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

February 19, 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 Ugru, 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, Medical Gas

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 –December 11, 2014

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

1. Drug Supply Chain Security Act Overview
   Martha Russell –Director of Corporate Regulatory Affairs- Cardinal

TAB 3: Division Director's Report – Reginald Dixon

1. DDC Rules
2. SB 612 Cosmetic Product Registration
3. Declaratory Statements / Variance & Waiver- Informational purposes only

TAB 4: Other Business
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: February 19, 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. 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

1. December 11, 2014 Meeting Minutes
DRUG WHOLESALE DISTRIBUTOR ADVISORY COUNCIL
Draft Meeting Minutes
December 11, 2014
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, Michelle Mendez, Gary
Cacciatore, Jenn Ungru, Jeenu Philip. Mike Ayotte was absent.

TAB 1: Approval of August 14, 2014 Meeting Minutes

Motion by: Mr. Brock made a motion to approve, Seconded by: Dr. Mendez.
Motion Carried

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

1. 2015 Meeting Dates

After discussion the council made changes and agreed to dates for 2015.

TAB 3: Executive Director’s Report – Reginald Dixon

1. Secondary Wholesalers

Mr. Dixon stated this was a request from the last meeting. The Department is
reviewing the option of adding to our website.

Mr. Ellis stated I made the request for this information but with the new
federal changes we will not need to be identifying primary wholesalers its
authorized distributor.

Mr. Ellis suggested to Mr. Dixon not put forth much effort in this because of
the changes.

2. Drug Quality Security Act (DQSA) Update

Mr. Dixon gave a briefing on the DQSA and what the Department is doing to
prepare for legislation and the changes that need to be made to statute.

Mr. Marty Dix stated he had a question about chain pharmacy warehouses
that perform intra-company transfers. Under state law they are a wholesaler
but mainly do intra-company transfers. The federal law has them as
dispensers. Will they need a dispenser license to hold drugs and continue to
do intra-company transfers?
Mr. Dixon stated there has been discussion about this situation and the department is reviewing.

TAB 4: Other Business

Mr. Cacciatore encouraged the council and audience to review the guidance documents posted by the FDA in regards to the Drug Quality and Security Act.

Mr. Cacciatore stated he would entertain a motion to adjourn the meeting. Motion by Mr. Brock and Seconded by Dr. Mendez. Motion Carried.
1. DRUG SUPPLY CHAIN SECURITY ACT OVERVIEW
   MARTHA RUSSELL- Director of Corporate Regulatory Affairs, Cardinal
Drug Supply Chain Security Act

Drug Quality and Security Act

- The Drug Quality and Security Act was signed by the President on November 27, 2013.
- Contains two main “titles”:
  - Title I Drug Compounding: establishes national standards for compounding pharmaceuticals (not discussed here).
  - Title II Drug Supply Chain Security Act (DSCSA): establishes a national system for tracing pharmaceutical products through the supply chain, sets national licensing standards for wholesale distributors and third-party logistics providers, and preempts existing state licensing and pedigree requirements.
Critical Background:
What Prompted Federal Legislation?

- Looming 2015 Implementation of California "e-pedigree" law: required electronic tracking/tracing of all drug product packages—in real time—in an interoperable system

- Each link the chain would have to "scan" each item to capture transaction data

- With each successive distribution—the e-pedigree would have to be updated—and would grow exponentially and pharmacies would have to maintain massive amounts of data

- FDA statements that the CA law would serve as a national "template"

Definitions

- Product
- Transaction
- Manufacturer
- Repackager
- Dispenser
- Wholesale Distributor
- Distribute
- Illegitimate Product
- Suspect Product
- Licensed

- Package
- Prescription Drug
- Product Identifier
- Return
- Third Party Logistics Provider
- Trading Partner
- Transaction History
- Transaction Information
- Transaction Statement
Drug Supply Chain Security Overview: 3 parts

1. **Traceability**: Establishes a two phased national system for tracing pharmaceutical products through the supply chain.

2. **Licensing**: Establishes uniform national licensing standards for wholesale distributors and third-party logistics providers.

3. **Preemption**: Immediately preempts all state laws and regulations for tracing products through the supply chain (i.e., pedigree requirements) AND state laws and regulations regarding wholesale distributor and 3PL licensure.

---

DSCSA Part 1 of 3 – Traceability

1. **Traceability**: Establishes a two phased national system for tracing pharmaceutical products through the supply chain.

2. **Licensing**: Establishes uniform national licensing standards for wholesale distributors and **third-party logistics providers**.

3. **Preemption**: Immediately preempts all state laws and regulations for tracing products through the supply chain (i.e., pedigree requirements) AND state laws and regulations regarding wholesale distributor and 3PL licensure.
DSCSA Part 1 of 3 – SCOPE
Definition of “Products”

Manufacturers, Repackagers, Wholesale Distributors and Dispensers must pass, capture, receive, and maintain certain information about PRODUCTS with respect to each TRANSACTION.

• PRODUCTS.
  – Products = prescription drugs in finished dosage form that are for human use.
  – no OTC, medical devices, API, or drugs indicated for animal use
• A number of prescription drugs are exempted from the definition of product, including:
  – Blood and blood components intended for transfusion
  – Radioactive drugs and radioactive biologics
  – Imaging drugs
  – Intravenous products
  – Compounded drugs

DSCSA Part 1 of 3 – SCOPE
Definition of “Transaction”

Manufacturers, Repackagers, Wholesale Distributors and Dispensers must pass, capture, receive, and maintain certain information about PRODUCTS with respect to each TRANSACTION.

• TRANSACTIONS.
  – Transaction = change in ownership.
  – No third party logistic provider (3PL) involvement
• A number of transfers are exempted from the definition of transaction, including:
  -- Transfer of a product from one pharmacy to another (regardless of whether the two pharmacies are affiliated in any way) to fill a prescription for an identified patient.
  -- Distribution of minimal quantities of products by a licensed retail pharmacy to a licensed practitioner for office use******
  -- Distribution of a product pursuant to a sale or merger of a pharmacy or wholesale distributor
  -- Distribution of combination products (device + drug/device/biologic)
  -- Distributions for emergency medical reasons
Part 1: Traceability
Establishes a **two phased** national system for tracing pharmaceutical products through the supply chain
a) Phase 1: Product tracing – supply chain partners pass transactional data to subsequent purchasers (data exchange occurs with change of ownership only).
b) Phase 2: Product identifier – supply chain partners trace product identifiers thru the supply chain.

Phase 1
- Starting January 1, 2015:
  - **manufacturers** are required to pass **transaction data** to subsequent purchasers.
  - **repackagers** and **wholesale distributors** will be required to receive **transaction data** from manufacturers and pass **transaction data** to subsequent purchasers

- July 1, 2015: dispensers are required to receive **transaction data** and pass **transaction data** if they further distribute
DSCSA Part 1 of 3 – Traceability
Phase 1 of 2: Product Tracing

• What is “transaction data” that must be passed, received, and maintained by supply chain participants?

  Three pieces:
  • transaction information
  • transaction history
  • transaction statement

  These include information about the product and transaction (TI), the seller's compliance (TS), and the subsequent owners & transactions (TH).

Storing/Accessing Transaction Data

• The law allows a dispenser to have a third party maintain the transaction data required to be captured and stored by the pharmacy.

• The wholesale distributor can do this on behalf of a pharmacy; a written agreement will be required between the pharmacy and wholesaler(s).

• Some wholesalers have created web-portal systems for dispensers to access relevant information
DSCSA Part 1 of 3 – Traceability
Phase 2 of 2: Product Identifiers

- Phase 2
  - 10 years after enactment (November 2023), supply chain stakeholders will be required to electronically track product at the individual package level using the product identifier
    - **Product identifier**: A product identifier is a standardized graphic that carries the product’s standardized numerical identifier, lot number, and expiration date in both human and machine-readable format.
    - Unless FDA allows the use of other technologies, a 2D barcode shall be used for the package and case.
    - Data shall be exchanged in a secure, interoperable, electronic manner
    - A series of assessments, public meetings, and at least one pilot program will be conducted to **develop the precise requirements for**, and ensure the technological feasibility of, Phase 2.

---

DSCSA Part 1 of 3 – Traceability

**Timeline**

- **Enactment (Day 1) to December 31, 2014**: pedigree requirements as they exist today in the PDMA
  - Manufacturers and ADRs are exempt from providing pedigrees
    - ADR: Authorized Distributor of Record
- **January 1, 2015**: manufacturers pass transaction data to subsequent purchasers. Repackers and wholesale distributors required to receive transaction data from manufacturers and pass transaction data to subsequent purchasers.
- **July 1, 2015**: dispensers are required to receive *transaction data* and pass *transaction data* if they further distribute
DSCSA Part 1 of 3 – Traceability

Timeline continued...

- 2017: Four years after enactment, we are still in Phase 1, but we begin laying framework for Phase 2. Manufacturers must affix a product identifier to each individual package and homogenous case.

- 2018: Beginning five years after enactment, repackagers must affix a product identifier to each individual package and homogenous case.

- 2019: Beginning six years after enactment, wholesale distributors must only accept products that contain the required product identifier; and verify product identifier before redistributing returned products

- 2020: Beginning seven years after enactment, dispensers must only accept products that contain the required product identifier.

DSCSA Part 2 of 3 – Licensing

1. Traceability: Establishes a two phased national system for tracing pharmaceutical products through the supply chain.

2. Licensing: Establishes uniform national licensing standards for wholesale distributors and third-party logistics providers.

3. Preemption: Immediately preempts all state laws and regulations for tracing products through the supply chain (i.e., pedigree requirements) AND state laws and regulations regarding wholesale distributor and 3PL licensure.
DSCSA Part 2 of 3 – Licensing

- The Act sets out seven broad categories of licensing standards for **wholesale distributors and for 3PLs**.
  - Storage and handling, maintenance of records, bond, background checks, physical inspections.
  - November 2015: FDA will issue regulations to further define those standards.
  - Regulations will be FINAL by November 2015 and EFFECTIVE November 2017.
    - This gives states two years (November 2015 to November 2017) to revise their wholesale distribution and licensing requirements to match FDA’s.

---

DSCSA Part 2 of 3 – Licensing

- States will continue to license wholesale distributors and 3PLs, but they will be required to do so utilizing the federal standards that FDA establishes.
- In the absence of a home state licensing program that satisfies the federal requirements, a federal licensing program will be established to license wholesale distributors and 3PLs.
- DSCSA does not discuss a state’s licensing of manufacturers or repackers (just says that they are not to be considered wholesale distributors).
**DSCSA Part 3 of 3 – Preemption**

1. **Traceability**: Establishes a two phased national system for tracing pharmaceutical products through the supply chain.

2. **Licensing**: Establishes uniform national licensing standards for wholesale distributors and third-party logistics providers.

3. **Preemption**: Immediately preempts all state laws and regulations for tracing products through the supply chain (i.e., pedigree requirements); preempts state laws and regulations regarding wholesale distributor and 3PL licensure.

---

**DSCSA Part 3- Preemption**

Pedigree preemption: As of November 2013, eighteen states had state prescription drug pedigree requirements in effect. Immediately upon enactment, the DSCSA preempted all state pedigree laws and we were be left with one standard federal solution.
DSCSA Part 3- Preemption

Licensing Preemption

FDA recently released guidance on preemption:

(b) Wholesale Distributor and Third-Party Logistics Provider Standards—

(1) IN GENERAL.—Beginning on the date of enactment of the Drug Supply Chain Security Act, no State or political subdivision of a State may establish or continue any standards, requirements, or regulations with respect to wholesale prescription drug distributor or third-party logistics provider licensees that are inconsistent with, less stringent than, directly related to, or covered by the standards and requirements applicable under section 503(e) (as amended by such Act), in the case of a wholesale distributor, or section 584, in the case of a third-party logistics provider.

---

DSCSA Part 3- Preemption

- Licensing Preemption:
  - FDA guidance: “Beginning on November 27, 2013, States were preempted from establishing or continuing any standards, requirements, or regulations with respect to wholesale distributor licensees that are inconsistent with, less stringent than, directly related to, or covered by the standards or requirements...”
  - FDA’s guidance goes on to say that States may not impose standards, requirements, or regulations with respect to wholesale drug distributors that fall below the minimum standards established by Federal law.
    - Floor, ceiling, both?
  - FDA will finalize licensing standards in 2015. 3PL licensing standards will be “final” in 2016; Wholesale distributor licensing standards will be effective 2017.
  - States may continue to regulate wholesale distributors and 3PLs in areas that are not covered by the licensing standards in the Act.
Need to Know for Dispensers

- Requirements for receiving information/storage effective July 1, 2015

- Need to dialogue with wholesaler(s)—both primary and secondary about capabilities to assist pharmacy in accessing and storing information and your current technology vendor

- FDA Emphasis on Pharmacists "Knowing their Sources"

- Forthcoming FDA Guidance on "Treatment of Suspect Product"

Q&A

CardinalHealth.com/trace
TAB 3. DIRECTOR'S REPORT - REGINALD DIXON

1. DDC Rules
2. SB 612 Cosmetic Product Registration
3. Declaratory Statements / Variance Waivers
1. RULES REPORT
The following chart is a summary of the Division’s current rulemaking efforts.

<table>
<thead>
<tr>
<th>Rule #</th>
<th>Title</th>
<th>Purpose</th>
<th>Status</th>
<th>Next Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>61N-1.001</td>
<td>General Regulations; Definitions</td>
<td>Clear up the definitions of certain terms, as well as to define “limited quantities” as used in ss. 499.01(3) &amp; (4), F.S.</td>
<td>12/17/13 – Notice of Development filed; On hold pending outcome of 2015 Legislative session.</td>
<td></td>
</tr>
<tr>
<td>61N-1.010</td>
<td>Guidelines for Manufacturing Cosmetics</td>
<td>The rule adopts the federal guidelines for cosmetic manufacturing; the rule is necessary to bring Florida requirements in line with the federal guidelines.</td>
<td>2/6/15 – Notice of Development being reviewed.</td>
<td>File Notice of Development</td>
</tr>
<tr>
<td>61N-1.012</td>
<td>Records of Drugs, Cosmetics and Devices</td>
<td>Set forth recordkeeping requirements for Florida manufacturers engaging in “limited quantities” of Rx drugs obtained from non-Florida licensed entities.</td>
<td>12/17/13 – Notice of Development filed; On hold pending outcome of 2015 Legislative session.</td>
<td></td>
</tr>
<tr>
<td>61N-1.013</td>
<td>Prescription Drugs; Receipt, Storage and Security.</td>
<td>Set forth Rx drug storage requirements for Florida manufacturers engaging in “limited quantities” of Rx drugs obtained from non-Florida licensed entities.</td>
<td>12/17/13 – Notice of Development filed; On hold pending outcome of 2015 Legislative session.</td>
<td></td>
</tr>
<tr>
<td>61N-1.015</td>
<td>Licensing, Application, Permitting</td>
<td>Add language to incorporate updated licensing applications and to incorporate the application for the Restricted RX Drug Distributor-Blood Establishment permit.</td>
<td>2/20/14 – Notice of Development files.</td>
<td>Draft language, including revised application forms, then file Notice of Proposed Rule</td>
</tr>
<tr>
<td>61N-1.018</td>
<td>Fees</td>
<td>Specify fee for restricted Rx drug distributor – blood establishment permit;</td>
<td>4/17/14 – Notice of Development re-filed due to technical errors (language attached to notice of development)</td>
<td>Draft language and file Notice of Proposed Rule</td>
</tr>
<tr>
<td>61N-1.020</td>
<td>Forms</td>
<td>The Division proposes the amendments to identify and</td>
<td>2/20/14 – Notice of Development filed.</td>
<td>Withdraw Notice of Development</td>
</tr>
<tr>
<td>61N-1.023</td>
<td>Restricted Prescription Drug Distributor Permits; Special Provisions</td>
<td>Create/set forth the restricted Rx drug distributor permit; identify Rx drugs these permits can distribute per s. 499.01(2)(g)1.c., F.S.</td>
<td>12/17/14 – Notice of Development filed</td>
<td>Draft language and file Notice of Proposed Rule</td>
</tr>
</tbody>
</table>
2. SB 612 COSMETIC PRODUCT REGISTRATION
A bill to be entitled
An act relating to cosmetic product registration;
amending s. 499.015, F.S.; removing the requirement
that a person who manufactures, packages, repackages,
labels, or relabels a cosmetic in this state must
register such cosmetic biennially with the Department
of Business and Professional Regulation; amending ss.
499.003 and 499.041, F.S.; conforming provisions to
changes made by this act; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 499.015, Florida Statutes, is amended to
read:

499.015 Registration of drugs and devices, and cosmetics;
issuance of certificates of free sale.—

(1)(a) Except for those persons exempted from the
definition of manufacturer in s. 499.003, any person who
manufactures, packages, repackages, labels, or relabels a drug
or device, or cosmetic in this state must register such drug
or device, or cosmetic biennially with the department; pay a
fee in accordance with the fee schedule provided by s. 499.041;
and comply with this section. The registrant must list each
separate and distinct drug or device, or cosmetic at the time
of registration.

(b) The department may not register any product that does
not comply with the Federal Food, Drug, and Cosmetic Act, as
amended, or Title 21 C.F.R. Registration of a product by the
department does not mean that the product does in fact comply

CODING: Words struck are deletions; words underlined are additions.
with all provisions of the Federal Food, Drug, and Cosmetic Act, as amended.

(2) The department may require the submission of a catalog and specimens of labels at the time of application for registration of drugs or devices, and cosmetics packaged and prepared in compliance with the federal act, which submission constitutes a satisfactory compliance for registration of the products. With respect to all other drugs and devices, and cosmetics, the department may require the submission of a catalog and specimens of labels at the time of application for registration, but the registration will not become effective until the department has examined and approved the label of the drug or device, or cosmetic product. This approval or denial must include written notification to the manufacturer.

(3) Except for those persons exempted from the definition of manufacturer in s. 499.003, a person may not sell any product that he or she has failed to register in conformity with this section. Such failure to register subjects such drug or device, or cosmetic product to seizure and condemnation as provided in s. 499.062, and subjects such person to the penalties and remedies provided in this part.

(4) Unless a registration is renewed, it expires 2 years after the last day of the month in which it was issued. The department may issue a stop-sale notice or order against a person that is subject to the requirements of this section and that fails to comply with this section within 31 days after the date the registration expires. The notice or order shall prohibit such person from selling or causing to be sold any drugs or devices, or cosmetics covered by this part until he or
she complies with the requirements of this section.

(5) A product regulated under this section which is not included in the biennial registration may not be sold until it is registered and complies with this section.

(6) The department may issue a certificate of free sale for any product that is required to be registered under this part.

(7) A product registration is valid only for the company named on the registration and located at the address on the registration. A person whose product is registered by the department under this section must notify the department before any change in the name or address of the establishment to which the product is registered. If a person whose product is registered ceases conducting business, the person must notify the department before closing the business.

(8) Notwithstanding any requirements set forth in this part, a manufacturer of medical devices that is registered with the federal Food and Drug Administration is exempt from this section and s. 499.041(6) if:

(a) The manufacturer’s medical devices are approved for marketing by, or listed with the federal Food and Drug Administration in accordance with federal law for commercial distribution; or

(b) The manufacturer subcontracts with a manufacturer of medical devices to manufacture components of such devices.

(9) However, the manufacturer must submit evidence of such registration, listing, or approval with its initial application for a permit to do business in this state, as required in s. 499.01 and any changes to such information previously submitted at the time of renewal of the permit. Evidence of approval,
listing, and registration by the federal Food and Drug
Administration must include:

(a) For Class II devices, a copy of the premarket
notification letter (510K);

(b) For Class III devices, a federal Food and Drug
Administration premarket approval number;

(c) For a manufacturer who subcontracts with a manufacturer
of medical devices to manufacture components of such devices, a
federal Food and Drug Administration registration
number; or

(d) For a manufacturer of medical devices whose devices are
exempt from premarket approval by the federal Food and Drug
Administration, a federal Food and Drug
Administration registration number.

Section 2. Subsection (6) of section 499.003, Florida
Statutes, is amended to read:

499.003 Definitions of terms used in this part.—As used in
this part, the term:

(6) "Certificate of free sale" means a document prepared by
the department which certifies a drug or device, or cosmetic,
that is registered with the department as one that can be
legally sold in the state.

Section 3. Subsection (6) of section 499.041, Florida
Statutes, is amended to read:

499.041 Schedule of fees for drug, device, and cosmetic
applications and permits, product registrations, and free-sale
certificates.—

(6) A person that is required to register drugs or
devices, or cosmetic products, under s. 499.015 shall pay an
22-00649-15

117 annual product registration fee of not less than $5 or more than
118 $15 for each separate and distinct product in package form. The
119 registration fee is in addition to the fee charged for a free-
120 sale certificate.
121 Section 4. This act shall take effect July 1, 2015.

CODING: Words [stricken] are deletions; words [underlined] are additions.
3. DECLARATORY STATEMENTS / VARIANCE WAIVERS
IN RE: PETITION FOR EMERGENCY WAIVER AND VARIANCE FROM RULE 61N-1.023(2), FLORIDA ADMINISTRATIVE CODE,

PARALLON BUSINESS SOLUTIONS, LLC,

PETITIONER.

FINAL ORDER GRANTING IN PART AND DENYING IN PART PETITION FOR VARIANCE/WAIVER

The Department of Business & Professional Regulation, Division of Drugs, Devices, and Cosmetics (hereafter, "Department"), issues this final order granting in part and denying in part the Petition for Emergency Waiver/Variance, in accordance with Section 120.542, Florida Statutes (2014).

PRELIMINARY STATEMENT

On October 27, 2014, Petitioner, Parallon Business Solutions, LLC, (hereafter, "Parallon" or "Petitioner"), filed a petition for emergency waiver and variance from the requirements of Rule 61N-1.023(2), Florida Administrative Code (hereafter, "F.A.C."). Notice of the petition was published in the October 30, 2014, issue of the Florida Administrative Register, Volume 40, Number 212.

FINDINGS OF FACT

1. Parallon's corporate offices are located at One Park Plaza, Nashville, Tennessee 37203.

2. Parallon owns and operates three prescription drug distribution centers that are permitted by the Department as restricted prescription drug distributors—health
care entity: Central Shared Services LLC, doing business as (d/b/a) West Florida Supply Chain Services located at 12901 Starkey Road, Suite 1000, Largo, FL 33773, holding permit number 50:284; Central Shared Services LLC, d/b/a North Florida Supply Chain Services, located at 8501-1 Westside Industrial Drive, Jacksonville, FL 32219, holding permit number 50:285; and Central Shared Services LLC, d/b/a East Florida Supply Chain Services, located at 10094 Premier Parkway, Miramar, FL 33025, holding permit number 50:283.

3. Establishments permitted as a restricted prescription drug distributor—health care entity that are doing business in this state are subject to the provisions of Chapter 499, Florida Statutes, the Florida Drug and Cosmetics Act, and are subject to the rules that are adopted under the Act.

4. Section 499.01(1)(g), Florida Statutes (2014), establishes the restricted prescription drug distributor permit for those persons located in this state who engage in the distribution of prescription drugs which distribution does not meet the definition of “wholesale distribution” under Section 499.003(53), Florida Statutes (2014), or any person in this state who engages in the receipt or distribution of a prescription drug in this state for the purpose of processing its return for destruction. The Department is authorized to adopt rules regarding the distribution of prescription drugs by hospitals, health care entities, charitable organizations, other persons not involved in wholesale distribution, and blood establishments, which rules are necessary for the protection of the public health, safety, and welfare.
5. Rule 61N-1.023(2), F.A.C., provides:

(2) Restricted Rx Drug Distributor – Health Care Entity. This permit is required for a hospital or health care entity as defined in Section 499.003(15), F.S., for the limited purpose of transferring prescription drugs among hospitals or other health care entities that are (1) under common control as provided in Section 499.012(1)(a)3., F.S.; or (2) members of a group purchasing organization as provided for in Section 499.012(1)(a)1., F.S. For the purpose of this permit and transfers thereunder, an independent contractor cannot be under “common control” as defined in Section 499.012(1)(a)3., F.S. Transfers are limited to a facility under common control or member of the group purchasing organization, either of which must be licensed with a pharmacy permit that authorizes the acquisition and possession of prescription drugs. This permit also authorizes a warehouse or purchasing depot of a university to transfer prescription drugs to practitioner or non-practitioner researchers for university sponsored research conducted in accordance with Section 240.241, F.S. All requirements of paragraph (6) of this rule related to the Restricted Rx Drug Distributor – Institutional Research permit must be complied with for transfers under this provision. [Emphasis added].

6. Rule 61N-1.023, Florida Statutes, implements Section 499.01, 499.012, 499.0121, and former section 499.014, Florida Statutes. These provisions relate to state-required permits, licensure requirements, storage and handling of prescription drugs, and with respect to former section 499.014, requirements for distributions of legend drugs by hospitals and health care entities. Section 499.002, Florida Statutes, sets forth the intended purposes for Part I, Chapter 499, Florida Statutes:

499.002 Purpose, administration, and enforcement of and exemption from this part.—
(1) This part is intended to:
(a) Safeguard the public health and promote the public welfare by protecting the public from injury by product use and by merchandising deceit involving drugs, devices, and cosmetics.
(b) Provide uniform legislation to be administered so far as practicable in conformity with the provisions of, and
regulations issued under the authority of, the Federal Food, Drug, and Cosmetic Act and that portion of the Federal Trade Commission Act which expressly prohibits the false advertisement of drugs, devices, and cosmetics.

(c) Promote thereby uniformity of such state and federal laws, and their administration and enforcement, throughout the United States.

(2) The department shall administer and enforce this part to prevent fraud, adulteration, misbranding, or false advertising in the preparation, manufacture, repackaging, or distribution of drugs, devices, and cosmetics.

7. According to Parallon, the distribution centers, which are permitted as restricted prescription drug distributor-health care entity, purchase prescription drugs from authorized suppliers and distribute the drugs to approved facilities under common control with licensed pharmacies.

8. The Parallon distribution centers do not have pharmacy permits or licensed pharmacies onsite.

9. Parallon asserts that its distribution centers need to be able to receive prescription drugs back from the facilities to whom they transfer prescription drugs, in order to appropriately manage drug surpluses and shortages among the recipient facilities and provide timely dispensing of needed medications to patients.

10. Parallon further asserts that if Parallon is unable to accept prescription drugs back from one facility and distribute to another facility to account for inventory surpluses and shortages, the recipient facilities may be without sufficient prescription drug inventory when needed, thus impacting the health and welfare of patients who rely on the medications.
11. Parallon asserts that the distribution centers, by their very nature as prescription drug distribution centers, are authorized to acquire and possess prescription drugs.

12. According to Parallon, due to the common control requirement of Rule 61N-1.023, Florida Administrative Code, all drugs transferred back to the distribution centers would remain inside the system of commonly-controlled facilities, safeguarding the integrity of the drugs and protecting the public welfare.

13. Petitioner asserts that Rule 61N-1.023(2), F.A.C., was developed for a prior business model that contemplated hospitals with onsite pharmacies as distributors. Petitioner states that the rule has not been updated to account for industry changes that now use warehouses, which lack onsite pharmacies, for distributors.

14. According to Petitioner, the literal application of Rule 61N-1.023(2), F.A.C., as employed by the Department, results in a substantial hardship, violates principles of fairness, and impedes furtherance of the purposes of Chapter 499, Florida Statutes.

15. Petitioner states that the purposes of the statutes underlying Rule 61N-1.023(2), F.A.C., can be achieved by means other than strict compliance with the rule.

16. Parallon asserts that it has incurred considerable construction costs in updating its infrastructure to proceed with the proposed drug distribution model. According to Parallon, construction necessary to allow Parallon to proceed with the proposed drug distribution model is projected to be finished on November 8, 2014.
17. Parallon anticipates being able to activate this business model and begin accepting drug deliveries on December 9, 2014. After that date, Parallon asserts, without a waiver and variance Parallon will be exposed to tangible and immediate costs from lost revenue, contingency arrangements, inefficient drug distribution, and business uncertainty.

18. Parallon requests that the Department issue a final order granting Parallon a waiver and variance from Rule 61N-1.023(2), F.A.C., as follows:

A. A waiver from the limitation in Rule 61N-1.023(2), F.A.C., that prescription drug transfers must be made only to a facility under common control licensed with a pharmacy permit that authorizes the acquisition and possession of prescription drugs; and

B. A variance permitting Parallon to transfer prescription drugs from the receiving facilities under common control back to Parallon distribution centers, which are not licensed with pharmacy permits.

CONCLUSIONS OF LAW

19. The Department has jurisdiction to issue this final order pursuant to Section 120.542(8), Florida Statutes (2014).

20. Petitioner has standing to seek this Emergency Petition for Waiver/Variance.

21. Section 120.542(2), Florida Statutes, provides:

(1) Strict application of uniformly applicable rule requirements can lead to unreasonable, unfair, and unintended results in particular instances. The Legislature finds that it is appropriate in such cases to adopt a procedure for agencies to provide relief to persons subject to regulation. A public employee is not a person subject to regulation under this section for the purpose of petitioning for a variance or waiver to a rule that affects that public employee in his or her capacity as a public employee.
Agencies are authorized to grant variances and waivers to requirements of their rules consistent with this section and with rules adopted under the authority of this section. An agency may limit the duration of any grant of a variance or waiver or otherwise impose conditions on the grant only to the extent necessary for the purpose of the underlying statute to be achieved. This section does not authorize agencies to grant variances or waivers to statutes or to rules required by the Federal Government for the agency’s implementation or retention of any federally approved or delegated program, except as allowed by the program or when the variance or waiver is also approved by the appropriate agency of the Federal Government. This section is supplemental to, and does not abrogate, the variance and waiver provisions in any other statute.

(2) Variances and waivers shall be granted when the person subject to the rule demonstrates that the purpose of the underlying statute will be or has been achieved by other means by the person and when application of a rule would create a substantial hardship or would violate principles of fairness. For purposes of this section, “substantial hardship” means a demonstrated economic, technological, legal, or other type of hardship to the person requesting the variance or waiver. For purposes of this section, “principles of fairness” are violated when the literal application of a rule affects a particular person in a manner significantly different from the way it affects other similarly situated persons who are subject to the rule.

22. The Department has construed the language in Rule 61N-1.023(2), F.A.C., to prohibit the transfer of prescription drugs by a hospital or health care entity holding the restricted prescription drug distributor—health care entity permit to facilities under common control that are not permitted with a pharmacy permit that allows them to acquire and possess prescription drugs. Section 499.005(21), Florida Statutes (2014), prohibits the wholesale distribution of a prescription drug that was purchased by a public or private hospital or other health care entity, or that was donated or supplied at a reduced rate to a charitable organization. Thus, the statute would prohibit the Parallon
health care entities from transferring prescription drugs to entities other than hospitals or other health care entities under common control with the distribution centers, which entities also have a pharmacy permit that authorizes the acquisition and possession of prescription drugs.

23. Based on the foregoing, Petitioner’s request for a waiver from the limitation in Rule 61N-1.023(2), F.A.C., that prescription drug transfers are limited to those made to a facility under common control licensed with a pharmacy permit that authorizes the acquisition and possession of prescription drugs, is denied. This denial is based on the fact that if the prohibition was removed, Parallon would then be free to distribute drugs that have been purchased and held by a health care entity to any entity it chooses to distribute to, regardless of whether that entity is under common control with the Parallon distribution centers and regardless of whether such entities have pharmacy permits that authorize the acquisition and possession of prescription drugs. This would be a clear violation of the requirements of the statute.

24. As indicated in Section 120.542 above, an agency may not grant a variance or waiver to a statute. Since granting the waiver as requested by Petitioner in paragraph 16A above would be the equivalent to granting a waiver from the provisions of Section 499.005(21), Florida Statutes (2014), the request is denied.

25. Petitioner is correct that the Department has previously interpreted Rule 61N-1.023(2), Florida Statutes, to allow transfers from an entity permitted as a restricted prescription drug distributor-health care entity to a facility under common control that has a pharmacy permit that authorizes the acquisition and possession of prescription drugs, but prohibits the return of any of the transferred drugs to the distribution centers.
because such centers do not have pharmacy permits that authorize the acquisition and possession of prescription drugs. However, Petitioner is also correct that the purposes of the statute would be served if the distribution centers were allowed a variance from the rule to receive back from the pharmacies the drugs that the centers transferred to them. This is so because the purpose of the provision—to ensure that prescription drugs are distributed to entities that are authorized to receive and possess them, would be satisfied by allowing a permitted entity to receive back from entities under common control those drugs that it had transferred to the facilities.

26. Such returns of any surplus drugs back to the distribution centers would enhance the centers' ability to control and ensure appropriate quantities of prescription drugs are available to reach the intended recipients—patients.

27. Florida Law requires an establishment to maintain records of prescription drugs to protect the public health, safety, and welfare and Petitioner must comply with these requirements. See Section 499.0121, Florida Statutes and Rule 61N-1.012, F.A.C.

28. Petitioner is correct that the Rule 61N-1.023(2) was based on a business model of a hospital distributing to pharmacies under its control, and the pharmacies being able to distribute the drugs back to the hospital through the hospital pharmacy. However, Petitioner is also correct that the fact that the distribution centers hold permits as restricted prescription drug distributors—health care entity means the distribution centers are authorized to purchase and receive prescription drugs. Thus, the purposes of the statute—to protect the public health by ensuring that prescription drugs are
distributed to entities that are authorized to receive and possess them, would be satisfied.

29. Section 120.542, Florida Statutes (2013), places the burden on Petitioner to demonstrate that the underlying purpose of the statute will be or has been achieved by some other means.

30. Petitioner has met the burden of demonstrating that allowing the distribution centers to receive prescription drugs back from the facilities to which the centers transferred the drugs, achieves the purpose of the statute.

31. Petitioner has met the burden of demonstrating that substantial economic and technological hardship would result if Rule 61N-1.023, F.A.C., was strictly applied to Petitioner.

32. Granting the petition for waiver/variance would not remove the safety provisions of the Rule and would sufficiently protect the public.

33. Based on the foregoing, Petitioner's request for a variance and waiver as set forth in paragraph 18A and 18B above, is denied in part and granted in part, as follows:

A. Petitioner's request for a waiver from the limitation in Rule 61N-1.023(2), F.A.C., that prescription drug transfers must be made only to a facility under common control licensed with a pharmacy permit that authorizes the acquisition and possession of prescription drugs, IS DENIED, for the reasons set forth above; and

B. Petitioner's request for a variance permitting Parallon to transfer prescription drugs from the receiving facilities under common control back to Parallon distribution centers, which are not licensed with pharmacy permits, IS GRANTED for the reasons set forth herein above.
Done and ordered this 8th day of December, 2014, at Tallahassee, Leon County, Florida.

KEN LAWSON, Secretary  
Department of Business & Professional Regulation  

BY:  
Reginald D. Dixon, Division Director  
Division of Drugs, Devices and Cosmetics  
1940 North Monroe Street, Suite 26A  
Tallahassee, FL 32399-1047  
Telephone: (850) 717-1800  
Facsimile: (850) 414-8240

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Order has been furnished by U.S. mail to Gabriel V. Warren, Esquire, Rutledge Escenia, P.A., 119 South Monroe Street, Suite 202, Tallahassee, Florida 32302, this 8th day of December, 2014.

Agency Clerk

Copies furnished to:

Reginald D. Dixon  
DDC Division Director

Kathryn B. Price  
DDC Chief Attorney
NOTICE OF RIGHTS TO APPEAL

THIS FINAL ORDER CONSTITUTES FINAL AGENCY ACTION AND MAY BE APPEALED BY ANY PARTY ADVERSELY AFFECTED PURSUANT TO SECTION 120.68, FLORIDA STATUTES, AND RULE 9.110, FLORIDA RULES OF APPELLATE PROCEDURE, BY FILING A NOTICE OF APPEAL CONFORMING TO THE REQUIREMENT OF RULE 9.110(C), FLORIDA RULES OF APPELLATE PROCEDURE, BOTH WITH THE APPROPRIATE DISTRICT COURT OF APPEAL ACCOMPANIED BY THE APPROPRIATE FILING FEE AND WITH THE AGENCY CLERK, 1940 NORTH MONROE STREET, NORTHWOOD CENTRE, TALLAHASSEE, FLORIDA 32399-2217, WITHIN THIRTY DAYS OF RENDITION OF THIS FINAL ORDER.
STATE OF FLORIDA  
DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION  
DIVISION OF DRUGS, DEVICES AND COSMETICS

In re: Parallon Business Solutions, LLC's  
Petition for Waiver and Variance before the  
Florida Department of Business and  
Professional Regulation

VW 2014-384

PETITION FOR EMERGENCY WAIVER AND VARIANCE FROM RULE 61N-1.023(2)

Pursuant to section 120.542, Florida Statutes, and Florida Administrative Code Rule 28-104.004, Parallon Business Solutions, LLC ("Parallon"), by and through its undersigned counsel, petitions the State of Florida, Department of Business and Professional Regulation ("DBPR" or "Department") for a permanent emergency waiver and variance from Florida Administrative Code Rule 61N-1.023(2). In support of this Petition, Parallon states:

Identity of Petitioner

1. Parallon is formally known as Parallon Business Solutions, LLC, and its corporate offices are located at One Park Plaza, Nashville, Tennessee 37203. For purposes of this proceeding, Parallon’s address and contact is that of its undersigned counsel.

2. Parallon owns and operates three (3) prescription drug distribution centers that are licensed by the Department as Restricted Rx Drug Distributors—Health Care Entity. These distribution centers do business under the names West Florida Supply Chain Services, North Florida Supply Chain Services, and East Florida Supply Chain Services. The distribution centers purchase prescription drugs from authorized suppliers and distribute these drugs to approved facilities under common control with licensed pharmacies. As a restricted prescription drug distributor, Parallon is subject to regulation under Chapter 499, Part I, Florida Statutes, and Florida Administrative Code Chapter 61N-1.

RECEIVED
OCT 27 2014

DBPR Agency Clerk
Applicable Rule

3. Rule 61N-1.023(2) authorizes the Department to issue restricted prescription drug distributor permits to health care entities that meet certain criteria.

4. Rule 61N-1.023(2) states in relevant part:

This permit is required for a hospital or health care entity as defined in Section 499.003(15), F.S., for the limited purpose of transferring prescription drugs among hospitals or other health care entities that are (1) under common control as provided in Section 499.012(1)(a)3., F.S.; or (2) members of a group purchasing organization as provided for in Section 499.012(1)(a)1., F.S. For the purpose of this permit and transfers thereunder, an independent contractor cannot be under "common control" as defined in Section 499.012(1)(a)3., F.S. Transfers are limited to a facility under common control or member of the group purchasing organization, either of which must be licensed with a pharmacy permit that authorizes the acquisition and possession of prescription drugs.

5. The Department construes the language of Rule 61N-1.023(2) as prohibiting the transfer of prescription drugs to facilities that are not licensed with pharmacy permits, such as the distribution centers. Parallon seeks a waiver and variance from the rule as construed.

Statute Implemented

6. Rule 61N-1.023(2) states that it implements sections 499.01, 499.012, 499.0121, and 499.014, Florida Statutes. These sections generally describe the various drug distribution permits authorized by statute, including the application and operating requirements associated with those permits.

7. The primary purposes of these sections and the rest of Chapter 499, Part I, Florida Statutes, as stated in section 499.002, Florida Statutes, are to:

(a) Safeguard the public health and promote the public welfare by protecting the public from injury by product use and by merchandising deceit involving drugs, devices, and cosmetics.

(b) Provide uniform legislation to be administered so far as practicable in conformity with the provisions of, and regulations issued under the authority of,

---

1 Section 499.014, Florida Statutes, was renumbered as section 499.01(2)(g), Florida Statutes.
the Federal Food, Drug, and Cosmetic Act and that portion of the Federal Trade Commission Act which expressly prohibits the false advertisement of drugs, devices, and cosmetics.

(c) Promote thereby uniformity of such state and federal laws, and their administration and enforcement, throughout the United States.

8. The waiver and variance sought by Parallon fully serve the purposes of these statutes.

**Type of Action Requested**

9. Parallon requests a permanent waiver and variance from the limitation in Rule 61N-1.023(2) that prescription drug transfers must be made only to a facility under common control licensed with a pharmacy permit that authorizes the acquisition and possession of prescription drugs. Parallon requests that it be permitted to transfer prescription drugs from the receiving facilities under common control back to its distribution centers, which are not licensed with pharmacy permits.

**Facts Demonstrating a Substantial Hardship**

10. Parallon distribution centers are currently precluded by Rule 61N-1.023(2) from accepting drug transfers back from the facilities to which they distribute because the distribution centers do not possess pharmacy permits. The distribution centers need to be able to accept the transfer of prescription drugs back from these facilities in order to appropriately manage drug surpluses and shortages among the recipient facilities and provide timely dispensing of needed medication to patients.

11. Parallon distribution centers need to be able to receive prescription drugs back from the facilities to which they distribute. If Parallon is unable to receive prescription drugs back from one facility and redistribute to another facility to account for inventory surpluses and shortages, then the recipient facilities may be without sufficient prescription drug inventory
when it is needed, thus impacting the health and welfare of the patients that rely on these medications. Surplus drug inventory results in waste and lost revenue, while drug shortages increase patient risk and greatly inflate costs to meet supply needs under pressing circumstances. Permitting the proposed activity comports with the spoke and wheel distribution model contemplated by the purposes of the statutes. It will also greatly improve efficiency in health care delivery and potentially lower costs.

12. Parallon distribution centers do not have pharmacy permits or licensed pharmacies onsite. However, the distribution centers are authorized to acquire and possess prescription drugs by their very nature as drug distribution centers. Due to the common control requirement of the Restricted Rx Drug Distributor—Health Care Entity permit, all drugs transferred back to the distribution centers would remain inside the system of commonly controlled facilities, safeguarding the integrity of the drugs and protecting the public welfare. Rule 61N-1.023(2) was developed for a prior business model that contemplated hospitals with onsite pharmacies as distributors. It has not been updated to account for industry changes that now use warehouses, which lack onsite pharmacies, as distributors.

13. The literal application of Rule 61N-1.023(2), as employed by DBPR, results in a substantial hardship, violates the principles of fairness, and impedes furtherance of the purposes of Chapter 499, Part I, Florida Statutes.

The Waiver and Variance Would Serve the Statutory Purposes

14. As previously indicated, the purposes of the statutes underlying Rule 61N-1.023(2), namely Chapter 499, Part I, Florida Statutes, can be achieved by means other than strict compliance with the rule.
15. Parallon will continue to comply with all other requirements placed on Restricted Rx Drug Distributor—Health Care Entity permit holders by Chapter 499, Part I, Florida Statutes, and related administrative regulations. Parallon will also continue to uphold its obligations to make prescription drugs available in a safe and timely manner for the ultimate health and welfare of Florida patients.

Emergency Circumstances

16. To date, Parallon has incurred considerable construction costs in updating its infrastructure to proceed with the proposed drug distribution model. Construction necessary to allow Parallon with the proposed drug distribution model is projected to be finished on November 8, 2014. Parallon anticipates being able to activate this business model and begin accepting drug deliveries on December 9, 2014. After that date, without a waiver and variance Parallon will be exposed to tangible and immediate costs from lost revenue, contingency arrangements, inefficient drug distribution, and business uncertainty.

17. As detailed above, Parallon will suffer immediate adverse effects in the form of lost revenue, incurred costs from contingency arrangements, and overall business uncertainty if the waiver and variance is not issued more expeditiously than the ordinary time frame of 90 days.

Conclusion

Parallon requests that the Department issue a Final Order granting Parallon a waiver and variance to Rule 61N-1.023(2) as follows:

18. A waiver from the limitation in Rule 61N-1.023(2) that prescription drug transfers must be made only to a facility under common control licensed with a pharmacy permit that authorizes the acquisition and possession of prescription drugs; and
19. A variance permitting Parallon to transfer prescription drugs from the receiving facilities under common control back to Parallon distribution centers, which are not licensed with pharmacy permits.

Respectfully submitted this 27th day of October 2014.

[Signature]

Gabriel F. V. Warren
FL Bar No. 84777
Rutledge Ecenia, P.A.
119 South Monroe Street, Suite 202
Tallahassee, Florida 32302
Tel. 850-681-6788
Fax 850-681-6515
gwarren@rutledge-ecenia.com
Attorney for Parallon Business Solutions, LLC

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that the original of the foregoing document was filed via hand delivery with the Agency Clerk of the Department of Business and Professional Regulation at 1940 North Monroe Street, Suite 92, Tallahassee, Florida 32399-2202; via electronic mail to Reginald Dixon, Esq, reggie.dixon@myfloridalicense.com, and Kathryn Price, Esq., kathryn.price@myfloridalicense.com on this 27th day of October 2014.

[Signature]
STATE OF FLORIDA
DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION

In Re: Petition for Declaratory Statement,

Owens and Minor Distributions, Inc.,
Petitioner:

_________________________________________

DECLARATORY STATEMENT

The Department of Business & Professional Regulation, Division of Drugs, Devices, and Cosmetics, (Department) issues this Declaratory Statement in accordance with Section 120.565, Florida Statutes.

PRELIMINARY STATEMENT

On October 9, 2014, the Department received a petition for declaratory statement (Exhibit A) filed by Owens and Minor Distribution, Inc., (Petitioner). Petitioner operates three wholesale distributor warehouses in Florida. The Petitioner is seeking a declaratory statement as to the requirements of resident and non-resident wholesale distributors, repackagers, manufacturers, and third party logistics providers to obtain state licensure and comply with the recordkeeping requirements of Chapter 499, Florida Statutes, in light of changes in applicable federal law.

The Department published notice of the petition for declaratory statement in the October 14, 2014, issue of the Florida Administrative Register, Volume 40, Number 200.
FINDINGS OF FACT

The following findings of fact are based on the information submitted by Petitioner. The Department takes no position as to the accuracy of the facts, but merely accepts them as submitted for purposes of this Declaratory Statement.

1. Petitioner's three wholesale distributor warehouses are: Owens and Minor Distribution, Inc., 4807 Northeast 63rd Avenue, Gainesville, Florida 32609, holding permit number 22:20179; Owens and Minor Distribution, Inc., 8489 Westside Industrial Drive, Jacksonville, Florida 32219, holding permit number 22:20152; and Owens and Minor Distribution, Inc., 14599 N.W. 8th Street, Sunrise, Florida 33256, holding permit number 22:414.

2. Petitioner states that the Owens and Minor distributor warehouses buy, receive, and distribute "medical convenience kits (drug kits)" as that term is referenced in Section 499.01212 (3)(i), Florida Statutes, and Section 581 of the Drug Quality and Security Act (DQSA or Act), paragraph (24)(B)(xiii).

3. Owens and Minor distribution warehouses (Owens and Minor) centers also buy, receive, and distribute to their customers "IV solutions"\(^1\) as that term is referenced in Section 581 of the DQSA, paragraph (24)(B)(xiv), that they receive from resident and non-resident wholesale drug distributors, third party logistics providers (3PLs), repackagers, and manufacturers.

4. Owens and Minor has been receiving drug kits and IV solutions from vendors who believe that the DQSA has preempted pedigree and authentication requirements, as well as the licensing and recordkeeping requirements of Sections

\(^1\) Petitioner uses the term "IV solutions"; Section 581 of the DQSA, paragraph (24)(b)(xiv), refers to "intravenous product."
499.01 and 499.0121(6)(a)2, Florida Statutes, and Rule 61N-1.012(1)(a)2, Florida Administrative Code, for those products that the DQSA exempts from the definition of "transaction" in Section 581 (24) of the DQSA.

5. Owens and Minor asserts that it cannot verify their vendor's drug kits and IV solutions and also cannot meet the recordkeeping requirements of Section 499.0121(6)(a)1.-5., Florida Statutes, and Rules 61N-1.012(1)(a) and (2), Florida Administrative Code.3

6. Owens and Minor alleges that it is being forced to cancel orders, return merchandise and quarantine product, resulting in a substantial financial burden and possibly leading to shortages at the health care entities it serves.

7. Petitioner wishes to avoid administrative and criminal prosecution for violating Chapter 499, Florida Statutes, and the administrative rules adopted thereunder, by requesting this declaratory statement to clarify its rights under the statutes and rules referenced herein.

8. Petitioner asserts that the following laws apply to Petitioner's set of circumstances:

   A. Section 499.01(1), Florida Statutes (2014), provides, in relevant part:
      (1). Prior to operating, a permit is required for each person and establishment that intends to operate as:
      (a) A prescription drug manufacturer;
      (b) A prescription drug repackager;
      (c) A nonresident prescription drug manufacturer;
      (d) A prescription drug wholesale distributor;
      (e) An out-of-state prescription drug wholesale distributor.

---

2 Though Petitioner referred to Rule 64N-1, the correct citation is to Rule 61N-1, Florida Administrative Code.
3 Owens and Minor requested pedigree information not records required by Rule 61N-1.012(1) and (2), Florida Administrative Code, and 499.0121(6), Florida Statutes. (See Exhibit A1 and A2 of Petition for Declaratory Statement)
B. Section 499.01(2), Florida Statutes (2014), provides, in relevant part:

(2) The following permits are established:
(a) Prescription drug manufacturer permit.—A prescription drug manufacturer permit is required for any person that is a manufacturer of a prescription drug and that manufactures or distributes such prescription drugs in this state.
1. A person that operates an establishment permitted as a prescription drug manufacturer may engage in wholesale distribution of prescription drugs manufactured at that establishment and must comply with all of the provisions of this part, except s. 499.01212, and the rules adopted under this part, except s. 499.01212, which apply to a wholesale distributor.
2. A prescription drug manufacturer must comply with all appropriate state and federal good manufacturing practices.

(b) Prescription drug repackager permit.—A prescription drug repackager permit is required for any person that repackages a prescription drug in this state.
1. A person that operates an establishment permitted as a prescription drug repackager may engage in wholesale distribution of prescription drugs repackaged at that establishment and must comply with all the provisions of this part and the rules adopted under this part that apply to a wholesale distributor.
2. A prescription drug repackager must comply with all appropriate state and federal good manufacturing practices.
(c) Nonresident prescription drug manufacturer permit.—A nonresident prescription drug manufacturer permit is required for any person that is a manufacturer of prescription drugs, unless permitted as a third party logistics provider, located outside of this state or outside the United States and that engages in the wholesale distribution in this state of such prescription drugs. Each such manufacturer must be permitted by the department and comply with all of the provisions required of a wholesale distributor under this part, except s. 499.01212.
1. A person that distributes prescription drugs for which the person is not the manufacturer must also obtain an out-of-state prescription drug wholesale distributor permit or third
party logistics provider permit pursuant to this section to engage in the wholesale distribution of such prescription drugs. This subparagraph does not apply to a manufacturer as defined in s. 499.003(30)(e).

(d) Prescription drug wholesale distributor permit.—A prescription drug wholesale distributor is a wholesale distributor that may engage in the wholesale distribution of prescription drugs.

(e) Out-of-state prescription drug wholesale distributor permit.—An out-of-state prescription drug wholesale distributor is a wholesale distributor located outside this state which engages in the wholesale distribution of prescription drugs into this state and which must be permitted by the department and comply with all the provisions required of a wholesale distributor under this part.

(p) Third party logistics provider permit.—A third party logistics provider permit is required for any person that contracts with a prescription drug wholesale distributor or prescription drug manufacturer to provide warehousing, distribution, or other logistics services on behalf of a manufacturer or wholesale distributor, but who does not take title to the prescription drug or have responsibility to direct the sale or disposition of the prescription drug. Each third party logistics provider permittee shall comply with the requirements for wholesale distributors under ss. 499.0121 and 499.01212, with the exception of those wholesale distributions described in s. 499.01212(3)(a), and other rules that the department requires.

Section 499.01212(3)(i), Florida Statutes (2014), provides, in relevant part:

499.01212 Pedigree Paper.—

(3) EXCEPTIONS. A pedigree paper is not required for:
The wholesale distribution of prescription drugs within a medical convenience kit if:

1. The medical convenience kit is assembled in an establishment that is registered with the United States Food and Drug Administration as a medical device manufacturer;
2. The medical convenience kit manufacturer purchased the prescription drug directly from the manufacturer or from a wholesaler that purchased the prescription drug directly from the manufacturer;
3. The medical convenience kit manufacturer complies with federal law for the distribution of the prescription drugs within the kit; and
4. The drugs contained in the medical kit are:
   a. Intravenous solutions intended for the replenishment of fluids and electrolytes;
   b. Products intended to maintain the equilibrium of water and minerals in the body;
   c. Products intended for irrigation or reconstitution;
   d. Anesthetics; or
   e. Anticoagulants.

This exemption does not apply to a convenience kit containing any controlled substance that appears in a schedule contained in or subject to chapter 893 or the federal Comprehensive Drug Abuse Prevention and Control Act of 1970.

D. Section 499.0121(6), Florida Statutes (2014), provides, in relevant part:

(6) RECORDKEEPING.—The department shall adopt rules that require keeping such records of prescription drugs as are necessary for the protection of the public health.
(a) Wholesale distributors must establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs. These records must provide a complete audit trail from receipt to sale or other disposition, be readily retrievable for inspection, and include, at a minimum, the following information:
1. The source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped;
2. The name, principal address, and state license permit or registration number of the person authorized to purchase prescription drugs;
3. The name, strength, dosage form, and quantity of the drugs received and distributed or disposed of;
4. The dates of receipt and distribution or other disposition of the drugs; and
5. Any financial documentation supporting the transaction.
(b) Inventories and records must be made available for inspection and photocopying by authorized federal, state, or local officials for a period of 2 years following disposition of the drugs or 3 years after the creation of the records, whichever period is longer.
(c) Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means must be readily available for authorized inspection during the retention period. Records that are kept at a central location outside of this state and that are not electronically retrievable must be made available for inspection within 2 working days after a request by an authorized official of a federal, state, or local law enforcement agency. Records that are maintained at a central location within this state must be maintained at an establishment that is permitted pursuant to this part and must be readily available.
(d) Each manufacturer or repacker of medical devices, over-the-counter drugs, or cosmetics must maintain records that include the name and principal address of the seller or transferor of the product, the address of the location from which the product was shipped, the date of the transaction, the name and quantity of the product involved, and the name and principal address of the person who purchased the product.
(e) When pedigree papers are required by this part, a wholesale distributor must maintain the pedigree papers separate and distinct from other records required under this part.

E.

Section 585(b)(1) of the DQSA provides:

"SEC. 585. UNIFORM NATIONAL POLICY.
(b) WHOLESALE DISTRIBUTOR AND THIRD-PARTY LOGISTICS PROVIDER STANDARDS.—

(1) IN GENERAL.—Beginning on the date of enactment of the Drug Supply Chain Security Act, no State or political subdivision of a State may establish or continue any standards, requirements, or regulations with respect to wholesale prescription drug distributor or third-party logistics
provider licensure that are inconsistent with, less stringent
than, directly related to, or covered by the standards and
requirements applicable under section 503(e) (as amended
by such Act), in the case of a wholesale distributor, or
section 584, in the case of a third-party logistics provider.

F. Section 581 of the DQSA provides:

"SEC. 581. DEFINITIONS

*(24) TRANSACTION.—

"(A) IN GENERAL.—The term 'transaction' means the
transfer of product between persons in which a change of
ownership occurs.

"(B) EXEMPTIONS.—The term 'transaction' does not
include—

"(xii) a combination product that is not subject to
approval under section 505 or licensure under section 351 of
the Public Health Service Act, and that is—

"(I) a product comprised of a device and 1 or more other
regulated components (such as a drug/device,
biologic/device, or drug/device/biologic) that are physically,
chemically, or otherwise combined or mixed and produced
as a single entity;

"(II) 2 or more separate products packaged together in a
single package or as a unit and comprised of a drug and
device or device and biological product; or

"(III) 2 or more finished medical devices plus one or
more drug or biological products that are packaged together
in what is referred to as a 'medical convenience kit' as
described in clause (xiii);

"(xiii) the distribution of a collection of finished medical
devices, which may include a product or biological product,
assembled in kit form strictly for the convenience of the
purchaser or user (referred to in this clause as a 'medical
convenience kit') if—"
"(I) the medical convenience kit is assembled in an establishment that is registered with the Food and Drug Administration as a device manufacturer in accordance with section 510(b)(2);

"(II) the medical convenience kit does not contain a controlled substance that appears in a schedule contained in the Comprehensive Drug Abuse Prevention and Control Act of 1970;

"(III) in the case of a medical convenience kit that includes a product, the person that manufacturers the kit—

"(aa) purchased such product directly from the pharmaceutical manufacturer or from a wholesale distributor that purchased the product directly from the pharmaceutical manufacturer; and

"(bb) does not alter the primary container or label of the product as purchased from the manufacturer or wholesale distributor; and

"(IV) in the case of a medical convenience kit that includes a product, the product is—

"(aa) an intravenous solution intended for the replenishment of fluids and electrolytes;

"(bb) a product intended to maintain the equilibrium of water and minerals in the body;

"(cc) a product intended for irrigation or reconstitution;

"(dd) an anesthetic;

"(ee) an anticoagulant;

"(ff) a vasopressor; or

"(gg) a sympathomimetic;

"(xiv) the distribution of an intravenous product that, by its formulation, is intended for the replenishment of fluids and electrolytes (such as sodium, chloride, and potassium) or calories (such as dextrose and amino acids);
"(xv) the distribution of an intravenous product used to maintain the equilibrium of water and minerals in the body, such as dialysis solutions;

9. Petitioner requests a declaratory statement as to the following:

a. Whether resident and non-resident prescription drug wholesale distributors, third party logistics providers, repackers and manufacturers doing business with the State of Florida must maintain a license with the State of Florida, DBPR if conducting distributions of DQSA exempted drug products, or whether entities conducting distributions of drug products exempted under the DQSA are no longer required to maintain State DBPR licensure as resident and non-resident prescription drug wholesale distributors, third party logistics providers, re-packers or manufacturers since distributions of these products are not by definition a "transaction" under Federal Law.

b. Whether resident and non-resident prescription drug wholesale distributors, third party logistics providers, repackers and manufacturers doing business with the State of Florida must continue to comply with the recordkeeping requirements of F.S. 499.0121(6)(a) 1-5 and FAC 64N-L012(l)(a) and (2) (sic), with regard to the sale or transfer of DQSA exempted prescription drug containing kits and IV solutions into or within Florida, or whether entities so engaged need not comply with recordkeeping laws since distributions of these products are not by definition a "transaction" under Federal Law.

c. Whether resident and non-resident prescription drug wholesale distributors, third party logistics providers, repackers and manufacturers doing business with the State of Florida must, starting January 1, 2015, provide prior to or at the time of each transaction, transaction history (TH), transaction information (TI) and a transaction statement (TS), defined by Section 581 of the DQSA paragraphs (25), (26) and (27) and further implemented into tracing requirements under Section 582 of the DQSA paragraph (b)(1)(A)(i) et. al., and paragraph (c)(1)(A)(i) et. al., for the sale and transfer (distribution) of "exempt" prescription drug containing kits and IV products into or within the State of...
Florida or whether entities so engaged need not comply with recordkeeping laws since distributions of these products are not by definition a "transaction" under Federal Law.

CONCLUSIONS OF LAW

10. The Department is the state agency charged with regulation of drugs, devices, and cosmetics, pursuant to Chapter 499, Florida Statutes.

11. The Department has jurisdiction to enter this order pursuant to Section 120.565, Florida Statutes, and Rule 28-105.003, Florida Administrative Code.

12. Section 120.565, Florida Statutes, provides:

120.565 Declaratory statement by agencies.—
(1) Any substantially affected person may seek a declaratory statement regarding an agency's opinion as to the applicability of a statutory provision, or of any rule or order of the agency, as it applies to the petitioner's particular set of circumstances.
(2) The petition seeking a declaratory statement shall state with particularity the petitioner's set of circumstances and shall specify the statutory provision, rule, or order that the petitioner believes may apply to the set of circumstances.
(3) The agency shall give notice of the filing of each petition in the next available issue of the Florida Administrative Weekly and transmit copies of each petition to the committee. The agency shall issue a declaratory statement or deny the petition within 90 days after the filing of the petition. The declaratory statement or denial of the petition shall be noticed in the next available issue of the Florida Administrative Weekly. Agency disposition of petitions shall be final agency action.

13. Rule 28-105.003, Florida Administrative Code, provides:
28-105.003 Agency Disposition.
The agency may hold a hearing to consider a petition for declaratory statement. If the agency is headed by a collegial body, it shall take action on a petition for declaratory statement only at a duly noticed public meeting. The agency may rely on the statements of fact set out in the petition without taking any position with regard to the validity of the facts. Within 90 days of the filing of the petition, the agency shall render a final order denying the petition or issuing a declaratory statement.

14. The Petitioner is substantially affected by the statutes and rule cited in paragraph nine above and has standing to seek a declaratory statement from the department.

15. The Department is authorized to enforce the provisions of Chapter 499, Florida Statutes.

16. Section 499.002 (1), Florida Statutes (2014), provides:

499.002 Purpose, administration, and enforcement of and exemption from this part.—
(1) This part is intended to:
(a) Safeguard the public health and promote the public welfare by protecting the public from injury by product use and by merchandising deceit involving drugs, devices, and cosmetics.
(b) Provide uniform legislation to be administered so far as practicable in conformity with the provisions of, and regulations issued under the authority of, the Federal Food, Drug, and Cosmetic Act and that portion of the Federal Trade Commission Act which expressly prohibits the false advertisement of drugs, devices, and cosmetics.
(c) Promote thereby uniformity of such state and federal laws, and their administration and enforcement, throughout the United States.

Based on the provision cited above, the Department seeks to develop and interpret its laws and rules to conform to federal laws and rules under the authority of the Federal Food, Drug, and Cosmetic Act, and as further described above.
17. Effective November 27, 2013, the DQSA was signed into law. The Act is comprised of Title I, the Compounding Quality Act, and Title II, the Drug Supply Chain Security Act.

18. The DQSA Title II requires a uniform national system for tracking and tracing prescription drugs through the supply chain, and a uniform licensing system for prescription drug wholesale distributors, and 3PLs.

19. Section 204 of the DQSA amends 21 USC Section 353(e), to include exemptions from the definition of "wholesale distribution:"

(a) AMENDMENTS.—

(1) REQUIREMENT.—Section 503(e) (21 U.S.C. 353(e)) is amended by striking paragraphs (1), (2), and (3) and inserting the following:

"(1) REQUIREMENT.—Subject to section 583:

(2) WHOLESALE DISTRIBUTION.—Section 503(e) (21 U.S.C. 353(e)), as amended by paragraph (1), is further amended by adding at the end the following:

"(4) For the purposes of this subsection and subsection (d), the term 'wholesale distribution' means the distribution of a drug subject to subsection (b) to a person other than a consumer or patient, or receipt of a drug subject to subsection (b) by a person other than the consumer or patient, but does not include—

"(M) the distribution of a collection of finished medical devices, which may include a product or biological product, assembled in kit form strictly for the convenience of the purchaser or user (referred to in this subparagraph as a 'medical convenience kit') if—

"(i) the medical convenience kit is assembled in an establishment that is registered with the Food and Drug
Administration as a device manufacturer in accordance with section 510(b)(2);

"(ii) the medical convenience kit does not contain a controlled substance that appears in a schedule contained in the Comprehensive Drug Abuse Prevention and Control Act of 1970;

"(iii) in the case of a medical convenience kit that includes a product, the person that manufacturers the kit—

"(I) purchased such product directly from the pharmaceutical manufacturer or from a wholesale distributor that purchased the product directly from the pharmaceutical manufacturer; and

"(II) does not alter the primary container or label of the product as purchased from the manufacturer or wholesale distributor; and

"(iv) in the case of a medical convenience kit that includes a product, the product is—

"(I) an intravenous solution intended for the replenishment of fluids and electrolytes;

"(II) a product intended to maintain the equilibrium of water and minerals in the body;

"(III) a product intended for irrigation or reconstitution;

"(IV) an anesthetic;

"(V) an anticoagulant;

"(VI) a vasopressor; or

"(VII) a sympathomimetic;

"(N) the distribution of an intravenous drug that, by its formulation, is intended for the replenishment of fluids and electrolytes (such as sodium, chloride, and potassium) or calories (such as dextrose and amino acids);
20. Petitioner describes its practices as buying, receiving, and distributing medical convenience kits as defined by Section 581 of the DQSA, paragraph 24(B)(xiii), and IV solutions (IV products) as defined in Section 581(24)(B)(xiv) of the Act.

21. A plain reading of the DQSA discloses that the amended law includes exemptions from the definition of "transaction," the effect of which is that items that are exempted are not required to meet tracking and tracing requirements as set forth in the amended act (transaction history, transaction information, transaction statement). See, Sec. 582(c) of the amended Act.

22. The DQSA also contains exemptions from "wholesale distribution," the effect of which is that items that are exempted do not require licensure as described under the federal law for wholesale distribution of the item. The entity must, however, have authority to possess prescription drugs and to sell prescription drugs. The exemptions from "transaction" and from "wholesale distribution" became effective on January 1, 2015, when the provisions that employ these terms became effective.4

23. As noted above, even though the DQSA exempts medical convenience kits and IV products from the requirement of wholesale distribution and from tracking and tracing requirements of the DQSA, it does not preclude states from enacting or continuing to enforce state requirements for recordkeeping or state requirements for licensure of those persons engaging in distributions that are not "wholesale distributions" or "transactions" under the amended Act.

---

4 Though technically, the definitions contained in Section 581 of the DQSA carry no effective date and could be deemed to be effective as of November 27, 2013, the provisions to which the definitions apply are not effective until January 1, 2015. The exemptions from "wholesale distribution" become effective January 1, 2015, according to Section 204(c) of the DQSA.
24. The DQSA sets forth licensing and tracking and tracing standards for transactions and wholesale distributions, and sets forth exemptions from those standards. This does not mean states are precluded from establishing or continuing in effect licensing standards and recordkeeping requirements for those distributions not considered wholesale distributions by the federal government. Such an interpretation would leave states with no authority to regulate distributors, repackers, and 3PLs who distribute prescription drugs in non-DQSA wholesale distributions and transactions, or to enforce recordkeeping requirements for the myriads of prescription drug transactions by entities, simply because such distributions are exempted from the tracking and tracing and wholesale distributor requirements of the amended Act.

25. Indeed, the DQSA is "not intended to pre-empt state requirements related to the distribution of prescription drugs, if such requirements are not related to product tracing as described in subsection (a), or wholesale distributor and third party logistics provider licensure as described in subsection (b) applicable under section 503(e), (as amended by the Drug Supply Chain Security Act) or this subchapter (or regulations issued thereunder)."

26. Currently, Florida Statutes do not exempt medical convenience kits from recordkeeping requirements of Chapter 499, and the administrative rules, though pedigree requirements do not apply. Likewise, Chapter 499, Florida Statutes, does not exempt distributions involving medical convenience kits and those involving IV products from licensure requirements. (Section 499.01(1)(g) and (2)(g), Florida Statutes). Regardless of the fact that the DQSA exempts medical convenience kits and IV products from the definitions of "transaction" and wholesale distribution", Florida is not
preempted from imposing licensure and recordkeeping requirements on non-wholesale distributions, just as it currently does under Chapter 499, Florida Statutes, with the permit requirements for the restricted distributors as described in Section 499.01(1)(g) and (2)(g), Florida Statutes (2014), and Rule 61N-1.023, Florida Administrative Code.

27. Accordingly, Petitioner's questions are answered as follows:

A. Resident and non-resident prescription drug wholesale distributors, third party logistics providers, repackers, and manufacturers distributing in or into the State of Florida products that are exempted from the definition of "transaction" under the DQSA, must maintain a license with this Department. The fact that products are exempted from the definition of "transaction" under the DQSA does not mean such products are currently exempted from prescription drug distribution recordkeeping requirements of Section 499.0121(6)(a) 1.-5., Florida Statutes, or Rule 61N-1.012, Florida Administrative Code. 

B. Resident and non-resident prescription drug wholesale distributors, third party logistics providers, repackers, and manufacturers distributing in or into the State of Florida products that are exempted from the definition of "transaction" under the DQSA, must comply with the recordkeeping requirements of Section 499.0121(6)(a)1.-5., Florida Statutes.

C. The Department declines to answer this inquiry as it relates solely to an interpretation of the DQSA, and not Chapter 499, Florida Statutes.

---

5 Not all requirements of Rule 61N-1.012, Florida Administrative Code, are currently applicable to Petitioner. The Department will initiate rulemaking to clarify rule requirements.
Done and ordered this 15th day of January, 2015, at
Tallahassee, Leon County, Florida.

KEN LAWSON, SECRETARY
Department of Business & Professional
Regulation

BY:
Reginald D. Dixon, Division Director
Division of Drugs, Devices and
Cosmetics
1940 North Monroe Street, Suite 26A
Tallahassee, FL 32399-1047
Telephone: (850) 717-1800
Facsimile: (850) 414-8240

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing has been
furnished by U.S. mail to Edwin A. Bayó Esquire, Grossman, Furlow, & Bayó, LLC,
2022-2 Raymond Diehl Road, Tallahassee, Florida 32308 this 14th day of January
2015.

[Signature]
Agency Clerk

Copies furnished to:
Reginald D. Dixon
DDC Division Director

Kathryn E. Price
DDC Chief Attorney
NOTICE OF RIGHTS TO APPEAL

THIS FINAL ORDER CONSTITUTES FINAL AGENCY ACTION AND MAY BE APPEALED BY ANY PARTY ADVERSELY AFFECTED PURSUANT TO SECTION 120.68, FLORIDA STATUTES, AND RULE 9.110, FLORIDA RULES OF APPELLATE PROCEDURE, BY FILING A NOTICE OF APPEAL CONFORMING TO THE REQUIREMENT OF RULE 9.110(C), FLORIDA RULES OF APPELLATE PROCEDURE, BOTH WITH THE APPROPRIATE DISTRICT COURT OF APPEAL ACCOMPANIED BY THE APPROPRIATE FILING FEE AND WITH THE AGENCY CLERK, 1940 NORTH MONROE STREET, NORTHWOOD CENTRE, TALLAHASSEE, FLORIDA 32399-2217, WITHIN THIRTY DAYS OF RENDITION OF THIS FINAL ORDER.
STATE OF FLORIDA
DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION
DRUGS, DEVICES AND COSMETICS PROGRAM

PETITION FOR DECLARATORY STATEMENT
BEFORE THE DEPARTMENT OF BUSINESS
& PROFESSIONAL REGULATION, DRUGS, DEVICES
AND COSMETICS PROGRAM, ON BEHALF OF
OWENS AND MINOR DISTRIBUTION, INC.

Owens and Minor Distribution, Inc.,
Petition for Declaratory Statement

Owens and Minor Distribution, Inc., ("Owens and Minor") by and through its
undersigned counsel, files this Petition for Declaratory Statement pursuant to Section
120.565, Florida Statutes and Rule 28-105.002, FAC and states:

1. Owens and Minor, a duly permitted drug wholesaler in the State of Florida, is
requesting that the Department of Business and Professional Regulation ("DBPR") declare
whether wholesale and manufacturer entities licensed as resident and non-resident wholesale
drug distributors, third party logistics providers, re-packers and manufacturers by the DBPR
must continue to maintain State of Florida DBPR licensure, under F.S. 499.01 if the only sell
and transfer (distribute) "exempt" prescription drug containing kits and IV products into or
within the State of Florida.

2. Owens and Minor is requesting that the Department of Business and
Professional Regulation ("DBPR") also declare whether wholesale and manufacturer entities
licensed as resident and non-resident wholesale drug distributors, third party logistic providers,
re-packers and manufacturers by the DBPR must continue to comply with Chapter 499 and the
corresponding FAC, 64N-1, (with the exception of applicable portions of F.S. 499.01212 with
regard to pedigree and authentication and other related sections of Florida Law preempted by
Section 585 of the Federal Drug Quality and Security Act and denoted in prior Florida Declaratory Statements, i.e., in Re: HD Smith Wholesale Drug Company, DS 2014-081 and In Re: Publix Supermarkets, Inc. DS 2014-007), and specifically must continue to comply with, F.S. 499.0121(6)(a) 1-5 and FAC 64N-1.012(1)(a) and (2), with regard to the sale or transfer of “exempt” prescription drug containing kits and IV solutions (medical convenience kits, IV solutions) into or within Florida.

3. Owens and Minor, is also requesting that the Department of Business and Professional Regulation (“DBPR”) declare whether wholesale and manufacturer entities licensed as resident and non-resident wholesale drug distributors, third party logistic providers, re-packers and manufacturers by the DBPR must provide, on and after January 1, 2015, transaction history (TH), transaction information (TI) and a transaction statement (TS), defined by Section 581 of the DQSA paragraphs (25), (26) and (27) and further implemented into tracing requirements under Section 582 of the DQSA paragraph (b)(1)(A)(i) et. al, and paragraph (c)(1)(A)(i) et. al., for the sale and transfer (distribution) of “exempt” prescription drug containing kits and IV products into or within the State of Florida.

4. Owens and Minor headquarters are located at 9120 Lockwood Boulevard Mechanicsville, VA, but for purposes of this Petition, its address shall be that of its undersigned attorney.

5. Owens and Minor operates numerous licensed entities that are permitted by the State of Florida as well as three Florida wholesale warehouses located in Gainesville, FL permit #2220179, Jacksonville, FL permit #2220152 and Sunrise, FL permit #22414.

6. These Owens and Minor distribution centers, buy, receive and distribute medical convenience kits as defined by Section 581 of the DQSA paragraph (24)(B)(xiii) and
F.S. 499.01212(3)(i) and IV solutions as defined by Section 581 of the DQSA paragraph (24)(B)(xiv) they receive from resident and non-resident wholesale drug distributors, third party logistic providers, re-packers and manufacturers to their customers throughout the State of Florida. [hereinafter “kits” and “IV solutions”]

Legal Basis for this Declaratory Statement

7. With certain exceptions, Florida law defines the term "wholesale distribution" in relevant part to include:

"Wholesale distribution" means distribution of prescription drugs to persons other than a consumer or patient." Section 499.003(54), Florida Statutes.

8. Florida law defines "distribute" or "distribution" as:

"Distribute" or "distribution" means to sell; offer to sell; give away; transfer, whether by passage of title, physical movement, or both; deliver; or offer to deliver. The term does not mean to administer or dispense and does not include the billing and invoicing activities that commonly follow a wholesale distribution transaction. Section 499.003(17), Florida Statutes.

9. Section 499.005(14), Florida Statutes, prohibits the purchase or receipt of a prescription drug from a person not authorized by Chapter 499, Florida Statutes to distribute such drugs.

10. Section 499.01(1), Florida Statutes, requires a permit in order to engage in drug distribution activities including kits and IV drugs.

11. A prescription drug is defined in F.S. 499.003(43) as "a prescription, medicinal, or legend drug, including, but not limited to, finished dosage forms or active pharmaceutical ingredients subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and
Cosmetic Act or s. 465.003(8), s. 499.007(13), or subsection (11), subsection (46), or subsection (53), ..."

12. Section 499.01212(3)(i), F.S., provides an exception ONLY to the requirement for pedigree, not recordkeeping, for the distribution of prescription drugs within the medical convenience kit meeting specific requirements. (kits)

13. Unless an applicable exception applies, the DBPR has required that an entity the buys and sells prescription drugs, excepted from pedigree or not, (specifically IV solutions and kits) must continue to comply with F.S. 499.01 (licensing) and F.S. 499.0121 storage and recordkeeping, specifically, F.S. 499.0121(6)(a) 1-5 and FAC 64N-1.012(1)(a) and (2). Florida Statute 499.0121(6)(a) states:

(a) Wholesale distributors must establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs. These records must provide a complete audit trail from receipt to sale or other disposition, be readily retrievable for inspection, and include, at a minimum, the following information:

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

2. The name, principal address, and state license permit or registration number of the person authorized to purchase prescription drugs;

3. The name, strength, dosage form, and quantity of the drugs received and distributed or disposed of;

4. The dates of receipt and distribution or other disposition of the drugs; and
5. Any financial documentation supporting the transaction.

14. The Department has enforcement authority to bring actions against persons violating the provisions of Chapter 499, Florida Statutes. This enforcement authority is set forth in Sections 499.002, 499.051, 499.06, 499.066, 499.061, and 499.067, Florida Statutes. Florida also imposes criminal sanctions for certain violations as set forth in Section 499.051, F.S.

15. On November 27, 2013, federal legislation designated as Public Law 113-54 (HR 3204), the "Drug Quality and Security Act" [hereinafter "DQSA"], was signed into law. The DQSA provides for preemption of state requirements for product tracing and statements of distribution history and other requirements. Specifically, Section 585 of the Act provides:

**SEC. 585. UNIFORM NATIONAL POLICY.**

(a) PRODUCT TRACING AND OTHER REQUIREMENTS.—Beginning on the date of enactment of the Drug Supply Chain Security Act, no State or political subdivision of a State may establish or continue in effect any requirements for tracing products through the distribution system (including any requirements with respect to statements of distribution history, transaction history, transaction information, or transaction statement of a product as such product changes ownership in the supply chain, or verification, investigation, disposition, notification, or recordkeeping relating to such systems, including paper or electronic pedigree systems or for tracking and tracing drugs throughout the distribution system) which are inconsistent with, more stringent than, or in addition to, any requirements applicable under section 503(e) (as amended by such Act) or this subchapter (or regulations issued thereunder), or which are inconsistent with—
(1) any waiver, exception, or exemption pursuant to section 581 or 582; or

(2) any restrictions specified in section 582. (emphasis added)

16. The DQSA provides for preemption of state wholesale distributor licensure laws beginning on its enactment. Specifically, Section 585 of the Act provides:

(b) WHOLESALE DISTRIBUTOR AND THIRD-PARTY LOGISTICS PROVIDER STANDARDS.

(1) IN GENERAL—Beginning on the date of enactment of the Drug Supply Chain Security Act, no State or political subdivision of a State may establish or continue any standards, requirements, or regulations with respect to wholesale prescription drug distributor or third-party logistics provider licensure that are inconsistent with, less stringent than, directly related to, or covered by the standards and requirements applicable under section 503(e) (as amended by such Act), in the case of a wholesale distributor, or section 584, in the case of a third-party logistics provider.

17. Further Section 581 of the Drug Quality and Security Act (DQSA) paragraph (24)(B)(xii) and (xiii) provides an exemption to medical convenience kits explaining that the term “transaction” does not apply to drug kits meeting the specific requirements of the law.

18. In addition, Section 581 of the DQSA paragraph (24)(B)(xiv) provides an exemption to products that are intended for replenishment of fluids and electrolytes that are administered intravenously (IV solutions) again explaining that the term “transaction” does not apply to these fluids.

19. A “transaction” is defined by Section 581 of the DQSA in paragraph (24)(A) meaning the transfer of product between persons in which a change of ownership occurs.
20. The DQSA dictates that manufacturers and wholesalers under Section 582 of the DQSA paragraph (b) and (c) must "(i) prior to, or at the time of, each transaction in which such manufacturer transfers ownership of a product, provide the subsequent owner with transaction history, transaction information, and a transaction statement, in a single document in an paper or electronic format..." (emphasis added).

21. Transaction information, under the DQSA includes: (section 585 paragraph (26))

(26) Transaction information.--The term 'transaction information' means—

(A) the proprietary or established name or names of the product;

(B) the strength and dosage form of the product;

(C) the National Drug Code number of the product;

(D) the container size;

(E) the number of containers;

(F) the lot number of the product;

(G) the date of the transaction;

(H) the date of the shipment, if more than 24 hours after the date of the transaction;

(I) the business name and address of the person from whom ownership is being transferred; and

(J) the business name and address of the person to whom ownership is being transferred.

22. Section 585(a) and (b) of the DQSA, as cited above, provides that no State or political subdivision of a State may establish or continue in effect any requirements for tracing products through the distribution system (including any requirements with respect to
statements of distribution history, transaction history, transaction information, or transaction
statement of a product as such product changes ownership in the supply chain, or verification,
investigation, disposition, notification, or recordkeeping relating to such systems... and no
state may not continue any standards, requirements, or regulations with respect to wholesale
prescription drug licensure that are inconsistent with, less stringent than, directly related to, or
covered by the standards and requirements applicable under section 503(e). It is unclear if
these pre-empted “standards, requirements, or regulations” include requirements under F.S.
499.0121(6)(a) 1-5 and FAC 64N-1.012(1)(a) and (2) or if the DQSA Transaction Information
will replace F.S. 499.0121(6)(a) 1-5 and FAC 64N-1.012(1)(a) and (2).

23. Owens and Minor has been receiving drug kits and IV solutions from vendors
who believe that the DQSA has pre-empted not only pedigree and authentication, as
acknowledged in the aforementioned Florida Declaratory Statements, but also, due to the broad
breath of the language, also pre-empted the licensing and recordkeeping requirements of F.S.
499.01 and S. 499.0121(6)(a) 1-5 and FAC 64N-1.012(1)(a) and (2) for those products
exempted by the DQSA, namely kits and IV solutions since no “transaction” is occurring. (see
Exhibit A1 & A2 – email string and noted vendor letter, edited for style not content)

24. Owens and Minor cannot verify their vendor’s kits and IV solutions and also
cannot meet the requirements of Florida law with regards to F.S. 499.0121(6)(a) 1-5 and FAC
64N-1.012(1)(a) and (2). (see Exhibit B – Packing list omitting requirements of F.S. 499.0121(6)
and also not listing their permit number. The invoice is EDI and does not contain the
information at issue.)
25. Owens and Minor is being forced to cancel orders, return merchandise and quarantine products resulting in substantial financial burdens and also potential shortages at the health care entities they service. This issue is only anticipated to escalate as time progresses.

26. Owens and Minor wishes to avoid administrative and criminal prosecution for violating Chapter 499 and 61N-1 FAC, and therefore is justified in requesting this declaratory statement to clarify its rights under the above statutes.

Wherefore, Owens and Minor requests that the DBPR issue a Final Order determining whether:

a. Resident and non-resident prescription drug wholesale distributors, third party logistics providers, re-packers and manufacturers doing business with the State of Florida must maintain a license with the State of Florida, DBPR if conducting distributions of DQSA exempted drug products, or whether entities conducting distributions of drug products exempted under the DQSA are no longer required to maintain State DBPR licensure as resident and non-resident prescription drug wholesale distributors, third party logistics providers, re-packers or manufacturers since distributions of these products are not by definition a "transaction" under Federal Law.

b. Resident and non-resident prescription drug wholesale distributors, third party logistics providers, re-packers and manufacturers doing business with the State of Florida must continue to comply with the recordkeeping requirements of F.S. 499.0121(6)(a) 1-5 and FAC 64N-1.012(1)(a) and (2), with regard to the sale or transfer of DQSA exempted prescription drug containing kits and IV solutions into or within Florida, or whether entities so engaged need not comply with recordkeeping laws since distributions of these products are not by definition a "transaction" under Federal Law.
c. Resident and non-resident prescription drug wholesale distributors, third party logistics providers, re-packers and manufacturers doing business with the State of Florida must, starting January 1, 2015, provide prior to or at the time of each transaction, transaction history (TH), transaction information (TI) and a transaction statement (TS), defined by Section 581 of the DQSA paragraphs (25), (26) and (27) and further implemented into tracing requirements under Section 582 of the DQSA paragraph (b)(1)(A)(i) et. al., and paragraph (c)(1)(A)(i) et. al., for the sale and transfer (distribution) of "exempt" prescription drug containing kits and IV products into or within the State of Florida or whether entities so engaged need not comply with recordkeeping laws since distributions of these products are not by definition a "transaction" under Federal Law.

CERTIFICATE OF SERVICE

I hereby certify that the original of the foregoing Petition for Declaratory Statement was hand delivered to the Agency Clerk, Department of Business & Professional Regulation, 1940 North Monroe Street, Suite 92, Tallahassee, FL 32399-2202, with courtesy copies via e-mail to Reginald Dixon, Executive Director and Kathryn Price, Chief Attorney, this 9th day of October, 2014.

Respectfully submitted,

Edwin A. Bayó
Fla. Bar No. 327727
Grossman, Furlow & Bayó, L.L.C.
2022-2 Raymond Diehl Rd.
Tallahassee, FL 32308
(850)385-1314/fax(850)385-4240
Counsel for Petitioner
Hi Amy,

For Exempt, packing slip must contain the drug detail information listed for the pedigree items to ensure compliance with Florida's Recordkeeping requirement (F.S. 499.0121 (6)(a)).

THANKS! 😊

Ina Richardson | Compliance Analyst | Jacksonville DC 59
Owens & Minor | 8489 Westside Industrial Drive, Jacksonville, FL 32219
p 904.596.4605 | Voip 60594605
ina.richardson@owens-minor.com | www.owens-minor.com

Ms. Richardson,

I apologize for the confusion surrounding this issue. However, please reference the federal Drug Quality And Security Act (H.R. 3204, Section 585) which was signed into law in November 2013. This section defines "no State or political subdivision of a State may establish or continue in effect any requirements for tracing products through the distribution system (including any requirements with respect to statements of distribution history, transaction history, transaction information, or transaction statement of product as such product changes ownership in the supply chain, or verification, investigation, disposition, notification, or recordkeeping relating to such systems, including paper or electronic pedigree systems or for tracking and tracing drugs throughout the distribution system) which are inconsistent with, more stringent than, or in addition to, any requirements applicable under section 503(e) or this subchapter".

Centurion kits are exempt from drug track and trace requirements. The federal Drug Quality and Security Act, H.R. 3204, supersedes the state of Florida's Recordkeeping requirement.

I hope this addresses any questions you may have regarding our medical convenience kits and pedigree information on the packing slips. If you have further questions or concerns, please do not hesitate to contact me.

Amy Ganton
Regulatory Affairs
Centurion Medical Products
517.545.1159
aganton@centurionmp.com

EXHIBIT A1
Ms. Richardson,

Please see the attached memo for an explanation of Centurion Medical Product’s business practice regarding pedigree (drug track and trace) requirements for the state of Florida. Please feel free to contact me directly with questions. Thank you.

Amy Ganton  
Research Affairs  
Centurion Medical Products  
517.545.1159  
aganton@centurionmp.com
September 18, 2014

RE: Track and Track Requirements for Centurion Kits Containing Prescription Drugs

Ms. Richardson,

This memo is in response to your inquiry regarding missing pedigree information on the packing lists for Centurion medical convenience kits.

On July 1, 2010, kits containing prescription drugs meeting specified criteria were exempted from drug track and trace requirements (i.e. pedigree) in the State of Florida. Since then, the federal Drug Quality and Security Act (H.R. 3204) was signed into law on November 27, 2013, which established a national system for tracing pharmaceutical products, and included an exemption for transactions involving kits consistent with the approach implemented by the State of Florida in 2010.

This exemption applies to kits provided the kit manufacturer and the product meet the following criteria:

- Kits are assembled in an establishment registered with the FDA as a device manufacturer;
- Kits do not contain prescription drug products classified as controlled substances;
- Prescription drugs included within kits are purchased directly from the pharmaceutical manufacturer or from a wholesale distributor that purchased them directly from the pharmaceutical manufacturer;
- The kit manufacturer does not alter the primary container or label of the prescription drug product as purchased from the manufacturer or wholesale distributor; and
- Prescription drug products included within kits are of a type exempted by the Act.

It should be noted Centurion kits containing prescription drugs meet these criteria, and are thereby exempted from prescription drug track and trace requirements.

I hope this addresses any questions you have regarding the omission of pedigree information on the packing lists. Please do not hesitate to contact me if you have further questions or concerns.

Regards,
Amy Ganton
Regulatory Analyst
517-545-1159
aganton@centurionmp.com
# Packing List

## Information
- Drop Ship PO: 18075
- Shipment No.: 990005
- Customer No.: SOUTHEASTERN FREIGHT
- Incoterms: WF WAREHOUSE FREIGHT
- Total Weight: 1535 LB
- Number of Packages: 4
- Carrier: SOUTHEASTERN FREIGHT
- Tracking/Pro: 
- External Order Text: 

## Receiving Instructions

## Purchase Order No. | Delivery# | Batch# | Material | Packed Quantity | Sales Unit
---|---|---|---|---|---
59-44772 | 81823100 |  | SB69BZ | 3.000 | CS
59-44772 | 81823100 |  | YL4045E | 15.000 | CS
59-44772 | 81823100 | 2014063001 | 66415 | 1.000 | CS
59-44772 | 81823100 | 2014061790 | 75175 | 1.000 | CS
59-44772 | 81823100 | 2014071490 | CIT4260 | 1.000 | CS
59-44772 | 81823100 | 2014062790 | CTR300MG | 1.000 | CS
59-44772 | 81823100 | 2014053090 | SUT10360 | 4.000 | CS
59-44772 | 81823100 | 2014060990 | VXHS910S | 1.000 | CS
59-44772 | 81823100 |  | 4538623 | 1.000 | PK
59-44772 | 81823100 |  | PCS260 | 6.000 | CS
59-44772 | 81823100 | 2014062503 | W234 | 1.000 | CS
59-44772 | 81823100 | 3000180358 | FM4AF | 2.000 | CS
59-44772 | 81823100 |  | 992102 | 1.000 | CS
59-44772 | 81823100 | 2014072190 | CKF5065L | 1.000 | CS
59-44772 | 81823100 |  | PALLET4 | | 
59-44772 | 81823100 | 2014060901 | MS120 | 9.000 | CS
59-44772 | 81823100 | 2014033190 | CKF105 | 1.000 | CS
59-44772 | 81823100 | 2014060990 | PE295 | 1.000 | CS
59-44772 | 81823100 | 2014050990 | DT14070 | 1.000 | CS
59-44772 | 81823100 | 2014060890 | DT14225 | 4.000 | CS
59-44772 | 81823100 | 2013102180 | MNS3790 | 1.000 | CS

## EXHIBIT B
STATE OF FLORIDA
DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION

IN RE: PETITION FOR WAIVER
BAPTIST HOSPITAL, INC.,

PETITIONER.

FINAL ORDER GRANTING WAIVER FROM REQUIREMENTS OF RULE 61N-1.023(2), FLORIDA ADMINISTRATIVE CODE

The Department of Business & Professional Regulation, Division of Drugs, Devices, and Cosmetics (hereafter, "Department"), issues this final order granting the Petition for Waiver, in accordance with Section 120.542, Florida Statutes (2014).

PRELIMINARY STATEMENT

On October 31, 2014, Petitioner, Baptist Hospital, Inc. (hereafter, "Baptist" or "Petitioner"), filed a petition for waiver of Rule 61N-1.023(2), Florida Administrative Code (hereafter, "F.A.C.") with the Department. Notice of the petition was published in the November 18, 2014, issue of the Florida Administrative Register, Volume 40, Number 224.

FINDINGS OF FACT

1. Petitioner is a 492-bed acute care hospital located at 1000 West Moreno Street, Pensacola, Florida 32501. Baptist is a wholly owned subsidiary of Baptist Health Care Corporation. Baptist is licensed by the Department as a restricted prescription drug distributor—health care entity, having been issued permit number 50:159. Petitioner also holds a license as a hospital and is registered with the Drug Enforcement Administration (hereafter, "DEA").
2. On or about August 22, 2014, the Department conducted a routine compliance inspection of Petitioner during which the Department asked questions about Baptist's delivery of medications to certain medical offices in which the physician is a full-time employee of a group practice that is a wholly owned subsidiary of either Baptist Hospital or Baptist Health Care Corporation (hereafter, "Physician Office Locations").

3. Baptist's pharmaceutical wholesaler is McKesson. The Physician Office Locations place prescription drug orders directly with McKesson or through Petitioner's inpatient pharmacy, which then forwards the order to McKesson.

4. The orders from the Physician Office Locations are placed under a separate McKesson account and are designated on the invoice as "Baptist Hospital, Inc./MG, Customer #0972041." Each invoice indicates the specific ordering physician's name along with the specific designation that it is under the Physician Office Locations' accounts. The orders are for a very limited quantity and for a limited drug formulary.

5. McKesson delivers the order to Petitioner, and Petitioner delivers the medications and the corresponding invoice to the Physician Office Locations. Petitioner maintains a copy of the invoice for audit purposes.

6. Petitioner does not touch the delivered prescription medication; Petitioner merely acts as a courier between McKesson and the Physician Office Locations.

7. Through this process, Petitioner delivers medications to approximately 28 Physician Office Locations.

8. Petitioner's parent company, Baptist Health Care Corporation, wholly owns and operates Petitioner as well as a sister entity of Petitioner, Baptist Health
Ventures, Inc. Therefore, both are commonly controlled by Baptist Health Care Corporation.

9. The 28 Physician Office Locations currently receiving prescription medications through Petitioner fall into one of two categories under Baptist Health Care Corporation: 1) The Physician Office Location is wholly owned and operated by Petitioner, Baptist Hospital, Inc.; or 2) the Physician Office Location is wholly owned and operated by its sister entity, Baptist Health Ventures, Inc.

10. Petitioner asserts that requiring the 28 Physician Office Locations to acquire pharmacy permits would create substantial hardship economically and legally, and would be unfair.

11. Petitioner asserts that the Department advised Petitioner that the type of pharmacy permit that Petitioner would need under the requirements of Rule 61N-1.023(2), F.A.C., is the Type B Modified Class II Institutional Pharmacy permit.

12. Petitioner requests that the waiver apply both retrospectively and prospectively for those Physician Office Locations under common ownership with Baptist Health Care Corporation as described herein. Petitioner asserts that it is adding new Physician Office Locations on a regular basis. The described processes for delivering prescription medication would remain unchanged for each subsequent Physician Office Location added.

13. Petitioner asserts that requesting the waiver is based on both principles of hardship and fairness. Petitioner argues that requiring Petitioner to obtain a Type B Modified Class II Institutional Pharmacy permit for 28 different locations would create a substantial hardship economically and legally. Petitioner further argues that applying for
these permits would incur a considerable amount of time, effort, and cost to apply for, collect detailed information about, pay for, and retain all information required for maintaining such permits as well as meeting all pharmacy committee and onsite pharmacy requirements for Type B Modified Class II Institutional Pharmacies listed in Rule 64B16-28.702, F.A.C.

14. As to fairness, Petitioner argues that under current law, physician offices are permitted to order and receive modest amounts of prescription medications directly from pharmaceutical distributors without a pharmacy permit; that Physician Office Locations are in fact physician offices ordering small amounts of medications that do not include controlled substances or expanded formularies; that the only difference is that Physician Office Locations’ ordering is done through Petitioner’s pharmacy wholesaler system and not directly with a pharmaceutical distributor; and that as such, it is unfair to require Physician Office Locations, which are obtaining the same quantity and limited types of medications as other physician offices, to apply for, pay for, and maintain such a permit simply because the medication is ordered through Petitioner’s pharmacy wholesaler, McKesson.

15. Rule 61N-1.023(2), F.A.C., provides:

(2) Restricted Rx Drug Distributor – Health Care Entity. This permit is required for a hospital or health care entity as defined in Section 499.003(15), F.S., for the limited purpose of transferring prescription drugs among hospitals or other health care entities that are (1) under common control as provided in Section 499.012(1)(a)3., F.S.; or (2) members of a group purchasing organization as provided for in Section 499.012(1)(a)1., F.S. For the purpose of this permit and transfers thereunder, an independent contractor cannot be under “common control” as defined in Section 499.012(1)(a)3., F.S. Transfers are limited to a facility under common control or member of the group purchasing
organization, either of which must be licensed with a pharmacy permit that authorizes the acquisition and possession of prescription drugs. This permit also authorizes a warehouse or purchasing depot of a university to transfer prescription drugs to practitioner or non-practitioner researchers for university sponsored research conducted in accordance with Section 240.241, F.S. All requirements of paragraph (6) of this rule related to the Restricted Rx Drug Distributor – Institutional Research permit must be complied with for transfers under this provision. [Emphasis added].

16. Petitioner requests a waiver from the requirements of the above-cited rule that each location to which Petitioner transfers prescription drugs have a pharmacy permit that authorizes the acquisition and possession of prescription drugs.

17. Petitioner asserts that the purposes of the underlying statute are to deter prescription drugs from leaving regulatory controls established in state law that serve to maintain the safety, integrity and efficacy of prescription drugs by requiring distributors to maintain proper documentation; ensure medications have not been adulterated; and guarantee that prescription medications have not been unlawfully introduced into the market.

18. Petitioner asserts that the purposes of the underlying statute would be satisfied since the Petitioner’s processes requires each Physician Office Location to review the medication received with the invoice and promptly report any discrepancies, and that the inventory is also cross-referenced with Petitioner’s invoice. Petitioner alleges that this protects the public by creating a double audit trail of the drugs thereby guarding against unlawful circulation of the drugs.
CONCLUSIONS OF LAW

19. The Department has jurisdiction to issue this final order pursuant to Section 120.542(8), Florida Statutes (2014).

20. Petitioner has standing to seek this Petition for Waiver.

21. Section 120.542(2), Florida Statutes (2014), provides:

(1) Strict application of uniformly applicable rule requirements can lead to unreasonable, unfair, and unintended results in particular instances. The Legislature finds that it is appropriate in such cases to adopt a procedure for agencies to provide relief to persons subject to regulation. A public employee is not a person subject to regulation under this section for the purpose of petitioning for a variance or waiver to a rule that affects that public employee in his or her capacity as a public employee. Agencies are authorized to grant variances and waivers to requirements of their rules consistent with this section and with rules adopted under the authority of this section. An agency may limit the duration of any grant of a variance or waiver or otherwise impose conditions on the grant only to the extent necessary for the purpose of the underlying statute to be achieved. This section does not authorize agencies to grant variances or waivers to statutes or to rules required by the Federal Government for the agency's implementation or retention of any federally approved or delegated program, except as allowed by the program or when the variance or waiver is also approved by the appropriate agency of the Federal Government. This section is supplemental to, and does not abrogate, the variance and waiver provisions in any other statute.

(2) Variances and waivers shall be granted when the person subject to the rule demonstrates that the purpose of the underlying statute will be or has been achieved by other means by the person and when application of a rule would create a substantial hardship or would violate principles of fairness. For purposes of this section, "substantial hardship" means a demonstrated economic, technological, legal, or other type of hardship to the person requesting the variance or waiver. For purposes of this section, "principles of fairness" are violated when the literal application of a rule affects a particular person in a manner significantly different
from the way it affects other similarly situated persons who
are subject to the rule.

22. The Department has construed the language in Rule 61N-1.023(2),
F.A.C., to prohibit the transfer of prescription drugs by a hospital or health care entity
holding the restricted prescription drug distributor—health care entity permit, to facilities
under common control that are not permitted with a pharmacy permit that allows them to
acquire and possess prescription drugs. Section 499.005(21), Florida Statutes (2014),
prohibits the wholesale distribution of a prescription drug that was purchased by a public
or private hospital or other health care entity, or that was donated or supplied at a
reduced rate to a charitable organization. Here, the statutory provision in Section
499.005(21), Florida Statutes (2014), is not implicated because Petitioner’s transfers of
the prescription drugs would be within its own commonly owned Physician Office
Locations, and not outside to any other distributor that Petitioner might choose.

23. Section 120.542, Florida Statutes (2014), places the burden on Petitioner
to demonstrate that the underlying purpose of the statute will be or has been achieved
by some other means.

24. Petitioner has demonstrated that the purposes of the underlying statute, to
protect the public health by ensuring that prescription drugs are safe, properly
documented, and that the prescription drugs are only distributed to those persons who
are lawfully able to possess them, are satisfied.

25. Petitioner has met the burden of demonstrating that substantial economic
hardship would result if Rule 61N-1.023(2), F.A.C., was strictly applied to Petitioner,
such that each Physician Office Location would be required to obtain and maintain licensure under Chapter 465, Florida Statutes.

26. Petitioner has failed to meet the burden of demonstrating, in the alternative, that the literal application of the rule would affect Petitioner in a manner significantly different from the way it affects other similarly situated persons who are subject to the rule. Physician’s offices that are not wholly owned by licensed hospitals and/or the hospital’s parent corporation are not similarly situated to the “Physician Office Locations” owned and operated by Petitioner.

27. Granting the petition for waiver would not remove the safety provisions of the Rule and would sufficiently protect the public.

28. Based on the foregoing, Petitioner’s request for a waiver from the limitation in Rule 61N-1.023(2), F.A.C., that prescription drug transfers are limited to those made to a facility under common control licensed with a pharmacy permit that authorizes the acquisition and possession of prescription drugs, is granted. Petitioner may transfer prescription drugs to the Physician Office Locations as described herein above.

29. This Order and the waiver granted herein operate prospectively from the date of filing.
Done and ordered this 24th day of January, 2015, at Tallahassee, Leon County, Florida.

KEN LAWSON, SECRETARY
Department of Business & Professional Regulation

BY:
Reginald D. Dixon, Division Director
Division of Drugs, Devices and Cosmetics
1940 North Monroe Street, Suite 26A
Tallahassee, FL 32399-1047
Telephone: (850) 717-1800
Facsimile: (850) 414-8240

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Order has been furnished by U.S. mail to Jody E. Okrzesik, 171 "E" Street, Suite 320, Pensacola, Florida 32501, this 28th day of January, 2015.

Agency Clerk

Copies furnished to:

Reginald D. Dixon
DDC Division Director

Kathryn E. Price
DDC Chief Attorney
NOTICE OF RIGHTS TO APPEAL

THIS FINAL ORDER CONSTITUTES FINAL AGENCY ACTION AND MAY BE APPEALED BY ANY PARTY ADVERSELY AFFECTED PURSUANT TO SECTION 120.68, FLORIDA STATUTES, AND RULE 9.110, FLORIDA RULES OF APPELLATE PROCEDURE, BY FILING A NOTICE OF APPEAL CONFORMING TO THE REQUIREMENT OF RULE 9.110(C), FLORIDA RULES OF APPELLATE PROCEDURE, BOTH WITH THE APPROPRIATE DISTRICT COURT OF APPEAL ACCOMPANIED BY THE APPROPRIATE FILING FEE AND WITH THE AGENCY CLERK, 1940 NORTH MONROE STREET, NORTHWOOD CENTRE, TALLAHASSEE, FLORIDA 32399-2217, WITHIN THIRTY DAYS OF RENDITION OF THIS FINAL ORDER.
IN RE: PETITION FOR WAIVER
BAPTIST HOSPITAL, INC.

VW 2014-419

PETITION FOR WAIVER OF RULE 61N-1.023(2)

Petitioner, Baptist Hospital, Inc. ("Petitioner" or "Baptist Hospital"), pursuant to section 120.565 of Florida Statute and rule 28-104.002 of the Florida Administrative Code, petitions the Florida Department of Business & Professional Regulation, Division of Drugs, Devices, and Cosmetics Program ("Department") for a waiver from rule 61N-1.023(2) of the Florida Administrative Code ("Waiver"). In support of this Waiver, Petitioner states as follows:

1. Petitioner, Baptist Hospital, is a 492-bed acute care hospital located at 1000 West Moreno Street, Pensacola, Florida, 32501. It is a wholly owned subsidiary of Baptist Health Care Corporation. Petitioner is licensed by the Department as a Restricted Prescription Drug Distributor – Health Care Entity operating under permit number 50159. Petitioner is also licensed as a hospital by AHCA, as well as by the D.E.A. To the best knowledge of Petitioner, it has not been disciplined by the Department during its 63 years of operation.

2. For purposes of this Petition, all correspondence and communication should be provided to undersigned in-house counsel for Petitioner at the address, telephone number, and facsimile number provided below.

3. On August 22, 2014, Don Yerbey, Field Inspector for the Department, conducted a routine compliance inspection of Petitioner ("Inspection"). During the Inspection, Petitioner's pharmacists were questioned about its processes, including the Petitioner's delivery of medications to certain medical offices in which the physician is a full-time employee of a
group practice that is a wholly owned subsidiary of either Baptist Hospital or Baptist Health Care Corporation ("Physician Office Locations").

4. After the Inspection, the Department requested that Petitioner's representatives appear at the Department's office in Tallahassee to further discuss and clarify Petitioner's processes.

5. On September 4th, 2014 in Tallahassee, Petitioner's representatives, David Gowarty, RPh., and Dave Crawford, RPh., met with the following Department representatives: Reginald Dixon, Director; Renee Ashbrook, Attorney, Chief of Compliance and Enforcement, and Don Yerbey, Field Inspector. Rule 61N-1.023(2) of the Florida Administrative Code was discussed that facilities receiving transfers of medications (such as the Physician Office Locations) under a Restricted Rx Drug Distributor license must be licensed with a "pharmacy permit that authorizes the acquisition and possession of prescription drugs." The permit that would be required under this statute for the Physician Office Locations Offices would be a Type B Modified Class II Institutional Pharmacy.

6. In the meeting, Petitioner's delivery process was further described as follows: Petitioner's Pharmaceutical Wholesaler is McKesson. Physician Office Locations place prescription orders directly with McKesson or through Petitioner's inpatient pharmacy, which then forwards the order to McKesson. The orders from the Physician Office Locations are placed under a separate McKesson account and are designated on the invoice as Baptist Hospital, Inc./MG, Customer #972041. Each invoice indicates the specific ordering physician's name along with the specific designation that it is under the Physician Office Location accounts. The orders are for a very limited quantity and limited drug formulary. McKesson delivers the order to Petitioner, and Petitioner delivers the medications and the corresponding invoice to the Physician Office Locations. Petitioner retains a copy of the invoice for audit purposes. The delivered prescription medications are untouched by Petitioner; it simply acts as a courier between McKesson and the Physician. Through this process, the Petitioner delivers prescription drugs to approximately 28 Physician Office Locations.
7. Based on the rule and the information stated herein, Petitioner respectfully requests that this Waiver be granted to Petitioner.

8. Florida Administrative Code 61N-1.023 (2) outlines the permits and provisions applicable to Restricted Rx Drug Distributor – Health Care Entity. This provision states that a permit is required for a hospital or health care entity as defined in section 499.003(15) of Florida Statute “for the limited purpose of transferring prescription drugs among hospitals or other health care entities that are under common control as provided in Section 499.012(1)(a)3., F.S.” It goes on to state that such transfers “are limited to a facility under common control . . . which must be licensed with a pharmacy permit that authorized the acquisition and possession of prescription drugs.” FLA. STAT. 499.003(15) (2010).

9. Pursuant to Florida Administrative Code 61N-1.023, Petitioner has and maintains a Restricted Rx. Drug Distributor – Health Care Entity permit. Petitioner has an unblemished history of substantial compliance with Florida laws governing prescription medications. Petitioner has fully cooperated with the Department and believes that it is in compliance with all Florida laws governing its operation, including those pertaining to its recordkeeping.

10. Petitioner’s parent company, Baptist Health Care Corporation, wholly owns and operates Petitioner as well as a sister entity of Petitioner, Baptist Health Ventures, Inc. Therefore, both are commonly controlled by Baptist Health Care Corporation.

11. The 28 Physician Office Locations currently receiving prescription medications through Petitioner falls into one of two categories under Baptist Health Care Corporation: a) the Physician Office Location is wholly owned and operated by Petitioner, Baptist Hospital, Inc. b) the Physician Office Location is wholly owned and operated by sister entity, Baptist Health Ventures, Inc. Therefore, all prescription medications being delivered to each Physician Office Location is a facility under the same common control.

12. A waiver or variance is appropriate where certain licensing requirements are too burdensome for an applicant. Univ. of So. Fla ex. rel. Fla. Bd. of Regents v. Dep’t. of Children and
Family Services, 787 So.2d 223, 224 (Fla. Dist. Ct. App., 2001). Moreover, section 120.542 (2) of the Florida Statutes provides that a state agency shall grant waivers of their own rules when a person subject to the rule demonstrates that he or she can achieve or has achieved the purpose of the underlying statute by other means and when application of the rule would "create a substantial hardship or would violate principles of fairness." Fla. Stat. 120.542 (2) (2013). A substantial hardship is defined as "a demonstrated economic, technological, legal or other type of hardship to the person requesting the variance or waiver." Id. The statute states that principles of fairness are violated when "the literal application of the rule affects a particular person in a manner significantly different from the way it affects other similarly situated persons who are subject to the rule." Id.

13. Petitioner is requesting this Waiver based on both hardship and principles of fairness. Requiring Petitioner (or each Physician Office Location) to obtain a Type B Modified Class II Institutional Pharmacy permit for 28 different locations would create a substantial hardship economically and legally. Applying for these permits would incur a considerable amount of time, effort and cost to apply for, collect detailed information about, pay for, and retain all information required for maintaining such permits as well as meeting all pharmacy committee and onsite pharmacist requirements for Type B Modified Class II Institutional Pharmacies listed in rule 64B16-28.702 of the Florida Administrative Code.

14. There is also a fairness aspect to this Waiver request. Under Florida law, physician offices are permitted to order and receive modest amounts of prescription medications directly from pharmaceutical distributors without a pharmacy permit. Physician Office Locations are in fact physician offices ordering small amounts of medications that do not include controlled substances or expanded formularies. The only difference is that the ordering is done through Petitioner’s Pharmacy Wholesaler system and not directly with a pharmaceutical distributor. As such, it is unfair to require Physician Office Locations, which are obtaining the same quantity and limited types of medications as other physician offices, to apply for, pay for, and
maintain such a permit simply because the medication is ordered through Petitioner’s pharmacy wholesaler, McKesson. In fact, Petitioner’s audit process is arguably more stringent than that of independent physicians who order medications directly from drug distributors because the invoicing and supply chain records is maintained not only by the Physician Office Location, but also by the Petitioner.

15. The purpose of the underlying statute is to deter prescription drugs from leaving the regulatory controls established in state law that serve to maintain the safety, integrity and efficacy of prescription drugs by requiring distributors to maintain proper documentation, ensure medications have not been adulterated, and guaranteeing that prescription medications are not unlawfully introduced into the market. See, e.g., Bio-Med Plus, Inc. v. State, Dept. of Health, 915 S.2d 669 (Fla. Dist. Ct. App., 2005).

16. Petitioner’s processes meets the underlying purposes of the statute since Petitioner requires each Physician Office Location to review the medication received with the invoice and promptly report any discrepancies. This inventory is also cross referenced with Petitioner’s invoice. This protects the public by creating a double audit trail of the drugs thereby guarding against unlawful circulation of the drugs.

17. The fact that Petitioner does not touch the drugs but is merely a courier for ordering the medications serves the statute’s underlying purpose of ensuring medications are not adulterated prior to delivery. Furthermore, because the medications are delivered directly to Petitioner in sealed totes designated for each physicians’ office as part of a large daily shipment, the medications are at less risk for being stored at improper temperatures while awaiting delivery to smaller physician offices. This more frequent delivery procedure ostensibly decreases the risk of inadvertent adulteration due to improper storage.

18. Petitioner requests this Waiver apply both retrospectively and prospectively for those Physician Office Locations that fall under common ownership with Baptist Health Care Corporation as described herein. Petitioner is adding new Physician Office Locations on a
regular basis. The described processes for delivering prescription medications would remain unchanged for each subsequent Physician Office Location added. All would be under common ownership of Petitioner or BHC. As such, the same criteria for this Waiver would apply to future Physician Office Locations.

19. For the reasons outlined above, the Department should grant Petitioner’s request for a permanent Waiver of its requirement for each Physician Office Location to obtain a Type B Modified Class II Institutional Pharmacy permit since allowing such Waiver eliminates the hardship and unfairness of obtaining such permit, while still satisfying the underlying purpose of the rule.

WHEREFORE, Petitioner, Baptist Hospital, respectfully requests that pursuant to Section 120.565, the Department grant Petitioner’s request for a waiver of any and all rules that the Department interprets as requiring Petitioner to obtain pharmacy licenses for Physician Office Locations that receives medications through Petitioner.

Respectfully Submitted,

Jody E. Okrzesik, Esq.
Florida Bar No. 0693091
Baptist Health Care Corporation
171 North “E” St., Suite 320
Pensacola, Florida 32501
Telephone: 850-469-7721
Facsimile: 850-434-4841
Email: jody.okrzesik@bhcpns.org

Cc: Joint Administrative Procedures Committee, Room 680, Pepper Building, 111 W. Madison St., Tallahassee, FL 32399-1400
TAB 4. OTHER BUSINESS