

STATE OF FLORIDA  
DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION

<b>FILED</b>	
Department of Business and Professional Regulation Deputy Agency Clerk	
CLERK	Brandon Nichols
Date	9/29/2014
File #	2014-07367

In Re: Petition for Declaratory  
Statement,

H.D. Smith Wholesale Drug Company,

Petitioner.

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**DS 2014-087**

**DECLARATORY STATEMENT**

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

**PRELIMINARY STATEMENT**

On July 9, 2014, the Department received a petition for declaratory statement (Exhibit A) filed by H.D. Smith Wholesale Drug Company (hereinafter, "HDS" or "Petitioner"), located at 1901 N.W. 25<sup>th</sup> Avenue, Pompano Beach, Florida 33069-5226. Petitioner holds wholesale distributor permits from the Department. Petitioner is seeking a declaratory statement regarding the applicability of Section 499.01(2)(s), Florida Statutes (2013), (currently, Section 499.001(2)(p), Florida Statutes), the requirement to obtain a permit as a third party logistics provider, to Petitioner's facts.

The Department published notice of the petition for declaratory statement in the August 21<sup>st</sup> 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. HDS is a prescription drug wholesale distributor operating in Florida and out of state.

2. HDS holds permit number 22:1454 at 1901 N.W. 25<sup>th</sup> Avenue, Pompano Beach, Florida 33069-5226. Petitioner also holds permit number 23:2382, as an out-of-state prescription drug wholesale distributor at 6001 Global Distribution Way, Suite 102, Louisville, Kentucky 40228.

3. HDS asserts that it has historically and continues to comply with the requirements of Florida law that it only engage in transactions with properly licensed parties as it relates to the distribution of prescription drugs.

4. HDS asserts that certain third party logistics providers (hereafter, "3PL, 3PLs") shipping product to HDS for distribution in Florida have taken the position that a Florida 3PL license is not required due to the provisions of the Drug Quality and Security Act (DQSA).

5. According to HDS, it has held to its belief that a permit as a 3PL in Florida is still required. HDS asserts that the disagreement regarding the interaction of state and federal law has made it difficult in certain instances for HDS to obtain products and provide these medications to Florida pharmacies.

6. HDS asserts that if it obtains and distributes product from an unlicensed 3PL and if the Department determines that the 3PL should have been permitted, then

HDS will be subject to sanctions for violating Chapter 499, Florida Statutes. Accordingly, HDS asserts that it is therefore sufficiently and substantially affected and is justified in requesting this declaratory statement to clarify its rights under the referenced statutes and rules.

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

A. Sections 499.01(1)(p) and (2)(p), Florida Statutes (2014), provide:

**499.01 Permits.—**

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

\* \* \*  
(p) a third party logistics provider  
\* \* \*

(2) The following permits are established:

\* \* \*  
(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 drugs or have the responsibility to direct the sale or disposition of the prescription drug. Each third party logistics provider shall comply with 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.

8. HDS asserts that the following provisions of the DQSA apply to Petitioner's facts:

A. Section 581(22) of the DQSA provides:

**SEC. 581. DEFINITIONS.**

\* \* \*

“(22) **THIRD-PARTY LOGISTICS PROVIDER.**—The term ‘third-party logistics provider’ means an entity that provides or coordinates warehousing, or other logistics services of a product in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of a product, but does not take ownership of the product, nor have responsibility to direct the sale or disposition of the product.

B. Section 584 of the DQSA provides:

**“SEC. 584. NATIONAL STANDARDS FOR THIRD-PARTY LOGISTICS PROVIDERS.**

“(a) **REQUIREMENTS.**—No third-party logistics provider in any State may conduct activities in any State unless each facility of such third-party logistics provider—

“(1)(A) is licensed by the State from which the drug is distributed by the third-party logistics provider, in accordance with the regulations promulgated under subsection (d); or

“(B) if the State from which the drug distributed by the third-party logistics provider has not established a licensure requirement, is licensed by the Secretary, in accordance with the regulations promulgated under subsection (d); and

“(2) if the drug is distributed interstate, is licensed by the State into which the drug is distributed by the third-party logistics provider if such State licenses third-party logistics providers that distribute drugs into the State and the third-party logistics provider is not licensed by the Secretary as described in paragraph (1)(B).

C. Section 585 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 wholesale distributor, or section 584, in the case of a third party logistics provider.

(2) STATE REGULATION OF THIRD-PARTY LOGISTICS PROVIDERS.—No State shall regulate third party logistics providers as wholesale distributors.

9. Petitioner requests a declaratory statement “determining that if HDS obtains prescription drug product from a 3PL for distribution in Florida, then the 3PL must hold a valid Florida 3PL license.

### **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. Section 499.002, Florida statutes, provides, in relevant part:

**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.

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\*

15. The Petitioner is substantially affected by the statutes cited in paragraph seven above and has standing to seek a declaratory statement from the Department.

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

17. Prior to November 27, 2013, Section 499.01(2)(s), Florida Statutes, was interpreted to require an entity meeting the requirements set forth therein and distributing from within this state to obtain a permit as a 3PL. In addition, a 3PL from another state meeting the requirements of the provision would need a Florida permit to distribute prescription drugs into this state. As of November 27, 2013, new federal provisions were signed into law under the DQSA. In addition to the provisions cited by Petitioner, the DQSA contains several other provisions applicable to 3PLs.

18. Section 581(9)(B) of the DQSA provides:

**Sec. 581 Definitions.**

In this subchapter:

(9) Licensed.—The term “licensed” means—

\* \* \*

“(B) In the case of a third party logistics provider, having a valid license in accordance with section 584(a) or section 582(a)(7), as applicable; and

\* \* \*

19. Section 582 of the DQSA provides:

**Sec. 582. Requirements.**

“(a) In General

\* \* \*

“(7) THIRD-PARTY LOGISTICS PROVIDER LICENSES.—Until the effective date of the third-party logistics provider licensing regulations under section 584, a third-party logistics provider shall be considered ‘licensed’ under section 581(9)(B) unless the

Secretary has made a finding that the third-party logistics provider does not utilize good handling and distribution practices and publishes notice thereof.

20. The DQSA amends Section 21 U.S.C. §353(e), as follows:

21 U.S.C. §353(e)(5) provides:

“(5) THIRD PARTY LOGISTICS PROVIDERS.—Notwithstanding paragraphs (1) through (4), each entity that meets the definition of a third party logistics provider under section 581(22) shall obtain a license as a third party logistics provider as described in section 584(a) and is not required to obtain a license as a wholesale distributor if the entity never assumes an ownership interest in the product it handles.”

21. Section 584(b), of the DQSA provides:

REPORTING.—Beginning 1 year after the date of enactment of the Drug Supply Chain Security Act, a facility of a third-party logistics provider shall report to the Secretary on an annual basis pursuant to a schedule determined by the Secretary—

“(1) the State by which the facility is licensed and the appropriate identification number of such license; and

“(2) the name and address of the facility and all trade names under which such facility conducts business.

22. Sections 585 (b)(3), (b)(4), and (c) of the DQSA provide:

“(3) ADMINISTRATION FEES.—Notwithstanding paragraph (1), a State may administer fee collections for effectuating the wholesale drug distributor and third-party logistics provider licensure requirements under sections 503(e) (as amended by the Drug Supply Chain Security Act), 583, and 584.

“(4) ENFORCEMENT, SUSPENSION, AND REVOCATION.—  
Notwithstanding paragraph (1), a State—

“(A) may take administrative action, including fines, to enforce a requirement promulgated by the State in accordance with section 503(e) (as amended by the Drug Supply Chain Security Act) or this subchapter;



“(B) may provide for the suspension or revocation of licenses issued by the State for violations of the laws of such State;

“(C) upon conviction of violations of Federal, State, or local drug laws or regulations, may provide for fines, imprisonment, or civil penalties; and

“(D) may regulate activities of licensed entities in a manner that is consistent with product tracing requirements under section 582.

“(c) EXCEPTION.—Nothing in this section shall be construed to preempt 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).”.

23. Currently, Section 499.01(2)(p), Florida Statutes (2014), which requires 3PLs to comply with the wholesale distributor requirements and with pedigree requirements (unless the 3PL is performing a wholesale distribution of a prescription drug for a manufacturer), is inconsistent with the new federal standards.

24. It is not clear from a reading of the other relevant provisions of the DQSA regarding 3PL licensure whether the Department is pre-empted from permitting 3PLs in this interim period prior to the effective date of the regulations referenced in section 584 of the DQSA, or whether the Department is authorized to continue its current permitting program for 3PLs. However, it is clear that Section 585(c) of the DQSA allows state licensure that is not inconsistent with the federal standards. Therefore, so long as the department does not require 3PLs to meet the distributor and pedigree requirements, the Department can continue to license 3PLs.

25. In a declaratory statement, the Department is limited to providing a statement of how statutes over which the agency has regulatory authority, agency rules

or agency orders affect the Petitioner. Accordingly, the Department cannot interpret the provisions of the DQSA regarding 3PL licensure as it applies to Petitioner's facts.

26. However, there is no prohibition against the Department determining in a declaratory statement whether its statutes (or portions thereof) are pre-empted by a federal statute, and how that statute, whether pre-empted or not, affects a Petitioner.

27. The Department determines that the requirements of the Department's 3PL licensing program that relate to 3PLs being treated as wholesale distributors and the requirements for pedigrees will not be administratively enforced by the Department.<sup>1</sup>

28. Section 499.002(1), Florida Statutes, states that Chapter 499, Part I, is intended to 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. The Department is charged with promoting uniformity of state and federal laws and their administration and enforcement throughout the United States. In addition, the Department is charged with administering and enforcing Part I, Chapter 499, Florida Statutes, to prevent fraud, adulteration, misbranding, or false advertising in the preparation, manufacture, repackaging or distribution of drugs, devices, and cosmetics.

29. In keeping with its legislative mandates set forth in Section 499.002, Florida Statutes, and notwithstanding the DQSA's various provisions regarding 3PL licensure, the Department will continue its present 3PL permitting program<sup>2</sup> and will continue to require permits for 3PLs distributing prescription drugs from or into this

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<sup>1</sup> Nothing herein should be construed to limit or affect the state's authorization to enforce its criminal statutes, including those in Chapter 499, Florida Statutes.

<sup>2</sup> The Department will not administratively enforce the provisions that require 3PLs to be treated as wholesale distributors and will not administratively enforce the pedigree requirements for 3PLs.

state. Accordingly, the Department declares that if HDS obtains prescription drug product from a 3PL for distribution in Florida, then the 3PL must hold a valid Florida 3PL license.

Done and ordered this 29<sup>th</sup> day of September, 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  
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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 Michael J. Glazer, Ausley McMullen, Post Office Box 391, 123 South Calhoun Street, Tallahassee, FL 32301, this 29<sup>th</sup> day of September, 2014.

*for:*   
Agency Clerk

**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.

Copies furnished to:

Reginald D. Dixon  
DDC Division Director

Kathryn E. Price  
DDC Chief Attorney

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

<b>FILED</b>	
<small>Department of Business and Professional Regulation Deputy Agency Clerk</small>	
CLERK	Brandon Nichols
Date	<b>7/9/2014</b>
File #	

**IN RE: H.D. SMITH WHOLESALE DRUG  
COMPANY'S PETITION FOR DECLARATORY  
STATEMENT BEFORE THE DEPARTMENT OF  
BUSINESS AND PROFESSIONAL REGULATION,**

**DS 2014-087**

**H.D. SMITH'S PETITION FOR DECLARATORY STATEMENT**

H.D. Smith Wholesale Drug Co. ("HDS"), by and through its undersigned attorneys, and pursuant to section 120.565 and Florida Administrative Code Chapter 28-105, hereby files this Petition for Declaratory Statement and says:

**INTRODUCTION**

1. HDS is requesting that the Department of Business and Professional Regulation ("DBPR") determine whether a third party logistics provider ("3PL") must still be licensed to conduct activities in Florida despite any of the provisions of the new federal Drug Quality and Security Act.

2. The Petitioner is H.D. Smith Wholesale Drug Co. HDS is located at 1901 N.W. 25th Avenue, Pompano Beach, Florida 33069-5226 and holds Florida Prescription Drug Wholesale Distributor license number 221454 issued by DBPR. HDS also holds Florida Out-of-State Prescription Drug Wholesale Distributor license number 232382 located at 6001 Global Distribution Way, Suite 102, Louisville, Kentucky 40228. For purposes of this Petition, the contact information for HDS is through its undersigned counsel.

**RECEIVED**

JUL 09 2014

DBPR Agency Clerk

**STATUTES ON WHICH THE DECLARATORY STATEMENT IS SOUGHT**

**Florida Law**

3. DBPR may bring actions against persons violating the provisions of Chapter 499, Florida Statutes. Criminal sanctions also apply to certain violations, as set forth in section 499.0051, Florida Statutes. Sections 499.002, 499.0051, 499.066, 499.0661, and 499.067, Florida Statutes, and related administrative rules set forth DBPR's enforcement authority.

4. Section 499.01, Florida Statutes lists the categories of persons and establishments that are required to have a permit from DBPR. Section 499.01(1)(s), Florida Statutes list "a third party logistics provider"

5. Section 499.01(2)(s), Florida Statutes provides:

(s) 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.

6. DBPR has developed an application for a 3PL permit; Form No. DBPR-DDC-220, which is hereby incorporated by reference. This same form is used regardless of whether the 3PL establishment is located in Florida or elsewhere.

**Drug Quality and Security Act**

7. 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.<sup>1</sup>

8. Section 581(22) of DQSA defines a third-party logistics provider as follows:

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

9. State law licensing of wholesale distributors and 3PLs is subject to an express preemption provision in DQSA as follows:

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 584, in the case of a third-party logistics provider.

(2) STATE REGULATION OF THIRD-PARTY LOGISTICS PROVIDERS.— No State shall regulate third-party logistics providers as wholesale distributors.

10. While DQSA prohibits a state from regulating 3PLs as wholesale distributors, DQSA also provides:

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<sup>1</sup> Title II of DQSA, entitled “Drug Supply Chain Security” has been codified at 21 U.S.C. §§360eee through 360eee-4. Section references in this Petition are to those in Public Law 113-54 rather than the United States Code references.

SEC. 584. NATIONAL STANDARDS FOR THIRD-PARTY LOGISTICS PROVIDERS.

(a) REQUIREMENTS.— No third-party logistics provider in any state may conduct activities in any State unless each facility of such third-party logistics provider—

(1)(A) is licensed by the State from which the drug is distributed by the third-party logistics provider, in accordance with the regulations promulgated under the subsection (d); or

(B) if the State from which the drug distributed by the third-party logistics provider has not established a licensure requirement, is licensed by the Secretary, in accordance with the regulations promulgated under subsection (d); and

(2) if the drug is distributed interstate, is licensed by the State into which the drug is distributed by the third-party logistics provider if such State licenses third-party logistics providers that distribute drugs into the State and the third-party logistics provider is not licensed by the Secretary as described in paragraph (1)(B).

**STATEMENT OF FACTS AND MANNER IN WHICH HDS IS SUBSTANTIALLY AFFECTED**

11. HDS is a prescription drug wholesaler. HDS has historically and continues to comply with the requirements of Florida law that it only engage in transactions with properly licensed parties as it relates to the distribution of prescription drugs.

12. Certain 3PLs shipping products to HDS for distribution in Florida have taken the position that a Florida 3PL license is not required due to the provisions of DQSA.

13. HDS has held to its belief that a 3PL license is required. This disagreement regarding the interaction of state and federal law has made it difficult in certain instances for HDS to obtain products and provide these medications to Florida pharmacies.

14. HDS is substantially affected by these regulations. If HDS obtains and distributes product from an unlicensed 3PL and if DBPR determines that the 3PL should have been



licensed, then HDS is subject to sanctions for violating Chapter 499, Florida statutes. HDS is therefore sufficiently and substantially affected and is justified in requesting this declaratory statement to clarify its rights under the referenced statutes and rule.

WHEREFORE, HDS respectfully requests that DBPR issue a Final Order determining that if HDS obtains prescription drug products from a 3PL for distribution in Florida, then the 3PL must hold a valid Florida 3PL license.

Respectfully submitted this 9th day of July, 2014.

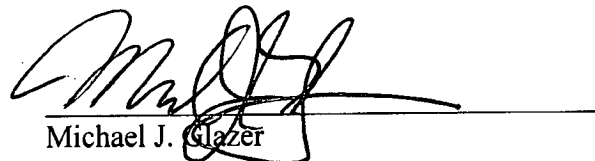


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Attorneys for H.D. Smith Wholesale Drug  
Company

**CERTIFICATE OF SERVICE**

I hereby certify that the original of the foregoing Petition for Declaratory Statement was hand delivered to: Agency Clerk, Department of Business & Professional Regulation, 1940 North Monroe Street, Suite 92, Tallahassee, Florida 32399-2202, with a copy sent by electronic mail to Reginald Dixon at [reggie.dixon@myfloridalicense.com](mailto:reggie.dixon@myfloridalicense.com) this 9th day of July, 2014.



Michael J. Glazer