

**STATE OF FLORIDA
DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION**

FILED	
Department of Business and Professional Regulation	
Deputy Agency Clerk	
CLERK	Brandon Nichols
Date	4/15/2014
File #	2014-02648

**In Re: Petition for Declaratory
Statement,**

**Publix Super Markets, Inc.,
Petitioner.**

DS 2014-007

DECLARATORY STATEMENT

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

PRELIMINARY STATEMENT

On January 14, 2014, the Division received a petition for declaratory statement (Exhibit A) filed by Publix Super Markets, Inc. ("Publix" or "Petitioner"), which owns and operates community pharmacies and a chain pharmacy warehouse in this state. The Petitioner is seeking a declaratory statement regarding the applicability of Sections 499.003(54), 499.003(17), 499.005(14)¹, and 499.01, Florida Statutes, and Rule 61N-1.012, Florida Administrative Code, to the Petitioner's facts. Petitioner also seeks a statement as to the Department's enforcement authority as set forth in Sections 499.002, 499.051, 499.06, 499.061, 499.066 and 499.067, as applied to Petitioner's facts.

¹ Petitioner included the language for Section 499.005(14), Florida Statutes, but inadvertently referenced Section 499.005(16), Florida Statutes, which refers to medical gases.

The Department published notice of the petition for declaratory statement in the January 30, 2014, issue of the Florida Administrative Register.

FINDINGS OF FACT

The following findings of fact are based on the information submitted by the 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. Publix owns and operates 596 community pharmacies within the state of Florida. The pharmacies are licensed by the Florida Department of Health. These pharmacies do not possess Florida prescription drug wholesale distributor permits.

2. Publix also owns and operates a chain pharmacy warehouse that is licensed by the Department as a wholesale distributor, holding permit number 22:1471. This Publix chain pharmacy warehouse purchases prescription drugs from authorized suppliers and distributes these drugs to Publix pharmacies.

3. Publix controls all of its pharmacies and controls its chain pharmacy warehouse.

4. Publix asserts that its pharmacies need to be able to do the following:

A. sell or distribute prescription drugs from one Publix pharmacy to another Publix pharmacy when a pharmacy may need or want a particular drug that another Publix pharmacy has or a pharmacy has too much inventory of a drug and needs to make sure that other Publix pharmacies have adequate inventory to provide timely dispensing of needed medications to patients; and

B. sell or distribute prescription drugs from a Publix pharmacy to the Publix chain pharmacy warehouse, without providing a pedigree paper.

5. Publix also asserts that if Publix is unable to sell or distribute drugs to other pharmacies, these pharmacies may be without adequate drug inventory at the

time a prescription is received, thus impacting the health and welfare of Publix's patients and Publix's ability to dispense to them. Publix expects to see improved efficiencies both in the delivery of health care and the associated costs if it is able to sell or distribute drugs to other pharmacies it controls.

6. Petitioner also asserts that the pharmacies should not be required to pass a pedigree because the Publix chain pharmacy warehouse is not required to provide a pedigree paper to a Publix pharmacy so the pharmacies have no pedigree to provide and it makes compliance with the pedigree requirement impossible.

7. Further, Petitioner asserts that Publix needs to be able to distribute its drugs back to the Publix chain pharmacy warehouse to better manage its pharmacies' drug inventory and to prevent inventory shortages.

8. If Publix pharmacies are required to obtain permits as wholesale drug distributors, Publix will incur costs in completing applications, paying application fees, and for the time spent dealing with inspectors. Moreover, if the sale or transfer of drugs from one Publix pharmacy to another is a wholesale drug distribution requiring a permit from the Department, pedigree paper requirements may also be imposed on these distributions increasing Publix's recordkeeping costs unnecessarily.

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

A. Section 499.003(17), Florida Statutes (2013), provides:

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

* * *

(17) "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.

B. Section 499.003(54), Florida Statutes (2013), provides:

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

* * *

(54) “Wholesale distribution” means distribution of prescription drugs to persons other than a consumer or patient, but does not include:

* * *

(b) Any of the following activities, which is not a violation of s. 499.005(21) if such activity is conducted in accordance with rules established by the department:

* * *

4. The revocation of a sale or the return of a prescription drug to the person’s prescription drug wholesale supplier.

C. Section 499.005(14), Florida Statutes, (2013), provides:

499.005 Prohibited Acts.--It is unlawful for a person to perform or cause the performance of any of the following acts in this state:

* * *

(14) The purchase or receipt of a prescription drug from a person that is not authorized under this chapter to distribute prescription drugs to that purchaser or recipient.

D. Section 499.01, Florida Statutes (2013), provides:

499.01.1 Permits.--

(1) Prior to operating, a permit is required for each person and establishment that intends to operate as:

* * *

(d) a prescription drug wholesale distributor

E. Rule 61N-1.012(3)(f), Florida Administrative Code, provides:

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

* * *

(3) Pedigree Papers.

* * *

(f) Returns.

1. When a distribution of a prescription drug by a wholesale distributor to a pharmacy or a health care entity, including a practitioner, licensed and authorized under Florida law to purchase and receive the prescription drug is the result of a mistake in ordering or shipment, the return of that prescription drug by the recipient to the wholesale distributor need not be reflected in a pedigree paper. [Emphasis added]

* * *

10. The Department is authorized to administer and enforce Part I, Chapter 499, Florida Statutes; to enter and inspect permitted and unpermitted establishments for the purpose of enforcing Part I and to determine compliance with Part I; to conduct investigations, issue stop sale, stop use, removal, or hold orders upon probable cause; to seize and condemn drugs, devices or cosmetics; to conduct inspections as necessary to protect the public; to impose administrative fines and other remedies as set forth in applicable law; and to issue cease and desist orders, suspension orders, and remove certain affiliated parties; as specifically set forth in Sections 499.002, 499.051, 499.06, 499.062, 499.066, and 499.067, Florida Statutes.

11. Petitioner asserts the following with respect to the Federal laws, including the Drug Quality and Security Act (DQSA) of 2013:

A. Section 503(e) of the Food Drug and Cosmetic Act provides an exemption from the definition of "wholesale distribution" for "intracompany sales" as follows:

(3) For the purposes of this subsection and subsection (d) of this section—

* * *

(B) the term "wholesale distribution" means distribution of drugs subject to subsection (b) of this section to other than the consumer or patient but does not include intracompany sales and does not include distributions of drugs described in subsection (c)(3)(B) of this section.

- B. 21 CFR § 205.2, Guidelines for State Licensing of Wholesale Prescription Drug Distributors, provides:

Sec. 205.2 Purpose.

The purpose of this part is to implement the Prescription Drug Marketing Act of 1987 by providing minimum standards, terms, and conditions for the licensing by states licensing authorities of persons who engage in wholesale distribution in interstate commerce of prescription drugs.

- C. 21 CFR §205.3 (f)(1), provides:

Sec. 205.3 Definitions.

* * *

(f) wholesale distribution means the distribution of prescription drugs to persons other than a consumer or patient, but does not include:

(1) Intracompany sales;

- D. Section 204 of the DQSA provides for "National Standards for Prescription Drug Wholesale Distributors". Section 204(b)(2) amends Section 503(e) of the Food, Drug and Cosmetic Act [21 U.S.C. 353(e)] in relevant part, by adding the following new language at the end of this section:

(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—

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

E. The term “affiliate” is defined by Section 204 of the DQSA as:

[T]he term *affiliate* means a business entity that has a relationship with a second business entity if, directly or indirectly—

(a) one business entity controls, or has the power to control, the other business entity; or (b) a third party controls, or has the power to control, both of the business entities.

F. 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.

G. 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.

12. Publix requests a statement from the Department declaring the following:
 - A. Publix pharmacies' sale of prescription drugs from one Publix pharmacy to other Publix pharmacies is not the "wholesale distribution" of prescription drugs.
 - B. Publix pharmacies' transfer of prescription drugs from one Publix pharmacy to other Publix pharmacies is not the "wholesale distribution" of prescription drugs.
 - C. Publix pharmacies' sale of prescription drugs from one Publix pharmacy to other Publix pharmacies does not require any type of Florida prescription drug wholesale distributor's permit.
 - D. Publix pharmacies' transfer of prescription drugs from one Publix pharmacy to other Publix pharmacies does not require any type of Florida prescription drug wholesale distributor's permit.
 - E. Publix pharmacies' sale of prescription drugs to the Publix chain pharmacy warehouse is not the "wholesale distribution" of prescription drugs.

- F. Publix pharmacies' transfer of prescription drugs to the Publix chain pharmacy warehouse is not the "wholesale distribution" of prescription drugs.
- G. Publix pharmacies' sale of prescription drugs to the Publix chain pharmacy warehouse does not require any type of Florida prescription drug wholesale distributor's permit and does not require Publix to provide pedigree papers for these returns.
- H. Publix pharmacies' transfer of prescription drugs to the Publix chain pharmacy warehouse does not require any type of Florida prescription drug wholesale distributor's permit and does not require Publix to provide pedigree papers for these returns.

CONCLUSIONS OF LAW

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

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

15. 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.

16. 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.

17. 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.

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

19. Prior to November 27, 2013, Sections 499.003(17), 499.003(54), 499.01(1), and 499.005(16), Florida Statutes, were interpreted by the Department to mean that unless an exemption applied, when a pharmacy transferred or sold a prescription drug to another pharmacy, the sale or transfer met the definition of a "wholesale distribution," which required each pharmacy to be permitted as a wholesale distributor, or a retail pharmacy drug wholesale distributor. Further, under prior interpretations, when a wholesale distributor, such as the chain pharmacy warehouse, sold or transferred prescription drugs to a pharmacy, a distribution occurred, and when a pharmacy returned prescription drugs to the chain pharmacy warehouse, which was

its supplier, no distribution occurred, but a pedigree was required, unless the return was the result of a mistake in ordering or shipment. When prescription drugs were sold or transferred in a wholesale distribution, the drugs must have been accompanied or preceded by a prescription drug pedigree from the distributor to the recipient, with a pedigree being provided to each subsequent distributor.

20. Effective November 27, 2013, the Drug Quality and Security Act (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.

21. 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, repackagers, and third party logistics providers.

22. Currently, wholesale distributors are still required to obtain a permit to operate in this state, and to be in compliance with federal law. See, Sections 582-585, Drug Quality and Security Act.

23. In light of the preemption language in Section 585 of the Act as set forth in paragraph 11 above, it is clear that states can no longer enforce licensing requirements that are inconsistent with, less stringent than, directly related to, or covered by the standards and requirements that are applicable under the amended law. This means that state licensure requirements meeting these criteria are no longer effective, and any state-imposed licensure requirement must yield to the new federal licensure standards. Federal licensing requirements become effective January 1, 2015, with licensing standards being established by regulation by the Secretary of the Food and Drug Administration within two years after enactment of the DQSA, or by November 27, 2015.

24. In the interim period, the minimum federal standards for state licensing of wholesale distributors that are currently effective, the Prescription Drug Marketing Act, 21 C.F.R. §205, (“PDMA”), is applicable to prescription drug distributor licensing. Therefore, Florida must adopt the minimum licensing standards from the PDMA in lieu of the preempted licensing standards in Chapter 499, Florida Statutes. Regarding licensure as a wholesale distributor, 21 C.F.R. § 205.3(f)(1), exempts *intracompany sales* from the definition of a “wholesale distribution.” Thus, Publix pharmacies distributing to other Publix pharmacies or to the Publix chain pharmacy warehouse in an intracompany sale would not be required to obtain permits as wholesale distributors.²

25. With respect to pedigree requirements, in light of the preemption language in Section 585 of the Act, states may not establish or continue in effect any requirement for tracing products through the distribution system (including any requirement with respect to statements of distribution history, transaction history, transaction information, or transaction statement of a product as the 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). The federal tracking and tracing requirements become effective January 1, 2015. In the interim period, current federal minimum standards for wholesale distribution of prescription drugs, set forth in 21 C.F.R. §203, are applicable, and states may enforce those requirements of the PDMA.

² It must be noted that the term “intracompany sales” is used in the PDMA, which is effective now, while the term “intracompany distribution” is used in the amended law, 21 U.S.C. §353(e)(4)(A), which become effective January 1, 2015.

26. Accordingly, applying the foregoing to Petitioner's facts, Petitioner's requests for declarations are answered as follows:

- A. Publix pharmacies' sale of prescription drugs from one Publix pharmacy to other Publix pharmacies is not the wholesale distribution of prescription drugs.
- B. Publix pharmacies' transfer of prescription drugs from one Publix pharmacy to other Publix pharmacies is not the wholesale distribution of prescription drugs, so long as such transfers are intracompany sales.
- C. Publix pharmacies' sale of prescription drugs from one Publix pharmacy to other Publix pharmacies does not require a Florida prescription drug wholesale distributor permit.
- D. Publix pharmacies' transfer of prescription drugs from one Publix pharmacy to other Publix pharmacies does not require prescription drug pedigrees to be provided at this time, so long as such transfers are intracompany sales. In the future, federal tracking and tracing requirements may apply.
- E. Publix pharmacies' sale of prescription drugs to the Publix chain pharmacy warehouse is not the wholesale distribution of prescription drugs.
- F. Publix pharmacies' transfer of prescription drugs to the Publix chain pharmacy warehouse is not the wholesale distribution of

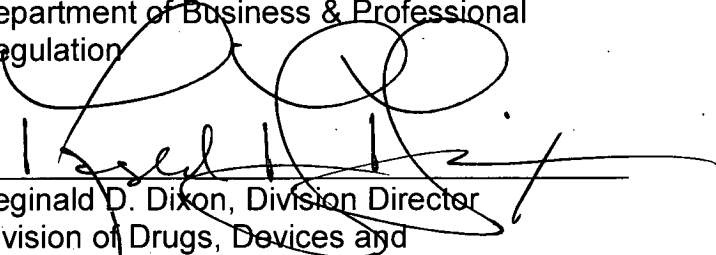
prescription drugs, so long as such transfers are intracompany sales.

- G. Publix pharmacies' sale of prescription drugs to the Publix chain pharmacy warehouse does not require a Florida prescription drug wholesale distributor permit and does not require Publix to provide pedigree papers for these returns.
- H. Publix pharmacies' transfer of prescription drugs to the Publix chain pharmacy warehouse does not require a Florida prescription drug wholesale distributor's permit, so long as such transfers are intracompany sales, and does not require Publix to provide pedigree papers for these returns.

Done and ordered this 11th day of April, 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 has been
furnished by U.S. mail to Martin R. Dix, Esquire, Akerman LLP, 106 East College
Avenue, Suite 1200, Tallahassee, Florida 32301, this 15th day of April,
2014.


for: 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.

BEFORE THE STATE OF FLORIDA
DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION

FILED	
Department of Business and Professional Regulation Deputy Agency Clerk	
CLERK	Brandon Nichols
Date	1/24/2014
File #	

In Re: Publix Super Markets, Inc.'s Petition for
Declaratory Statement before the Florida Department
of Business and Professional Regulation)

DS 2014-007

Publix Super Markets, Inc.'s Petition for Declaratory Statement

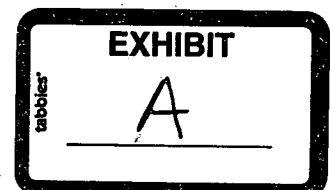
Publix Super Markets, Inc., ("Publix") by and through its undersigned counsel, files this Petition for Declaratory Statement pursuant to Section 120.565, Florida Statutes and Rule 28-105.002, FAC. As grounds therefore, Publix states:

1. Publix is requesting that the Department of Business and Professional Regulation ("Department") declare that the sale or transfer of prescription drugs from one Publix pharmacy to another and from a Publix pharmacy to the Publix chain pharmacy warehouse is not the wholesale distribution of prescription drugs and, if not the wholesale distribution of prescription drugs, that these activities may be undertaken without any type of wholesale drug distribution permit and without the need for a drug pedigree.

2. Publix headquarters is located at Publix Super Markets, Inc., 3300 Publix Corporate Pkwy., Lakeland, FL 33811-3311, e-mail: Jonn.Hoppe@publix.com, phone: 863-499-8577, fax: 863-284-3380, but for purposes of this Petition, its contact shall be through its attorney: Martin R. Dix, Akerman LLP, 106 East College Avenue, Suite 1200, Tallahassee, FL 32301 e-mail: martin.dix@akerman.com, phone: 850-224-9634, fax: 850-222-0103.

3. Publix owns and operates 596 permitted community pharmacies within the State of Florida. These pharmacies do not possess Florida wholesale distribution permits.

4. These Publix pharmacies need to be able to sell or distribute prescription drugs from one Publix pharmacy to another Publix pharmacy when a pharmacy may need or want a



particular drug that another Publix pharmacy has or a pharmacy has too much inventory of a drug and needs to make sure that other Publix pharmacies have adequate inventory to provide timely dispensing of needed medications to patients.

5. Publix also owns and operates a chain pharmacy warehouse that is licensed by the Department as a wholesale drug distributor. This Publix chain pharmacy warehouse purchases prescription drugs from authorized suppliers and distributes these drugs to Publix pharmacies. Publix pharmacies need to be able to sell or distribute prescription drugs from a Publix pharmacy to the Publix chain pharmacy warehouse.

The Laws on Which the Declaratory Statement is Sought

6. 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.

7. 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.

8. Section 499.005(16), 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.

9. Section 499.01, Florida Statutes, requires a permit in order to engage in wholesale drug distribution activities.

10. Generally, unless an applicable exemption applies, when a pharmacy sells or transfers prescription drugs from one pharmacy to another, the Department has considered this to be the distribution of prescription drugs.

11. When a pharmacy sells or transfers a drug to its chain pharmacy warehouse, this was also considered to be the distribution of a prescription drug. The definition of "wholesale distribution" exempts certain activities if undertaken in accordance with Department rules including:

4. The revocation of a sale or the return of a prescription drug to the person's prescription drug wholesale supplier. Section 499.003(54)(b)4., Florida Statutes.

12. The Department's rules require a drug pedigree paper for returns to the wholesaler except when the order is the result of a mistake in ordering or shipment. Rule 61N-1.012, FAC.

13. Unless an applicable exemption applies, the Department has required that a pharmacy selling or distributing a prescription drug to another pharmacy obtain a type of wholesale distributor permit.

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, Florida Statutes.

15. Section 503(e) of the Food Drug and Cosmetic Act provides an exemption from the definition of "wholesale distribution" for "intracompany sales" as follows:

(3) For the purposes of this subsection and subsection (d) of this section—

.....
(B) the term "wholesale distribution" means distribution of drugs subject to subsection (b) of this section to other than the consumer or patient but does not

include intracompany sales and does not include distributions of drugs described in subsection (c)(3)(B) of this section.

16. By federal regulation, the Food and Drug Administration ("FDA") rules also exempt "intracompany sales". 21 CFR 205.3(f)(1).

17. The purpose of these regulations is to:

...implement the Prescription Drug Marketing Act of 1987 by providing minimum standards, terms, and conditions of the licensing by State licensing authorities of persons who engage in wholesale distributions in interstate commerce of prescription drugs. 21 CFR 205.2

18. 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.

19. Section 204 of the DQSA provides for "National Standards for Prescription Drug Wholesale Distributors".

20. Section 204(b)(2) amends Section 503(e) of the Food, Drug and Cosmetic Act [21 U.S.C. 353(e)] in relevant part by adding the following new language at the end of this

section:

(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—

(A)

...intracompany distribution of any drug between members of an affiliate or within a manufacturer;

21. The term affiliate is defined by Section 204 of the DQSA as:

[T]he term *affiliate* means a business entity that has a relationship with a second business entity if, directly or indirectly—

(a) one business entity controls, or has the power to control, the other business entity; or (b) a third party controls, or has the power to control, both of the business entities.

22. 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.

How the Statutes, Rules, or Orders May Substantially Affect Publix in Its Particular Set of Circumstances

23. Publix pharmacies need to be able to sell or distribute prescription drugs from one Publix pharmacy to another Publix pharmacy when a pharmacy may need or want a particular drug or a pharmacy has too much inventory of a drug without obtaining a retail pharmacy wholesaler permit to do so. If Publix is unable to sell or distribute drugs to other pharmacies, these pharmacies may be without adequate drug inventory at the time a prescription is received thus impacting the health and welfare of Publix's patients and Publix's ability to dispense to them. Publix expects to see improved efficiencies both in the delivery of health care and the associated costs if it is able to sell or distribute drugs to other pharmacies it controls.

24. Publix pharmacies also need to be able to sell or distribute prescription drugs from a Publix pharmacy to the Publix chain pharmacy warehouse without providing a pedigree paper. The Publix chain pharmacy warehouse is not required to provide a pedigree paper to a Publix pharmacy so the pharmacy has no pedigree to provide and it makes compliance with this requirement impossible. Publix needs to be able to distribute its drugs back to the Publix chain

pharmacy warehouse to better manage its pharmacies drug inventory and to prevent inventory shortages.

25. If Publix pharmacies are required to obtain permits as wholesale drug distributors, Publix will incur costs in completing applications, paying application fees, and for the time spent ~~dealing with inspectors. Moreover, if the sale or transfer of drugs from one Publix pharmacy to~~ another is a wholesale drug distribution requiring a permit from the Department, pedigree paper requirements may also be imposed on these distributions increasing Publix's recordkeeping costs unnecessarily.

26. Publix controls all of its pharmacies and controls its chain pharmacy warehouse and these entities are therefore affiliates of Publix for purposes of the DQSA and its sales from one pharmacy to another are intracompany sales.

27. Section 585(b) of the DQSA provides that a 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).

28. The FDA regulations state that the standards in 21 CFR 205 are minimum standards that must be met by the states and Florida should therefore apply the intracompany sales exemption consistent with the federal law and regulation.

29. If Section 503(e)(3)B of the Food, Drug and Cosmetic Act or Section 204(a)(2) of the DQSA supersede the above Florida laws on this topic, Publix pharmacies would be allowed to sell or distribute drugs to its other pharmacies and to its pharmacy drug warehouse without this being considered to be a drug distribution requiring a Florida permit.

30. Publix wishes to avoid administrative and criminal prosecution for violating Chapter 499 and therefore is justified in requesting this declaratory statement to clarify its rights under the above statutes.

Wherefore, Publix requests that the Department issue a Final Order determining that:

a. ~~Publix pharmacies' sale of prescription drugs from one Publix pharmacy to other~~
Publix pharmacies is not the "wholesale distribution" of prescription drugs.

b. Publix pharmacies' transfer of prescription drugs from one Publix pharmacy to other Publix pharmacies is not the "wholesale distribution" of prescription drugs.

c. Publix pharmacies' sale of prescription drugs from one Publix pharmacy to other Publix pharmacies does not require any type of Florida prescription drug wholesale distributor's permit.

d. Publix pharmacies' transfer of prescription drugs from one Publix pharmacy to other Publix pharmacies does not require any type of Florida prescription drug wholesale distributor's permit.

e. Publix pharmacies' sale of prescription drugs to the Publix chain pharmacy warehouse is not the "wholesale distribution" of prescription drugs.

f. Publix pharmacies' transfer of prescription drugs to the Publix chain pharmacy warehouse is not the "wholesale distribution" of prescription drugs.

g. Publix pharmacies' sale of prescription drugs to the Publix chain pharmacy warehouse does not require any type of Florida prescription drug wholesale distributor's permit and does not require Publix to provide pedigree papers for these returns.

h. Publix pharmacies' transfer of prescription drugs to the Publix chain pharmacy warehouse does not require any type of Florida prescription drug wholesale distributor's permit and does not require Publix to provide pedigree papers for these returns.

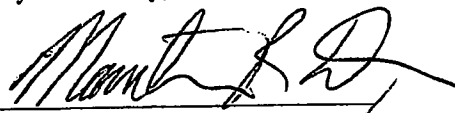
Respectfully submitted this 24th day of January 2014.



Martin R. Dix
FL Bar #499080
Akerman LLP
106 E. College Avenue, Suite 1200
Tallahassee, FL 32301
Tel. 850-224-9634
Fax. 850-222-0103
martin.dix@akerman.com
ATTORNEYS FOR PUBLIX SUPER
MARKETS, INC.

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 (Reggie.Dixon@myfloridalicense.com) and Robert Jernigan (Robert.Jernigan@myfloridalicense.com) this 24th day of January, 2014.



Martin R. Dix