requirements.**

Equipment, machinery and utensils used in manufacturing, processing, packaging, or relabeling of cosmetics must be specifically designed and constructed for the intended purpose to prevent corrosion, accumulation of static material, and adulteration with lubricants, coolants, dirt, and sanitizing agents. The equipment must be:

(a) Maintained in a clean and orderly condition, sanitized at appropriate times, and stored in a manner that protects against splash, dust, and other contaminants;

(b) Constructed to facilitate adjustment, cleaning, and maintenance;

(c) Constructed to ensure accurate measuring, mixing, and weighing operations;

(d) Calibrated regularly or checked according to a standard operating procedure with results documented; and,

(e) Removed from use if it is defective, does not meet recommended tolerances, or cannot be repaired and calibrated immediately.

##### **(4) Personnel requirements.**

(a) Personnel supervising or performing cosmetics manufacturing must have the education, training, experience, or combination thereof, to perform their assigned functions.

(b) Personnel coming in direct contact with cosmetic raw materials, in-process materials, finished products, or contact surfaces must wear clean clothing appropriate for the duties they perform and necessary protective apparel (for example, uniforms, gloves, safety glasses, and hair restraints).

(c) Personnel must maintain adequate personal cleanliness, and be free from abnormal sources of microbiological contamination (for example, sores and infected wounds).

(d) Eating food, drinking beverages, or using tobacco must be restricted to designated areas away from storage and processing areas.

- (e) All personnel and visitors must be supervised while in the manufacturing facility.
  - (f) Only authorized personnel shall be allowed access into production, storage, and product control areas.
- (5) Raw materials requirements.

Raw materials must be identified, stored, examined, tested, inventoried, handled, and controlled. In particular, raw materials must be:

- (a) Stored and handled to prevent mistakes (i.e., mix-ups or selection errors), contamination with microorganisms or other chemicals, and degradation from exposure to excessive environmental conditions (e.g., heat, cold, sunlight, moisture, etc.);
- (b) Held in closed containers and stored off the floor;
- (c) Maintained in containers that are labeled with the identity, lot number, and control status (release or quarantine);
- (d) Sampled and tested for conformance with specifications and to ensure the absence of filth, microorganisms, and other adulterants prior to processing or usage; and,
- (e) Specifically identified and controlled to prevent the use of materials that would be injurious to users if such material were incorporated into a cosmetic product and such product were used under the conditions of use prescribed in the labeling or advertisement of the product or under such conditions as are customary or usual.

(6) Water requirements.

(a) There must be established procedures for ensuring that the water used as a cosmetic ingredient is being tested or monitored regularly.

(b) The entire system for supplying water used as a cosmetic ingredient must be set up to avoid stagnation and risks of contamination (this system shall be routinely cleaned and sanitized according to a standard operation procedure that ensures no biofilm build-up).

(7) Product requirements.

Cosmetic manufacturers shall develop and maintain written manufacturing and control standard operating procedures addressing formulations, processing instructions, in-process control methods, packaging instructions, and instructions for operating equipment; the procedures must include provisions to ensure that:

- (a) The selection, weighing, and measuring of raw materials and the determination of finished yield are verified;
- (b) Major equipment, transfer lines, containers and tanks used for processing, holding, or filling are identified to indicate contents, batch identification or designation, stage of processing and control status;
- (c) There are measures to prevent contamination with microorganisms, chemicals, filth, or other extraneous material;
- (d) There are in-process controls to ensure product uniformity, integrity (for example, in-process batch weights), accurate fill of mixing containers, and adequacy of mixing;
- (e) The tamper-resistant packaging and labeling for liquid oral hygiene products and vaginal products meet the requirements of 21 CFR 700.25;
- (f) The storage and handling of packaging materials that are intended to come into direct contact with the product prevent selection errors and microbiological or chemical contamination; and,
- (g) Finished product packages bear permanent, unique lot or control numbers and there is a coding system that corresponds to these numbers.

(8) Laboratory controls.

Cosmetic manufacturers shall develop and maintain laboratory controls addressing sample collection techniques, product development specifications, test methods, laboratory equipment, and technician qualifications; the laboratory controls shall include provisions to ensure that:

- (a) Raw materials (including water), in-process and finished product samples are tested or examined for identity and compliance with applicable specifications (for example, physical and chemical properties), microbial contamination, and hazards or other chemical contamination; and,
- (b) Returned cosmetics are examined for deterioration, contamination, and compliance with the manufacturer's product development specifications.

(9) Internal audit requirements.

Cosmetic manufacturers must have internal audit procedures that ensure:

- (a) Internal audits are conducted randomly and on demand for a specific reason;
- (b) Internal audits are conducted by individuals who do not have direct responsibility for the matters being audited;

- (c) All observations made during the internal audit are evaluated and shared with management, production, quality control, and lab personnel who are responsible for developing and implementing corrective measures; and,
  - (d) Internal audit follow-up confirms the completion or implementation of corrective actions.
- (10) Complaints, adverse events and recall requirements.

Cosmetic manufacturers must have standard operating procedures sufficient to:

- (a) Facilitate the receipt, processing, evaluation and follow up on written and oral complaints;
- (b) Facilitate the identification and retrieval of reported adverse incidents involving allegations of bodily injury or harm;
- (c) Facilitate the effective and efficient identification and recall of products, including market withdrawal; and,
- (d) Ensure notification of adverse incidents and product recalls to state and federal regulatory agencies; such notification shall be no later than 30 calendar days of receipt of the adverse incident and no later than 10 calendar days where the manufacturer has declared a product recall.

*Rulemaking Authority 499.05 FS. Law Implemented 499.05, 499.008, 499.009 FS. History—New 7-1-96, Formerly 10D-45.0505, 64F-12.010, Amended 7-5-15.*



**61N-1.012 Records of Drugs, Cosmetics and Devices.**

(1) through (16) No change.

(17) For purposes of prescription drugs obtained in "limited quantities" for research and development ("R&D") purposes under Section 499.01(3) and (4)(b), F.S. and Rule 61N-1.001(2)(n), F.A.C., the records required pursuant to Section 499.0121(6), F.S., must identify the R&D requirements, acquisition schedule and use of each drug acquired relative to anticipated and ongoing R&D activities. These records must be created in advance of or contemporaneously with the particular R&D activities, and are subject to inspection under 499.051, F.S. Non-clinical/pre-clinical R&D quantities must be updated annually, and clinical quantities must be updated semiannually. The researcher must maintain all other records required under Chapter 499, including, without limitations, Section 499.01(3) or (4)(b), and applicable federal laws.

*Rulemaking Authority ~~499.003, 499.01(2)(g)~~, 499.05, 499.0121 FS. Law Implemented 499.01, ~~499.003~~, 499.012, 499.0121, 499.01212, 499.028, 499.04, 499.041, 499.05, 499.051, 499.052, 499.06, ~~499.063, 499.064~~, 499.066, 499.067 FS. History—New 1-1-77, Amended 12-12-82, 7-8-84, 1-30-85, Formerly 10D-45.53, Amended 11-26-86, 2-4-93, 7-1-96, Formerly 10D-45.053, Amended 1-26-99, 4-17-01, 10-7-03, 1-1-04, 6-15-04, 8-2-04, 1-19-06, 8-6-06, Formerly 64F-12.012, Amended 3-4-13, Amended*

---





**61N-1.013 Prescription Drugs; Receipt, Storage and Security.**

(1) No change.

(2) No change.

(3)(a) through (c) No change.

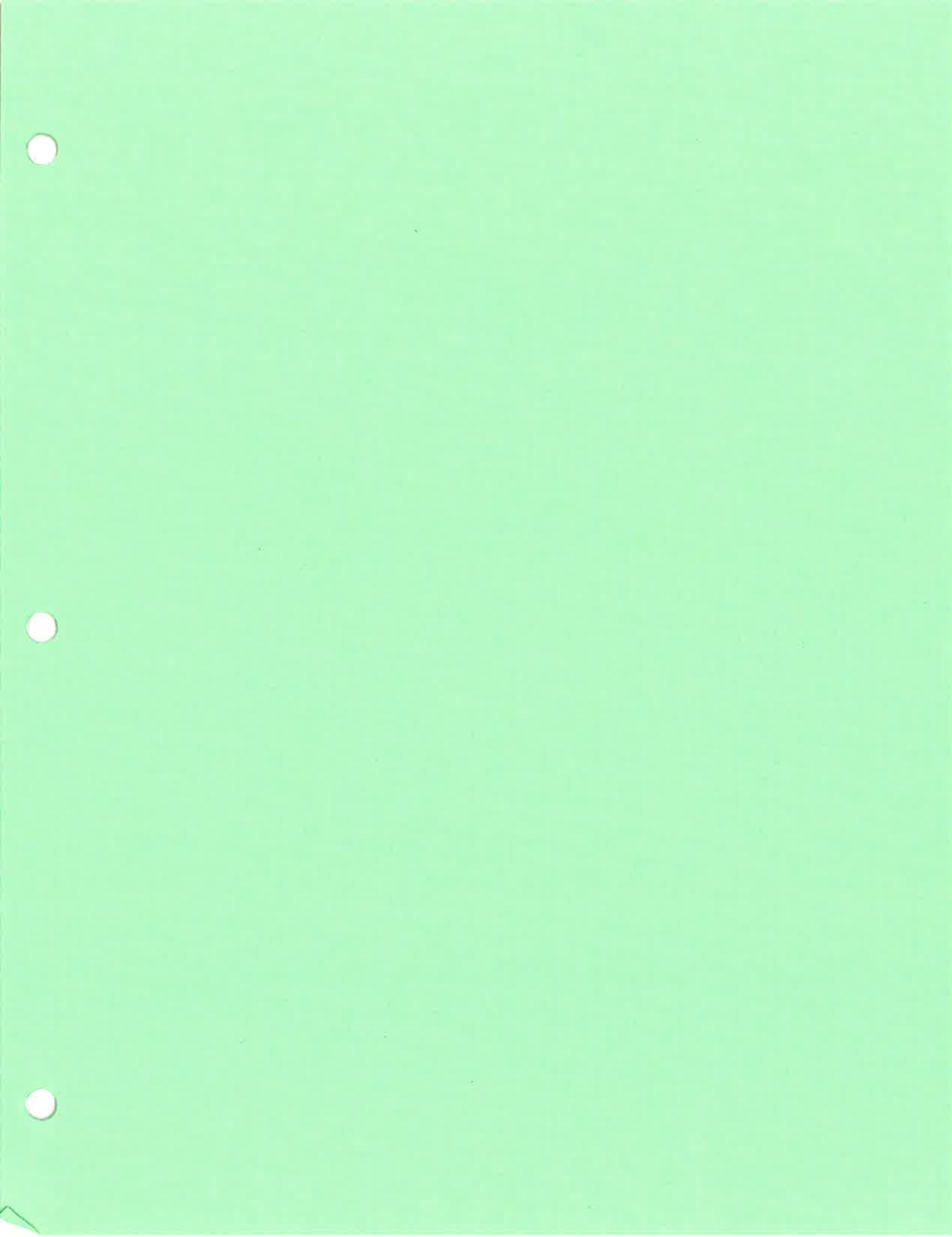
(d) Facility requirements for the storage and handling of prescription drugs.

1. through 2. No change.

3. Prescription drugs obtained in "limited quantities" for research and development ("R&D") purposes under Section 499.01(3) and(4)(b), F.S. and Rule 61N-1.001(2)(n), F.A.C., must be physically segregated from all other products intended for manufacturing, compounding, dispensing, or administration. In a manufacturer's establishment, these drugs must also be stored and maintained in a separate and clearly designated area.

(4) through (7) No change.

*Rulemaking Authority 499.0121(1), 499.05 FS. Law Implemented ~~499.004~~, 499.006, 499.007, 499.01, 499.0121, 499.028(6), 499.052 FS. History—New 7-8-84, Amended 1-30-85, Formerly 10D-45.535, Amended 11-26-86, 7-1-96, Formerly 10D-45.0535, Amended 1-26-99, 4-17-01, 1-1-04, 1-19-06, 11-18-07, Formerly 64F-12.013, Amended \_\_\_\_\_.*



## Notice of Development of Rulemaking

### **DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION**

#### **Drugs, Devices and Cosmetics**

RULE NO.: RULE TITLE:

61N-1.015 Licensing, Application, Permitting

PURPOSE AND EFFECT: The Division proposes the rule amendments to add language to incorporate updated licensing applications and to incorporate the application for the Restricted Rx Drug Distributor – Blood Establishment permit.

SUBJECT AREA TO BE ADDRESSED: Drug, Devices and Cosmetics – Applications and Permitting

RULEMAKING AUTHORITY: 499.01, 499.012, 499.0121(1), 499.0122, 499.013, 499.014, 499.028, 499.04, 499.041, 499.05, 499.62, 499.63, 499.64, 499.66, 499.67, 499.701 FS.

LAW IMPLEMENTED: 499.01, 499.012, 499.0121, 499.0122, 499.013, 499.028(6), 499.04, 499.004, 499.041, 499.05, 499.06, 499.006, 499.007, 499.052, 499.062, 499.063, 499.064, 499.066, 499.067 FS.

IF REQUESTED IN WRITING AND NOT DEEMED UNNECESSARY BY THE AGENCY HEAD, A RULE DEVELOPMENT WORKSHOP WILL BE NOTICED IN THE NEXT AVAILABLE FLORIDA ADMINISTRATIVE REGISTER.

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE DEVELOPMENT AND A COPY OF THE PRELIMINARY DRAFT, IF AVAILABLE, IS: Dinah Greene, 1940 N. Monroe Street, Suite 26A, Tallahassee, FL 32399, (850)717-1802

THE PRELIMINARY TEXT OF THE PROPOSED RULE DEVELOPMENT IS NOT AVAILABLE.

#### 61N-1.015 Licensing, Application, Permitting.

This section addresses the application and permitting requirements of persons regulated under ~~Part I~~ of Chapter 499, F.S.

(1) Any person that is required ~~under Sections 499.001-.081, F.S.,~~ to have a permit shall apply to the department for the appropriate permit on forms indicated in this rule. Inquiries regarding requests for an application or licensing may be directed to The Department of Business and Professional Regulation, Drugs, Devices, and Cosmetics Program, at 1940 N. Monroe Street, Tallahassee, Florida 32399 or telephone number (850)717-1800. Applications may be downloaded from the department's bureau's web site at [www.myfloridalicense.com](http://www.myfloridalicense.com).

(2) No change.

(3) No change.

(a) No change.

(b) A person permitted as a ~~Compressed~~ Medical Gases Manufacturer that is applying for either a ~~Compressed~~ Medical Gases Wholesale Distributor Wholesaler permit or a Medical Oxygen Retail Establishment ~~Retailer~~ permit at that address does not require another on-site inspection and is not required to pay an initial application/on-site inspection fee when applying for the additional permit.

(c) A person permitted as a Medical Oxygen Retail Establishment ~~Retailer~~ that is applying for a ~~Compressed~~ Medical Gases Wholesale Distributor ~~Wholesaler~~ permit at that address does not require another on-site inspection and is not required to pay the initial application/on-site inspection fee when applying for the additional permit. A person permitted as a Medical Oxygen Retail Establishment ~~Retailer~~ that has the establishment registered with the FDA for transfilling activity which is applying for a ~~Compressed~~ Medical Gases Manufacturer's permit at that address does not require another on-site inspection and is not required to pay the initial application/on-site inspection fee when applying for the additional permit.

(d) No change.

(4) No change.

(5) Notification to the department regarding the change of address of a permitted establishment must be in writing. A Change of Address form is available on the department's web site. Notification regarding the closing of a permitted establishment shall also include the name and address of a person to contact for up to two years after the closing of the business for access to required records.

(6) Manufacturer Permits.

(a) No change.

(b) No change.

(c) Application requirements for Prescription Drug Manufacturers ~~and prescription drug repackagers located in Florida~~ include:

1. Contact the department's Division of Drugs, Devices, and Cosmetics ~~Program~~ to request an application or download the application from the department's web site.

2. File with the department a completed application for a permit using an original Form DH 1033, "Application for Permit Under Chapter 499, F.S.," effective August 2004, which is incorporated by reference herein.

3. through 5. No change.

(d) Application requirements for Non-resident prescription drug (Rx) manufacturers.

1. through 2. No change.

3. Contact the department's Division of Drugs, Devices, and Cosmetics ~~Program~~ to request an application or download the application from the department's web site.

4. File with the department a completed application for a permit using an original Form DH 1033, "Application for Permit Under Chapter 499, F.S.," effective August 2004.

5. through 8. No change.

(e) Application requirements for Prescription Drug Repackagers include:

1. Contact the department's Division of Drugs, Devices, and Cosmetics Program to request an application or download the application from the department's web site.

2. File with the department a completed application for a permit using an original Form NUMBER, "TITLE," effective Month 9999, which is incorporated by reference herein.

3. Pay the appropriate fee(s) as required by Rule 61N-1.018, F.A.C.

4. Comply with all the requirements for permitting provided in Chapter 499, F.S., and this rule chapter.

5. Have an FDA establishment registration number.

(7) Wholesaler Permits.

(a) A person applying for or renewing a permit as a prescription drug wholesale distributor ~~wholesaler~~, or as a veterinary prescription drug wholesale distributor ~~wholesaler~~ located in Florida, must have an area for the storage of prescription drugs under controlled room temperature and refrigeration, as required by paragraph 61N-1.013(3)(d), F.A.C., whether or not the person intends to wholesale prescription drugs requiring storage under controlled room temperature conditions or refrigeration; except that a person who will act as a broker only of prescription drugs may apply for a "broker only" designation on the Prescription Drug wholesale distributor ~~Wholesaler~~ permit and then the requirement that the permitted address provide for "controlled room temperature" and refrigeration is waived. A "broker only" cannot take possession of prescription drugs under any circumstances.

(b) The Prescription Drug Wholesale Distributor's ~~Wholesaler's~~ bond and the bond for an Out-of-state Prescription Drug Wholesale Distributor ~~wholesaler~~ will be transferred by the department to subsequent permits issued pursuant to renewal applications if the bond or other equivalent means of security is in a form that will allow for such transfer. The bond will be refunded without interest, consistent with the provisions of Section 499.01(2)(d) and (2)(e) ~~499.012(2)~~, F.S. In order for another means of security to satisfy the bond requirement, the security must be in a form that the applicant or permittee cannot revoke, withdraw, cancel, or otherwise reduce the department's interest until the conditions upon which the bond can be refunded or released, as set forth in Section 499.01(2)(d) and (2)(e) ~~499.012(2)~~, F.S., have been satisfied. If the bond or other security is in a form that requires the department to initiate release of the bond or security, a prescription drug wholesaler or out-of-state prescription drug wholesaler should request in writing that the department release the bond or security within 45 days of satisfaction of the conditions in Sections 499.01(2)(d) and (2)(e) ~~499.012(2)(a) and (e)~~, F.S., that release department's interest in the bond or other security. The department must initiate release of the bond or security within 10 working days of satisfaction of the conditions in Sections 499.01(2)(d) and (2)(e) ~~499.012(2)(a) and (e)~~, F.S., unless the department has otherwise made a claim against the bond or security.

(c) A Prescription Drug Wholesale Distributor ~~Wholesaler~~ is authorized to wholesale all prescription drugs, including compressed medical gases and therefore does not require dual permits.

(d) Application requirements for Compressed Medical Gases Wholesale Distributors ~~Wholesalers~~ include:

1. Contact the department's Division of Drugs, Devices, and Cosmetics Program to request an application or download the application from the department's web site.
2. File with the department a completed application for a permit using an original Form DH 1033, "Application for Permit Under Chapter 499, F.S.," effective August 2004.
3. No change.
4. No change.

(e) Application requirements for Prescription Drug Wholesale Distributors ~~Wholesaler~~, Prescription Drug Wholesale Distributors ~~Wholesaler~~ – Broker Only, or Out-of-State Prescription Drug Wholesale Distributors ~~Wholesaler~~ include:

1. Contact the department's Division of Drugs, Devices, and Cosmetics Program for an application form(s) and fingerprint cards. Both the sales transaction (seller) and the physical movement (location from which the drugs are shipped) of prescription drugs are considered wholesale distribution. Therefore, if the seller (name and address as reflected on the invoice) is not the same as the location from which the drugs are shipped (name and address), such as in the case of brokers, different branches of the same company, or a contract warehouse, then both persons (the seller and location from which shipped) must be permitted under the Florida Drug and Cosmetic Act.

2. File with the department a completed application for a permit using an original Form DH 2124, "Prescription Drug Wholesaler/Out-of-State Prescription Drug Wholesaler Application" effective January 2004, which is incorporated by reference herein.

3. File with the department an original Form DH 2125, "Personal Information Statement" effective January 2004, which is incorporated by reference herein for the applicant's manager, next four highest ranking employees that are responsible for prescription drug operations, and all affiliated parties.

4. Submit a legible fingerprint card and \$47.00 per fingerprint card for each person required to submit a fingerprint card. These fingerprint cards must have been obtained from the department so that the cards will have the proper coding for processing and reporting.

5. Submit a \$100,000 bond or security as specified in Sections 499.012(2)(a) and (c), F.S., and paragraph (b) above. If you are

using a surety bond, the required bond form is DH 2128, "Surety Bond Form," effective June 2005, which is incorporated by reference herein.

6. If the applicant is located outside of Florida, submit a photocopy of the resident state's license or permit that authorizes the wholesale distribution of prescription drugs. If the resident state does not allow photocopying of the license or permit, the applicant may submit a verification of the license or permit from the issuing agency. If the resident state does not require a license or permit for the wholesale distribution activities of the applicant in that state, submit:

a. No change.

b. A statement signed by the applicant that the applicant will comply with all storage, handling, and recordkeeping requirements of the resident state related to the sale and physical distribution of prescription drugs into Florida, or if none exist in the resident state that the applicant will comply with all storage, handling, and recordkeeping requirements, as set forth in 21 C.F.R. 205.50 (as of ~~6/1/2015~~ ~~10/1/03~~) which is incorporated by reference herein, for the sale and physical distribution of prescription drugs into Florida.

7. Identify a person who has been Certified pursuant to Section ~~499.012(16)~~ ~~499.012(11)~~, F.S., to serve as the certified designated representative. If the prescription drug wholesale distributor ~~wholesaler~~ operates in 'shift' schedules, a different person per shift may be designated; however the shift hours for which each person is responsible must be clearly identified. You must use Notification of Designated Representative Form DH 2130, effective June 2005, which is incorporated by reference herein, for communicating changes in the designated representative.

8. No change.

9. No change.

(f) Application requirements for Retail Pharmacy Wholesale Distributor ~~Wholesaler~~ include:

1. Contact the department's Drugs, Devices, and Cosmetics Program to request an application or download the application from the department's web site.

2. File with the department a completed application for a permit using an original Form DH 1033, "Application for Permit Under Chapter 499, F.S.," effective August 2004.

3. through 5. No change.

(g) Application requirements for freight forwarders.

1. Contact the department's Division of Drugs, Devices, and Cosmetics ~~Program~~ to request an application or download the application from the department's web site.

2. File with the department a completed application for a permit using an original Form DH 1033, "Application for Permit Under Chapter 499, F.S.," effective August 2004.

3. No change.

4. No change.

(h) Application requirements for Veterinary Prescription Drug Wholesale Distributors ~~Wholesalers~~ include:

1. Contact the department's Division of Drugs, Devices, and Cosmetics ~~Program~~ to request an application or download the application from the department's web site.

2. File with the department a completed application for a permit using an original Form DH 1033, "Application for Permit Under Chapter 499, F.S.," effective August 2004, and the attachment for the Veterinary Prescription Drug Wholesaler permit, August 2004.

3. No change.

4. No change.

(8) Other Distributors. Persons conducting certain distributions of prescription drugs which are not considered wholesale distributions in the state of Florida must obtain a permit from the department prior to initiating that activity. These permits include Complimentary Drug Distributors, all of the designated Restricted Rx Drug Distributor permits as further discussed in Rule 61N-1.023, F.A.C., Medical Oxygen Retailers, and Veterinary Legend Drug Retailers.

(a) Application requirements for Complimentary Drug Distributors include:

1. Contact the department's Drugs, Devices, and Cosmetics Program for an application form or download the application from the department's web site. An out of the state manufacturer or distributor of complimentary or sample prescription drugs may obtain a "Complimentary Drug Distributor permit" for its headquarters or home office in lieu of a permit for each establishment from which complimentary prescription drugs are distributed. A manufacturer or distributor that uses a fulfillment house, shipping and

mailing service, or distributes through co-marketing agreements, must notify the department in writing of the contractor's name, address, and responsibilities prior to the distribution of prescription drug samples in or into this state. The headquarters or home office location is responsible for all recordkeeping requirements and for production of such records as required by Sections 499.0121 and 499.028, F.S., this rule and Rule 61N-1.012, F.A.C. A person located within the state that manufactures or distributes complimentary or sample prescription drugs directly or through its agents, employees, or independent contractors, must obtain a Complimentary Drug Distributor permit for each establishment located in Florida. A manufacturer or distributor that uses a fulfillment house, shipping and mailing service, or distributes through co-marketing agreements, any of which is located in Florida, must obtain a permit in the name of the manufacturer or distributor issued to the address of the fulfillment house, shipping and mailing service, or similar location. The manufacturer or distributor is responsible for all recordkeeping requirements and for production of such records as required by Sections 499.0121 and 499.028, F.S., this rule and Rule 61N-1.012, F.A.C.

2. File with the department a completed application for a permit using an original Form DH 1033, "Application for Permit Under Chapter 499, F.S.," effective August 2004.

3. Submit a copy of the applicant's license or permit which authorizes the possession of prescription drugs. If the issuing agency does not allow photocopying of a license or permit, the applicant may submit a verification of the license or permit from the issuing agency.

4. Pay the appropriate fee(s) as required by Rule 61N-1.018, F.A.C.

5. Comply with all the requirements for permitting provided in Chapter 499, F.S., and this rule chapter.

(b) Application requirements for Restricted Rx Drug Distributor – Health Care Entity include:

1. Contact the department's Drugs, Devices, and Cosmetics Program to request an application or download the application from the department's web site.

2. File with the department a completed application for a permit using an original Form DH 1033, "Application for Permit Under Chapter 499, F.S.," effective August 2004.

3. Submit a listing of all the locations under common control that will be receiving distributions under this permit. This listing must include the name and address of the facility and the pharmacy or other permit number which authorizes that location to possess prescription drugs. Additional locations must be communicated to the department in writing prior to the transfer of prescription drugs. Alternatively, depending on the basis for the application, provide a copy of the written contract evidencing the group purchasing organization and a listing of all the locations that will be receiving distributions under this permit because of joint membership in the group purchasing organization.

4. Comply with all the requirements for permitting provided in Chapter 499, F.S., and this rule chapter.

5. Pay the appropriate fee(s) as required by Rule 61N-1.018, F.A.C.

(c) Application requirements for Restricted Rx Drug Distributor – Charitable Organization include:

1. Contact the department's Drugs, Devices, and Cosmetics Program to request an application or download the application from the department's web site.

2. File with the department a completed application for a permit using an original Form DH 1033, "Application for Permit Under Chapter 499, F.S.," effective August 2004.

3. Submit proof of the charitable organization designation under section 501(c)(3) of the Internal Revenue Code.

4. If the FDA has initiated the enrollment program, submit the FDA central file number of the applicant.

5. Comply with all the requirements for permitting provided in Chapter 499, F.S., and this rule chapter.

6. Pay the appropriate fee(s) as required by Rule 61N-1.018, F.A.C.

(d) Application requirements for Restricted Rx Drug Distributor – Reverse Distributor or Restricted Rx Drug Distributor – Destruction include:

1. Contact the department's Drugs, Devices, and Cosmetics Program to request an application or download the application from the department's web site.

2. File with the department a completed application for a permit using an original Form DH 1033, "Application for Permit Under Chapter 499, F.S.," effective August 2004.

3. No change.

4. No change.

(e) Application requirements for Restricted Rx Drug Distributor – Government Programs include:

1. Contact the department's Drugs, Devices, and Cosmetics Program to request an application or download the application from



the department's web site.

2. File with the department a completed application for a permit using an original Form DH 1033, "Application for Permit Under Chapter 499, F.S.," effective August 2004.

3. Submit a detailed plan justifying the necessity for this permit in accordance with subsection 61N-1.023(5), F.A.C.

4. Submit a list of the intended contractors and subcontractors that will receive the entity's prescription drugs under this permit and the permit numbers that authorize them to administer or dispense. Also submit a copy of the provisions of the contract that address the requirements in Section 499.012(1)(a)1.d., F.S.

5. No change.

6. No change.

(f) Application requirements for a Restricted Rx Drug Distributor – Institutional Research include:

1. Contact the department's Drugs, Devices, and Cosmetics Program to request an application or download the application from the department's web site.

2. File with the department a completed application for a permit using an original Form DH 1033, "Application for Permit Under Chapter 499, F.S.," effective August 2004.

3. No change.

4. No change.

(g) Application requirements for a Veterinary Legend Drug Retailer include:

1. Contact the department's Drugs, Devices, and Cosmetics Program to request an application or download the application from the department's web site.

2. File with the department a completed application for a permit using an original Form DH 1033, "Application for Permit Under Chapter 499, F.S.," effective August 2004.

3. No change.

4. No change.

(h) Application requirements for a Medical Oxygen Retail Establishment ~~Retailer~~ include:

1. Contact the department's Drugs, Devices, and Cosmetics Program to request an application or download the application from the department's web site.

2. File with the department a completed application for a permit using an original Form DH 1033, "Application for Permit Under Chapter 499, F.S.," effective August 2004.

3. No change.

4. No change.

5. No change.

(9) Designated Representative.

(a) No change.

(b) Application requirements for Certification as a Designated Representative include:

1. Contact the department's Division of Drugs, Devices, and Cosmetics ~~Program~~ to request an application and fingerprint cards or download the application from the program's web site.

2. File with the department a completed application for certification using Form DH 2126 "Application for Certification as a Designated Representative," effective June 2005, which is incorporated by reference herein. An application is not deemed completed until the applicant has received a passing score on the laws and rules examination required by Section 499.012(16)(b)4., F.S. The applicant will be notified by regular mail at the applicant's home mailing address of the applicant's eligibility to schedule the laws and rules examination. Information on scheduling and other testing processes are included on the program's web site in a document entitled "*Candidate's Information Booklet*." If the applicant has not passed the laws and rules examination within six months of this notification, the department will initiate action to deny the Application for Certification as a Designated Representative. This six-month period for an applicant to pass the laws and rules examination does not extend the statutory requirement in Section 499.012(16)(f), F.S., for a Prescription Drug Wholesaler Distributor or an out-of-state Prescription Drug Wholesaler Distributor to employ a designated representative.

3. Submit a legible fingerprint card and \$47.00 per fingerprint card. The fingerprint card must have been obtained from the department so that the card will have the proper coding for processing and reporting.

4. No change.

5. No change.

(10) Permit renewals for all permits other than a prescription drug wholesaler, prescription drug wholesaler – broker only, or out-of-state prescription drug wholesaler. Submission of a renewal application represents to the department that conditions have not changed with the permitted person which would make the permitted person ineligible to renew the permit.

(a) A permit renewed during the grace period will expire 24 months after the last day of the anniversary month in which the previous permit expired.

(b) An applicant applying to renew a permit which has not expired, been revoked, suspended or otherwise terminated must:

1. File with the department a completed application for a permit using an “Application for Permit Renewal Under Chapter 499, F.S.,” Form DH 1034, effective January 2004, which is incorporated by reference herein. The permittee should contact the department if the renewal application has not been received at least 30 days prior to the permit’s expiration date.

2. NC

3. NC

4. Applicants renewing a Retail Pharmacy Wholesale Distributor’s ~~Wholesaler’s~~ permit must also submit a legible photocopy of the current community pharmacy permit.

(c) No change.

(11) Permit renewals for prescription drug wholesale distributor ~~wholesaler~~, prescription drug wholesale distributor ~~wholesaler~~ – broker only, or out-of-state prescription drug wholesale distributor ~~wholesaler~~.

(a) The program will mail an application for renewal of the prescription drug wholesaler, prescription drug wholesaler – broker only, or out-of-state prescription drug wholesaler permit at least 90 days prior to the expiration date of the permit.

(b) No change.

(c) File with the department a completed application for a permit using an original Form DH 2124, “Prescription Drug Wholesaler/Out-of-State Prescription Drug Wholesaler Application” effective January 2004.

(d) File with the department an original Form DH 2125, “Personal Information Statement” effective January 2004, for the applicant’s manager, next four highest ranking employees that are responsible for prescription drug operations, and all affiliated parties.

(e) Submit a legible fingerprint card for any person for whom a Personal Information Statement is submitted who has not previously submitted a fingerprint card on behalf of the applicant company. These fingerprint cards must have been obtained from the department so that the cards will have the proper coding for processing and reporting.

(f) No change.

(g) Submit a \$100,000 bond or security as specified in Sections 499.012(2)(a) and (c), F.S., and paragraph (7)(b) above. If you are using a surety bond, the required bond form is DH 2128, “Surety Bond Form,” effective June 2005.

(h) No change.

1. No change.

2. A statement signed by the applicant that the applicant will comply with all storage, handling, and recordkeeping requirements of the resident state related to the sale and physical distribution of prescription drugs into Florida, or if none exist in the resident state that the applicant will comply with all storage, handling, and recordkeeping requirements, as set forth in 21 C.F.R. 205.50 (as of 6/1/15 ~~10/1/03~~) which is incorporated by reference herein, for the sale and physical distribution of prescription drugs into Florida.

(i) No change.

(j) No change.

*Rulemaking Authority 499.01, 499.012, 499.0121(1), 499.0122, 499.013, 499.014, 499.028, 499.04, 499.041, 499.05, 499.62, 499.63, 499.64, 499.66, 499.67, 499.701 FS. Law Implemented 499.01, 499.012, 499.0121, 499.0122, 499.013, 499.028(6), 499.04, 499.004, 499.041, 499.05, 499.06, 499.006, 499.007, 499.052, 499.062, 499.063, 499.064, 499.066, 499.067 FS. History—New 12-12-82, Amended 7-8-84, 1-30-85, Formerly 10D-45.54, Amended 11-26-86, 2-4-93, 7-1-96, Formerly 10D-45.054, Amended 1-26-99, 4-17-01, 10-29-02, 7-6-03, 1-1-04, 9-13-04, 10-3-05, 1-19-06, Formerly 64F-12.015.*



### 61N-1.016 Product Registration.

(1)(a) Each product that is registered shall be registered either as a drug or cosmetic, but shall not have duplicate registrations. Products that are both a cosmetic and a drug must be registered as a drug.

(b) A formula marketed under different brand names, sizes, quantities, or distributors is not considered a separate and distinct product for registration purposes. Furthermore, the adding of color, flavor, or scents to a formula does not make a separate and distinct product for registration purposes, even for fragrance preparations where the scent is the primary product. However, the different variations must be listed with the division.

(c) The separate and distinct drug or cosmetic product for a person who performs limited manufacturing operations at an establishment such as only encapsulating, sterilizing or other processing or manipulation of the product, but not labeling, may be the product resulting from such processing and not each separate and distinct product to which the limited manufacturing operation is performed.

(d) The application forms incorporated by reference in this rule can be obtained by contacting the Division of Drugs, Devices and Cosmetics, 1940 N. Monroe Street, Suite 26A, Tallahassee, Florida 32399-1047, (850)717-1800.

(2)(a) Applicants applying for an initial product registration of a product must:

1. File with the department a completed application for the appropriate product registration using DBPR form number DBPR-DDC-228, "Application for Product Registration – Cosmetics (Main & Identical)," effective May 2015, available at <http://www.flrules.org/Gateway/reference.asp?No=Ref-05666>; or DBPR form number DBPR-DDC-229, "Application for Product Registration – Rx Drugs (Main & Identical)," effective May 2015, available at <http://www.flrules.org/Gateway/reference.asp?No=Ref-05666>; or DBPR form number DBPR-DDC-230, "Application for Product Registration – Repackaged Rx Drugs (Main & Identical)," effective May 2015, available at <http://www.flrules.org/Gateway/reference.asp?No=Ref-05666>; or DBPR form number DBPR-DDC-231, "Application for Product Registration – OTC Drugs (Main & Identical)," effective May 2015, available at <http://www.flrules.org/Gateway/reference.asp?No=Ref-05666>, all of which are incorporated by reference herein;

2. Submit a product label or copy thereof and all labeling associated with the main or identical product that provides information in addition to or other than what is on the product label for every product on the Application (An English translation is required for a product manufactured for export only which has labeling in a foreign language.);

3. Submit documentation that supports the product is allowed to be distributed in interstate commerce as per FDA regulations, such as:

a. Written documentation from the FDA which indicates approval of a drug through a new drug application – NDA, ANDA, IND, NADA, etc.; or

b. A copy of the section(s) of the Code of Federal Regulations (CFR) denoting the product's Drug Efficacy Study Implementation (DESI) designation; or

c. A copy of the section(s) of the CFR denoting the product remains pending final DESI review; or

d. A copy and summary of material(s) and authoritative literature reviewed during the applicant's investigation supporting that the product has not yet been reviewed in the DESI process; or

e. A copy and summary of material(s) and of authoritative literature supporting the product qualifying for grandfather status; or

f. The over-the-counter monograph category to which the drug belongs; or

g. A product category identifier if the product is a cosmetic; and,

4. Pay the appropriate fee pursuant to Rule 61N-1.018, F.A.C.

(b) Examples of material(s) and authoritative literature used as documentation to meet the requirements of subparagraph (2)(a)3. above include:

1. Sections of the United States Code (USC) or the CFR;

2. Letters, emails or other forms of communications from the FDA;

3. Evidence that the product is currently being marketed in the United States and that the FDA has actual or constructive knowledge that the product is being marketed in the United States;

4. The Merck Manual of Diagnosis and Therapy;

5. Physicians' Desk Reference;

6. Remington's Pharmaceutical Science;

7. Fully cited and copied U.S. medical or pharmaceutical journal articles;

8. DailyMed published by the U.S. National Library of Medicine;

9. Facts and Comparisons; or

10. American Drug Index.

(c) An applicant must amend its product registration list for new products prior to any sales by following the procedures for an initial product registration, listing only those products to be added. Registration for these products will expire concurrently with the biennial cycle for that establishment's other registered products. Fees will be prorated as provided for in subsection 61N-1.018(4), F.A.C.

(3) Product registration renewal.

(a) Applicants applying for renewal of a product registration must:

1. Submit DBPR form number DBPR-DDC-235, "Application for Product Registration Renewal," effective May 2015, available at <http://www.flrules.org/Gateway/reference.asp?No=Ref-05666>; which is incorporated by reference herein;

2. Submit a product label or copy thereof and all labeling associated with the product if the label or labeling has changed in any respect from the initial or previous renewal registration; and,

3. Pay the appropriate fee pursuant to Rule 61N-1.018, F.A.C.

(b) Registrations issued by the department within the grace period will automatically expire 24 months after the last day of the month in which the previous registration expired.

*Rulemaking Authority 499.05 FS. Law Implemented 499.01, 499.015, 499.04, 499.05, 559.79(2) FS. History--New 7-1-96, Formerly 10D-45.0542, Amended 1-26-99, 4-17-01, 1-1-04, Formerly 64F-12.016, Amended 8-2-15.*



**61N-1.018 Fees.**

(1) Biennial fees for a Manufacturer or Repackager permit are as follows:

	Biennial Fee
Prescription Drug Manufacturer	\$1500
Prescription Drug Repackager	\$1500
Device Manufacturer	\$1200
Cosmetic Manufacturer	\$800
Over-the Counter Drug Manufacturer	\$800
Medical Gas Manufacturer	\$1000
Non-resident Prescription Drug Manufacturer	\$1000

No manufacturer shall be required to pay more than one fee per establishment to obtain an additional manufacturing permit; but the manufacturer must pay the highest fee applicable to the operations in each establishment.

(2)(a) Biennial fees for a Wholesale Distributor or Freight Forwarder permit that is issued on a Biennial basis are as follows:

	Biennial Fee
Medical Gas Wholesale Distributor	\$600
Retail Pharmacy Drug Wholesale Distributor	\$100
Freight Forwarder	\$600
Veterinary Prescription Drug Wholesale Distributor	\$1000
Limited Prescription Drug Veterinary Wholesale Distributor	\$1000

(b) Annual fees for a Wholesale Distributor permit that is issued on an Annual basis are as follows:

	Annual Fee
Prescription Drug Wholesale Distributor (including Broker Only)	\$800
Out-of-State Prescription Drug Wholesale Distributor	\$800

(3) Biennial fees for Other permits are as follows:

	Biennial Fee
Complimentary Drug Distributor	\$500
Veterinary Prescription Drug Retail Establishment	\$600
Medical Oxygen Retail Establishment	\$600
Restricted Prescription Drug Distributor – Blood Establishment	\$600
Restricted Prescription Drug Distributor – Health Care Entity	\$600
Restricted Prescription Drug Distributor – Charitable Organization	\$600
Restricted Prescription Drug Distributor – Reverse Distributor	\$600
Restricted Prescription Drug Distributor – Destruction	\$600
Restricted Prescription Drug Distributor – Government Programs	\$600
Restricted Prescription Drug Distributor – Institutional Research	\$600
Third Party Logistics Provider	\$600
Health Care Clinic Establishment	\$255

(4) Miscellaneous Other fees are as follows:

	Fee
(a) Certification as Designated Representative	\$150
(b) Initial Application/On-site Inspection	\$150 Non-Refundable

The initial application/on-site inspection fee is non-refundable.

If the department determines it must re-inspect for an initial application because the applicant does not have security, climate control, a quarantine area, or written policies and procedures, as required by the particular permit for which the applicant is applying; fails to appear for a scheduled inspection; or is otherwise not ready or available for inspection or available to schedule an inspection on or after the date indicated on the application form, an additional on-site inspection fee of \$150 is required for each re-inspection.

(c) Bond/Security: Prescription Drug Wholesale Distributor or Out-of-State Prescription Drug Wholesale Distributor, as set	\$100,000
--	-----------

forth in Section 499.01(2)(d), (e), F.S.

(d) Bond/Security: Limited Prescription Drug Veterinary Wholesale, \$20,000  
as set forth in Section 499.01(2)(l), F.S.

(e) Change of Address:

A relocation fee of \$100 must be paid for each permitted person or establishment relocating for which an on-site inspection is required. If no on-site inspection is required, the relocation fee is \$25 per permit. If a permitted person has multiple permits under the same permitted name and address and relocates any or all permitted activities concurrently to the new location, then only one \$100 fee is required plus \$25 for each additional permit.

(f) Product Registration (for each drug or cosmetic product registered) \$30\*

\* The registration fee for a prescription drug or cosmetic product being amended to an existing product registration that has 12 months or less until it expires is \$15.

(g) Listed Identical Products \$15

(h) Free Sale Certificate \$25

Signature of Free Sale Certificate copy (requested concurrently) \$2

(i) Delinquent Establishment Permit Renewal (per permit) \$100

(5) The department shall assess other fees as provided in Chapter 499, Part I, F.S.

*Rulemaking Authority 499.01, 499.04, 499.05, 499.831, 499.832 FS. Law Implemented 499.01, 499.012, 499.015, 499.04, 499.041, 499.05, 499.028, 499.831, 499.832 FS. History—New 7-1-96, Formerly 10D-45.0544, Amended 4-17-01, 7-6-03, 1-1-04, 9-13-04, 2-14-06, 9-5-07, 3-10-09, Formerly 64F-12.018, Amended 6-3-15.*





**61N-1.020 Forms. REPEAL**

*Rulemaking Authority 499.01, 499.012, 499.0122, 499.013, 499.015, 499.018, 499.028, 499.04, 499.041, 499.05, 499.06, 499.62, 499.63, 499.64, 499.66, 499.67, 499.701 FS. Law Implemented 499.01, 499.012, 499.0122, 499.013, 499.015, 499.018, 499.028, 499.04, 499.041, 499.05, 499.06, 499.062, 499.063, 499.064, 499.066, 499.067 FS. History—New 12-12-82, Formerly 10D-45.56, Amended 11-26-86, 2-4-93, 7-1-96, Formerly 10D-45.056, Amended 1-26-99, 1-1-04, Formerly 64F-12.020, Repealed 6-30-15.*



Notice of Development of Rulemaking

**DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION**

**Drugs, Devices and Cosmetics**

RULE NO.: RULE TITLE:

61N-1.023 Restricted Prescription Drug Distributor Permits; Special Provisions

PURPOSE AND EFFECT: The Division proposes to amend the rules to set for the permitting requirements for the Restricted Rx Drug Distributor – Blood Establishment permit.

SUBJECT AREA TO BE ADDRESSED: Drug, Devices and Cosmetics – Restricted Rx Drug Distributor – Blood Establishment permit.

RULEMAKING AUTHORITY: 499.014, 499.05 FS.

LAW IMPLEMENTED: 499.01, 499.012, 499.0121, 499.014 FS.

IF REQUESTED IN WRITING AND NOT DEEMED UNNECESSARY BY THE AGENCY HEAD, A RULE DEVELOPMENT WORKSHOP WILL BE NOTICED IN THE NEXT AVAILABLE FLORIDA ADMINISTRATIVE REGISTER.

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE DEVELOPMENT AND A COPY OF THE PRELIMINARY DRAFT, IF AVAILABLE, IS: Dinah Greene, 1940 North Monroe Street, Suite 26A, Tallahassee, FL 32399, (850)717-1802

THE PRELIMINARY TEXT OF THE PROPOSED RULE DEVELOPMENT IS NOT AVAILABLE.

**61N-1.023 Restricted Prescription Drug Distributor Permits; Special Provisions.**

The following Restricted Prescription (Rx) Drug Distributor permits will be issued by the department:

(1) through (6) No change.

(7) Restricted Prescription Drug Distributor – Blood Establishment. This permit is required for a blood establishment, as defined in s. 381.06014, Florida Statutes, located in this state to engage, pursuant to s. 499.01(2)(g)1.c., Florida Statutes, in the distribution of the types of prescription drugs identified in s. 499.01(2)(g)1.c.(IV), Florida Statutes, other than blood or blood components intended for transfusion, to a health care entity in this state that is either licensed as a closed pharmacy or that provides health care services at that establishment.

*Rulemaking Authority 499.014, 499.05, FS. Law Implemented 499.01, 499.012, 499.0121, 499.014, 499.01(2) FS. History—New 7-1-96, Formerly 10D-45.059, Amended 1-26-99, 4-17-01, Formerly 64F-12.023, Amended \_\_\_\_\_.*

NAME OF PERSON ORIGINATING PROPOSED RULE: Reginald D. Dixon, Director

NAME OF AGENCY HEAD WHO APPROVED THE PROPOSED RULE: Ken Lawson, Secretary

DATE PROPOSED RULE APPROVED BY AGENCY HEAD:

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAR: February 20, 2014



## Notice of Meeting/Workshop Hearing

### DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION

#### Drugs, Devices and Cosmetics

RULE NO.:      RULE TITLE:

61N-1.027      Distribution of Emergency Use Medical Oxygen

The Division of Drugs, Devices and Cosmetics announces a workshop to which all persons are invited.

DATE AND TIME: June 10, 2015, 10:30 a.m. - 12:00 p.m.

PLACE: Department of Business and Professional Regulation, Professions Board Room, 1940 N. Monroe Street, Tallahassee, FL, 32399

GENERAL SUBJECT MATTER TO BE CONSIDERED: The subject area to be addressed in this rule is the distribution of medical oxygen for emergency use by persons authorized to receive emergency use oxygen.

#### 61N-1.027 Distribution of Emergency Use Medical Oxygen.

A medical oxygen retail establishment permitted under Chapter 499, F.S., Part III, shall not engage in the distribution of emergency use medical oxygen unless it meets the following requirements:

- (1) The permittee's permit is current;
- (2) The permittee has a policy and procedure in place governing its distribution of emergency use medical oxygen that complies with the requirements for wholesale distributors set forth in Section 499.90, F.S.;
- (3) The permittee creates, contemporaneously and no later than 24 hours after the distribution of emergency use medical oxygen to persons authorized to receive emergency use oxygen, records pertaining to the distribution that comply with the recordkeeping requirements set forth in Section 499.89, F.S.; and
- (4) The distribution of the emergency use medical oxygen does not occur between the parties for a time period of more than fourteen (14) calendar days.

Rulemaking Authority 499.85 FS. Law Implemented 499.83, 499.85, 499.86, 499.89, 499.90 FS. History-New \_\_\_\_\_.

A copy of the agenda may be obtained by contacting: Dinah Greene at The Division of Drugs, Devices and Cosmetics, 1940 N. Monroe Street, Suite 26A, Tallahassee, FL 32399-1047, (850)717-1802.

Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the agency at least 10 days before the workshop/meeting by contacting: Dinah Greene at The Division of Drugs, Devices and Cosmetics, 1940 N. Monroe Street, Suite 26A, Tallahassee, FL 32399-1047, (850)717-1802. If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770 (Voice).

If any person decides to appeal any decision made by the Board with respect to any matter considered at this meeting or hearing, he/she will need to ensure that a verbatim record of the proceeding is made, which record includes the testimony and evidence from which the appeal is to be issued.

For more information, you may contact: Dinah Greene at The Division of Drugs, Devices and Cosmetics, 1940 N. Monroe Street, Suite 26A, Tallahassee, FL 32399-1047, (850)717-1802.

**61N-1.027 Distribution of Emergency Use Medical Oxygen.**

A medical oxygen retail establishment permitted under Chapter 499, F.S., Part III, shall not engage in the distribution of emergency use medical oxygen unless it meets the following requirements:

- (1) The permittee's permit is current;
- (2) The permittee has a policy and procedure in place governing its distribution of emergency use medical oxygen that complies with the requirements for wholesale distributors set forth in section 499.90, F.S.;
- (3) The permittee creates, contemporaneously and no later than 24 hours after the distribution of emergency use medical oxygen to persons authorized to receive emergency use oxygen, records pertaining to the distribution that comply with the recordkeeping requirements set forth in section 499.89, F.S.; and
- (4) The distribution of the emergency use medical oxygen does not occur between the parties for a time period of more than fourteen (14) calendar days.

*Rulemaking Authority 499.85 FS. Law Implemented 499.83, 499.85, 499.86, 499.89, 499.90 F.S. History-New \_\_\_\_\_.*



## Notice of Meeting/Workshop Hearing

### **DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION**

#### **Drugs, Devices and Cosmetics**

The Division of Drugs, Devices and Cosmetics announces a workshop to which all persons are invited.

DATE AND TIME: August 6, 2015, 1:00 p.m.

PLACE: Department of Business and Professional Regulation, Professions Board Room, 1940 N. Monroe Street, Tallahassee, FL, 32399

GENERAL SUBJECT MATTER TO BE CONSIDERED: The subject area to be addressed in this rule is the distribution of medical oxygen for emergency use by persons authorized to receive emergency use oxygen.

61N-1.027 Distribution of Emergency Use Medical Oxygen.

A medical oxygen retail establishment permitted under Chapter 499, F.S., Part III, shall not engage in the distribution of emergency use medical oxygen unless it meets the following requirements:

- (1) The permittee's permit is current;
- (2) The permittee has a policy and procedure in place governing its distribution of emergency use medical oxygen that complies with the requirements for wholesale distributors set forth in Section 499.90, F.S.;
- (3) The permittee creates, contemporaneously and no later than 24 hours after the distribution of emergency use medical oxygen to persons authorized to receive emergency use oxygen, records pertaining to the distribution that comply with the recordkeeping requirements set forth in Section 499.89, F.S.; and
- (4) The distribution of the emergency use medical oxygen does not occur between the parties for a time period of more than fourteen (14) calendar days.

A copy of the agenda may be obtained by contacting: Dinah Greene at The Division of Drugs, Devices and Cosmetics, 1940 N. Monroe Street, Suite 26A, Tallahassee, FL 32399-1047, (850)717-1802.

Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the agency at least 10 days before the workshop/meeting by contacting: Dinah Greene at The Division of Drugs, Devices and Cosmetics, 1940 N. Monroe Street, Suite 26A, Tallahassee, FL 32399-1047, (850)717-1802. If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770 (Voice).

If any person decides to appeal any decision made by the Board with respect to any matter considered at this meeting or hearing, he/she will need to ensure that a verbatim record of the proceeding is made, which record includes the testimony and evidence from which the appeal is to be issued.

For more information, you may contact: Dinah Greene at The Division of Drugs, Devices and Cosmetics, 1940 N. Monroe Street, Suite 26A, Tallahassee, FL 32399-1047, (850)717-1802.



## Notice of Development of Rulemaking

### DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION

#### Drugs, Devices and Cosmetics

##### RULE NOS.:RULE TITLES:

- 61N-1.028 Product Tracking and Tracing – Definitions
- 61N-1.029 Product Tracking and Tracing – Manufacturer Requirements
- 61N-1.030 Product Tracking and Tracing – Wholesale Distributor Requirements
- 61N-1.031 Product Tracking and Tracing – Dispenser Requirements
- 61N-1.032 Product Tracking and Tracing – Repackager Requirements

PURPOSE AND EFFECT: To adopt and incorporate the federal requirements pertaining to the tracking and tracing of certain prescription drug products.

SUBJECT AREA TO BE ADDRESSED: The proposed rule development addresses the product tracking and tracing requirements for entities that engage in the manufacture, repackaging, wholesale distribution, and dispensing of specific prescription drug products falling under Title II, Drug Supply Chain Security Act, of the federal Drug Quality and Security Act.

RULEMAKING AUTHORITY: 499.05, 499.0121 FS.

LAW IMPLEMENTED: 499.002, 499.0121, 499.05, 499.052 FS.

IF REQUESTED IN WRITING AND NOT DEEMED UNNECESSARY BY THE AGENCY HEAD, A RULE DEVELOPMENT WORKSHOP WILL BE NOTICED IN THE NEXT AVAILABLE FLORIDA ADMINISTRATIVE REGISTER.

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, 1940 N. Monroe St., Suite 26A, Tallahassee, FL 32399-1047, [Dinah.Greene@myfloridalicense.com](mailto:Dinah.Greene@myfloridalicense.com), (850)488-1802

THE PRELIMINARY TEXT OF THE PROPOSED RULE DEVELOPMENT IS NOT AVAILABLE.



## **TAB 3: DIVISION DIRECTOR'S REPORT - REGGIE DIXON**

### **2. 2016 DDC POTENTIAL LEGISLATIVE PROPOSALS**

## DDC Potential Legislative Proposals

Current Situation	Proposed Change	Purpose	Statutory Citations
<p>The division becomes aware of various federal investigations / operations within the state of Florida against entities regulated by the division. The division's participation is limited during these investigations because the early disclosure of the information gathered during these joint operations could jeopardize the operations. Federal agencies have some significant confidentiality provisions and are hesitant to share this information with the division because there is no similar confidentiality provision under Florida law.</p> <p>Prescription drug wholesale distributor renewal applicants must submit a completed application, which includes an extensive personal information statement for each of its key personnel. The permits are renewed annually, so this information must be submitted annually, including an updated photograph of each key personnel. This is cumbersome and slows down the renewal process.</p> <p>Prescription drug wholesale distributors must renew annually; this renewal includes the annual submission of a complete application, which includes an extensive personal information statement for each key officer. This is cumbersome.</p>	<p>Amend Chapter 499 to create an exemption from public records for information the division obtains pursuant to joint investigations with the FDA, DEA, and other federal law enforcement agencies.</p>	<p>Would allow the division to work more cooperatively with federal law enforcement officials.</p>	<p>499.051</p>
	<p>Amend Chapter 499 to relax the amount of documentation submitted to the division for the renewal of prescription drug wholesale distributor permits.</p>	<p>Business friendly amendment that would expedite renewal applications.</p>	<p>499.012</p>
	<p>Amend Chapter 499 to change the renewal schedule of prescription drug wholesale distributors from one (1) year to two (2) years.</p>	<p>Business friendly amendment which would ease the burden on industry.</p>	<p>499.012</p>

## DDC Potential Legislative Proposals

Current Situation	Proposed Change	Purpose	Statutory Citations
Florida law currently conflicts with the federal law regarding the bond requirement for prescription drug wholesale distributors. Under federal law, a single bond of \$100,000 is required in any state; this bond is good for all the facilities that the entity operates. Additionally, if the entity's annual revenues are less than \$10 million, the bond requirement is lowered to \$25,000. Florida currently requires a \$100,000 bond for each facility operated by an entity that is permitted by Florida.	Amend Chapter 499 to conform to the federal bond requirements for prescription drug wholesale distributors.	Required by federal law.	499.01; 499.012
Florida law currently conflicts with the recently enacted federal Drug Quality & Security Act. There are numerous provisions relating to wholesale distribution and tracking of prescription drug products through the distribution chain that need to be adopted into Florida law.	Amend Chapter 499 to conform to the federal DQSA.	Required by federal law.	Numerous provisions within Chapter 499 would have to be amended and some new provisions created.
Division licensure and product registration applications do not expire. Thus, a deficient application will remain deficient in perpetuity. There are currently over 200 applications that have been pending since before 1/1/2014.	Amend Chapter 499 to cause applications to expire after 24 months if the agency has not taken final agency action on the applications.	Prevents applications from being pending in perpetuity. Clears out backlog of abandoned applications.	499.012
Applicants for licensure that require background checks must submit paper finger print cards to the division for processing. The receipt and manual processing of these cards slows the licensing process.	Amend Chapter 499 to allow the division to accept electronic / livescan finger prints from applicants for licensure.	Other areas of the department and other agencies currently accept electronic / livescan finger printing.	499.012

## DDC Potential Legislative Proposals

Current Situation	Proposed Change	Purpose	Statutory Citations
<p>Enforcement action by the division is the result of negotiated settlements that are based on either Administrative Complaints or Notices of Violations that have been issued after the alleged violations have been fully investigated and a formal investigative report has been submitted by the division's inspectors. There is no current method to address minor violations, where some sort of penalty should be imposed, without going through this process.</p> <p>The division administers the Cancer Drug Donation Program (CDDP); the program is suppose to facilitate the exchange of free cancer drugs and supplies from entities that possess such drugs and supplies to low income individuals that cannot afford to pay for such drugs. The program is marginally effective because of the restrictions on the drugs that can be donated.</p>	<p>Amend Chapter 499 to authorize the division's inspectors to issue citations to entities for minor violations.</p> <p>Amend Chapter 499 to relax the restrictions on the types of drugs that can be donated and to expand the types of entities that may be donors, e.g. Modified IIB permits.</p>	<p>Resolution of minor violations where some penalty should be imposed, but without the formal filing of an Administrative Complaint or Notice of Violation; other agencies have used citations to successfully address these types of violations.</p> <p>This would increase the availability of drugs and supplies thereby helping the most vulnerable individuals in the state.</p>	<p>New section would be created.</p> <p>499.029</p>



## DDC Potential Legislative Proposals

Current Situation	Proposed Change	Purpose	Statutory Citations
Chapter 499 prohibits the issuance to prescription manufacturing and wholesale distributing permits to all pharmacies permitted under chapter 465, except for nuclear pharmacies. In 2014, the Board of Pharmacy created a new pharmacy permit, a sterile compounding permit, which although a permit, is truly treated as if it were a license modifier, i.e., you can't have the sterile compounding permit without another type of pharmacy permit. All nuclear pharmacies must also have the sterile compounding permit. This creates a legal problem: we cannot issue a 499 permit to the nuclear pharmacy because of the sterile compounding permit.	Amend Chapter 499 to allow the division to issue a 499 permit to nuclear pharmacies that are also permitted as sterile compounding permittees by the Board of Pharmacy.	It was never the intent to prohibit nuclear pharmacies from having Chapter 499 permits. This was an oversight by the Board of Pharmacy.	499.012(2)(d)

## **TAB 4: OTHER BUSINESS**

### **1. 2016 MEETING DATES**

Meeting Date	Agenda Deadline	Type of Meeting
February 25, 2016		In Person Meeting
May 19, 2016		Conference Call
August 18, 2016		Discuss if this will be a Conference Call or In Person Meeting
December 1, 2016		Conference Call

**Council Members:**

These are 2016 Proposed Meeting Dates-

If you should have any questions please contact me at 850-717-1802.

**NOTE: I have checked these dates against the Board of Pharmacy calendar and other association's calendars.**