STATE OF FLORIDA
DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATI

In Re: Petition for Declaratory Statement,

DS 2014-039

Safecor Health, LLC,

Petitioner.
_____/

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 March 12, 2014, the Department received a petition for declaratory statement (Exhibit A) filed by Safecor Health, LLC (hereinafter, "Safecor" or "Petitioner"), located at 4060 Business Park Drive, Suite B, Columbus, Ohio, 43204. Petitioner is seeking a declaratory statement regarding the applicability of Sections 499.003(54)(b)7., 499.005(21), 499.0051(12)(a), 499.006(10) and 499.01212, Florida Statutes (2013), to 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, and 499.067, Florida Statutes, as applied to Petitioner's facts.

The Department published notice of the petition for declaratory statement in the March 17, 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. Safecor provides repackaging services to hospitals and other health care entities.

2. Safecor holds an out-of-state prescription drug wholesale distributor permit with the Department, having been issued permit number 23:2468 on June 19, 2013.

3. Safecor operates as a repackager, registered under Section 510 of the federal Food, Drug, and Cosmetic Act.

4. Safecor provides repackaging services to hospitals and other health care entities in a business model whereby the health care entity maintains ownership of the product but instructs its wholesaler to send such product directly to the repackager.

5. Petitioner asserts that it assists with the improvement of hospital patient safety programs through repackaging pharmaceuticals into unit dose bar coded medications.

6. Unit dose bar coded medications are a key component of a hospital's program that helps to ensure that a patient receives the correct medication at the correct dose.

7. Chapter 499, Florida Statutes, as presently configured, prohibits the out-of-state repackaging of prescription drugs purchased by a hospital or other health care

entity and prohibits the distribution of such repackaged prescription drugs into this state, unless the distribution is authorized under Section 499.01(2)(g)1.c., Florida Statutes.

8. Petitioner asserts that hospitals should be able to direct manufacturers or their wholesale suppliers to transfer prescription drugs directly to repackagers, whether inside or outside of Florida, and those repackagers should be able to transfer the drugs to the hospitals or other health care entities, and other health care entities that are under common control, after the drugs are repackaged.

9. Petitioner asserts that enabling it to provide repackaging services as described in paragraph eight above will improve hospital efficiency and provide an infrastructure that allows for better patient care.

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

A. Section 499.003(54)(b)7., 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:
>
> * * *
>
> 7. The transfer of a prescription drug by a hospital or other health care entity to a person licensed under this part to repackage prescription drugs for the purpose of repackaging the prescription drug for use by that hospital, or other health care entity and other health care entities that are under common control, if ownership of the prescription drugs remains with the hospital or other health care entity at all times. In addition to the recordkeeping requirements of s. 499.0121(6), the hospital or health care entity that transfers

prescription drugs pursuant to this subparagraph must reconcile all drugs transferred and returned and resolve any discrepancies in a timely manner.

B. Section 499.005(21), 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:

* * *

(21) The wholesale distribution of any prescription drug that was:
(a) Purchased by a public or private hospital or other health care entity; or
(b) Donated or supplied at a reduced price to a charitable organization,

unless the wholesale distribution of the prescription drug is authorized in s. 499.01(2)(g)1.c.

C. Section 499.0051(12)(a), Florida Statutes (2013), provides:

499.0051 Criminal Acts.--

* * *

(12) ADULTERATED AND MISBRANDED DRUGS; FALSE ADVERTISEMENT; FAILURE TO MAINTAIN RECORDS RELATING TO DRUGS. Any person who violates any of the following provisions commits a misdemeanor of the second degree, punishable as provided in s.775.082 or s.775.083; but, if the violation is committed after a conviction of such person under this subsection has become final, such person commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083, or as otherwise provided in this part:
(a) The manufacture, repackaging, sale, delivery, or holding or offering for sale of any drug that is adulterated or misbranded or has otherwise been rendered unfit for human or animal use.

* * *

D. Section 499.006(10), Florida Statutes (2013), provides:

499.006 Adulterated drug or device.— A drug or device is adulterated:

(10) If it is a prescription drug for which the required pedigree paper is nonexistent, fraudulent, or incomplete under the requirements of this part or applicable rules, or that has been purchased, held, sold, or distributed at any time by a person not authorized under federal or state law to do so. ....

E. Section 499.01212, Florida Statutes (2013), provides:

499.01212 Pedigree Paper.--
(1) APPLICATION. Each person who is engaged in the wholesale distribution of a prescription drug must, prior to, or simultaneous with each wholesale idstribution, provide a pedigree paper to the person who receives the drug.

* * *

11. Sections 499.002, 499.06, 499.061, 499.066, and 499.067, Florida Statutes, authorize the Department 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. In addition, criminal sanctions may apply to certain violations as set forth in section 499.0051, Florida Statutes.

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

A. 21 U.S.C. §353(e), is 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—

* * *

"(S) the transfer of a product by a hospital or other health care entity, or by a wholesale distributor or manufacturer operating at the direction of the hospital or other health care entity, to a repackager described in section 581(16)(B) and registered under section 510 for the purpose of repackaging the drug for use by that hospital, or other health care entity and other health care entities that are under common control, if ownership of the drug remains with the hospital or other health care entity at all times."

B. 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.

C. 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.

13. Safecor requests a declaratory statement from the Department as to the following:

A. If Safecor receives, for purposes of repackaging, finished pharmaceutical products that have been purchased by a public or private hospital or other health care entity and distributed to Safecor by or at the direction of the health care entity, whether Safecor may transfer those repackaged drugs to the public or private hospitals' or health care entities' locations in Florida which are under common control with the hospital or other health care entity that originally purchased the products, if ownership of the drug remains with the hospital or other health care entity at all times.

B. Whether any of the transfers of drugs, as described in subparagraph A above, would require Safecor to receive or provide a Florida-compliant pedigree paper.

CONCLUSIONS OF LAW

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

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

16. 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.

17. 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.

18. The Petitioner is substantially affected by the statutes cited in paragraph 10 above and has standing to seek a declaratory statement from the Department.

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

20. Prior to November 27, 2013, Sections 499.003(54)(b)7., 499.005(21), 499.0051(12)(a), 499.006(10), and 499.01212, Florida Statutes, were interpreted by the Department to prohibit the out-of-state repackaging of prescription drugs purchased by a hospital or other health care entity and to prohibit the distribution of such repackaged prescription drugs into this state, unless the distribution is authorized under Section 499.01(2)(g)1.c., Florida Statutes. Drugs distributed by entities that are not permitted as described in the scenario above would be adulterated within the meaning of Section 499.006(10), Florida Statutes.

21. 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.

22. 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.

23. Currently, wholesale distributors and repackagers are still required to obtain a permit to operate in this state, and to be in compliance with federal law. *See*, Sections 582-585, DQSA.

24. 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, which become effective January 1, 2015.

25. Section 499.003(54)(b)7., Florida Statutes, is a provision, standard, requirement, or regulation with respect to wholesale distributor licensure that is covered by a standard in the amended act. Likewise, the provision in Section 499.005(21), Florida Statutes that prohibits the distribution of prescription drugs purchased by a public or private hospital or other health care entity, is a provision, standard, requirement, or regulation with respect to wholesale distributor licensure that is inconsistent with the standard set forth in the amended act. As such, both Section 499.003(54)(b)7., and Section 499.005(21), Florida Statutes, are preempted by the amended act, and the Department will not apply the provision to Petitioner's circumstances.

26. As set forth in paragraph 12 above, the DQSA excludes from the definition of "wholesale distribution," the transfer of a product by a hospital or other health care entity, or by a wholesale distributor or manufacturer operating at the direction of the hospital or other health care entity, to a repackager described in Section 581(16)(B) and registered under Section 510 for the purpose of repackaging the drug for use by that hospital, or other health care entity and other health care entities that are under common control, if ownership of the drug remains with the hospital or other health care entity at all times. This provision seems to allow Petitioner, which is registered as a repackager under Section 510, to operate as described in paragraph eight above.

27. The amended language in paragraph 12 above will become effective January 1, 2015. The Department has previously taken the position that 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, (hereinafter, "PDMA"), is applicable to prescription drug distributor licensing, and that Florida would adopt the minimum licensing standards from the PDMA in lieu of the preempted licensing standards in Chapter 499, Florida Statutes. *See,* Declaratory Statement, In Re Petition for Declaratory Statement, Publix Supermarkets, Inc., Petitioner, Department case number DS2014-007. The PDMA does not address purchases of prescription drugs by hospitals or other health care entities, as an exemption to "wholesale distribution." The Department cannot interpret the federal requirements for Petitioner, or advise as to the effect of the exemption being excluded from the PDMA. However, in light of the preemption of Sections 499.003(54)(b)7. and 499.005(21), Florida Statutes, the Department will not proceed with enforcement action against Petitioner for operating in this interim period in accordance with the scenario set forth in paragraph eight, as further discussed below.[1]

28. With respect to pedigree requirements, in light of the preemption language in Section 585 of the Act, the Department acknowledges that the federal provisions preempt Section 499.01212, Florida Statutes, such that the Department will not require Petitioner to pass a pedigree, as described in Section 499.01212, Florida Statutes, in the scenario described in paragraph eight above.

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[1] The Petitioner should note that the Department's authority to regulate activity under Chapter 499, Florida Statutes, is limited to regulatory enforcement. While the interpretation of statutes by agencies charged with their enforcement is entitled to great deference and will not be overturned unless clearly erroneous, Gay v. Canada Dry Bottling Co., 59 So.2d 788, 790 (Fla. 1952), the department's interpretation does not bind the authority of Florida's criminal prosecutors to bring charges under this section.

29. Even though Section 499.01212, Florida Statutes, is preempted, the federal tracking and tracing requirements do not become effective until 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.

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

A. If Safecor receives, for purposes of repackaging, finished pharmaceutical products that have been purchased by a public or private hospital or other health care entity and distributed to Safecor by or at the direction of the health care entity, the Department will not prohibit Safecor from transferring those repackaged drugs to the public or private hospitals' or health care entities' locations in Florida which are under common control with the hospital or other health care entity that originally purchased the products, so long as ownership of the drug remains with the hospital or other health care entity at all times.

B. The transfers as described in paragraph A above would require Safecor to comply with minimum recordkeeping requirements, including tracking requirements as set forth in the PDMA. However, for transfers described in paragraph A, the Department will not require Safecor to receive or provide a Florida-compliant pedigree paper.

Done and ordered this 19th day of May, 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 Shannon Salimone, Esquire, Holland and Knight LLP, Post Office Drawer 810, Tallahassee, FL 32302, this 19th day of May, 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 & PROFESSIONAL REGULATIO

In Re: Safecor Health LLC's Petition for Declaratory Statement before the Florida Department of Business and Professional Regulation)

DS 2014-039

Safecor Health LLC's Petition for Declaratory Statement

Safecor Health, LLC, ("Petitioner") by and through its undersigned counsel, files this Petition for Declaratory Statement pursuant to Section 120.565, *Florida Statutes*, and Rule 28-105.002, *Florida Administrative Code*. As grounds therefore, Petitioner states:

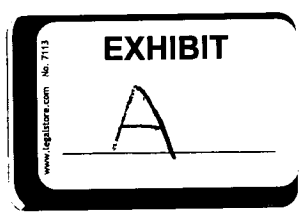
Introduction

1. Petitioner is requesting that the Department of Business and Professional Regulation ("Department") declare that certain of its activities relating to the repackaging of finished pharmaceutical products owned by a hospital or other health care entity are permissible in Florida.

2. Petitioner's headquarters is located at 4060 Business Park Drive, Suite B, Columbus, OH 43204, e-mail: sfischbach@safecorhealth.com, phone: 614-351-6117, fax: 866-518-8432, but for purposes of this Petition, all pleadings and correspondence should be directed to its attorney: Shannon Salimone; Address: Holland & Knight LLP, Post Office Drawer 810, Tallahassee, Florida 32302, e-mail: Shannon.salimone@hklaw.com, phone: 850.224.7000 , fax: 850.224.8832.

3. Petitioner provides repackaging services to hospitals and other health care entities.

4. Petitioner currently holds an out-of-state prescription drug wholesale distributor permit in Florida (number 232468).



5. Petitioner asserts that hospitals or other health care entities should be able to direct manufacturers or their wholesale suppliers to transfer drugs directly to repackagers, whether inside or outside of Florida, and those repackagers should be able to transfer the drugs to the hospitals, or other health care entities, and other health care entities that are under common control after they are repackaged.

Statutes on Which the Declaratory Statement is Sought

6. The Department 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 499.051, *Florida Statutes*. Sections 499.002, 499.0051, 499.06, 499.066, 499.061, and 499.067, *Florida Statutes*, set forth the Department's enforcement authority.

7. Section 499.003 (54)(b)(7), *Florida Statutes*, exempts from the definition of "wholesale distribution" the "transfer of a prescription drug by a hospital or other health care entity to a person licensed under this part to repackage prescription drugs for the purpose of repackaging the prescription drug for use by that hospital, or other health care entity and other health care entities that are under common control, if ownership of the prescription drugs remains with the hospital or other health care entity at all times. In addition to the recordkeeping requirements of s. 499.0121(6), the hospital or health care entity that transfers prescription drugs pursuant to this subparagraph must reconcile all drugs transferred and returned and resolve any discrepancies in a timely manner." If the repackager is outside of Florida and licensed as an out-of-state prescription drug wholesale distributor, this provision is not applicable.

8. Section 499.005(21)(a), *Florida Statutes*, prohibits "the wholesale distribution of any drug that was: (a) purchased by a public or private hospital or other healthcare entity."

9. Section 499.0051(12)(a) makes it a crime to, among other things, repackage or deliver a drug that is "adulterated." A drug can be deemed to be "adulterated" "[i]f it is a

prescription drug for which the required pedigree paper is nonexistent, fraudulent, or incomplete under the requirements of this part or applicable rules, or that has been purchased, held, sold, or distributed at any time by a person not authorized under federal or state law to do so." §499.006(10), Fla. Stat. (2013).

10. Section 499.01212 provides that "[e]ach person who is engaged in the wholesale distribution of a prescription drug must, prior to or simultaneous with each wholesale distribution, provide a pedigree paper to the person who receives the drug."

11. 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.

12. Section 204 of the DQSA provides for "National Standards for Prescription Drug Wholesale Distributors." The DQSA contains provisions that have expressly preempted certain State laws and regulations from the date of enactment, November 27, 2013. Specifically:

> "Beginning on the date of enactment of the [DQSA], 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.

Drug Quality and Security Act, Pub. L. No. 113-54, 127 Stat. 587, 638-639 (2013).

13. Accordingly, any wholesale distribution laws and regulations inconsistent with Section 204 of the DQSA were expressly preempted on November 27, 2013.

14. 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 . . .
>
> the transfer of a product by a hospital or other health care entity, or by a wholesale distributor or manufacturer operating at the direction of the hospital or other health care entity, to a repackager described in section.581 (16)(B) and registered under section 510 for the purpose of repackaging the drug for use by that hospital, or other health care entity and other health care entities that are under common control, if ownership of the drug remains with the hospital or other health care entity at all times.

Drug Quality and Security Act, Pub. L. No. 113-54, 127 Stat. 587, 632-634 (2013).

15. The DQSA provides for preemption of state wholesale distributor licensure laws beginning on its enactment. Specifically, Section 585 of the Food, Drug and Cosmetic Act, as amended by Section 205 of the DQSA, 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.

Drug Quality and Security Act, Pub. L. No. 113-54, 127 Stat. 587, 639 (2013)

Statement of Facts

16. Petitioner is a repackager described in Section 581(16)(B) and registered under section 510 of the federal Food, Drug and Cosmetic Act. Petitioner provides repackaging services to hospitals and other health care entities in a business model whereby the health care

entity maintains ownership of the product but instructs its wholesaler to send such product directly to the repackager.

17. Petitioner assists with the improvement of hospital patient safety programs through repackaging pharmaceuticals into unit dose bar coded medications. Unit dose bar coded medications are a key component of a hospital's program that helps ensure that a patient is receiving the correct medication and the correct dose at the time of administration.

18. In other states, Petitioner typically receives the finished products from a wholesaler, repackages them, and then ships them to the hospital that purchased the products, or to another health care entity under the same ownership or control as the hospital.

How the Statutes, Rules, or Orders May Substantially Affect Petitioner in Petitioner's Particular Set of Circumstances

19. Chapter 499 has been interpreted to prohibit a hospital from directing its wholesalers to deliver products to out-of-state repackagers. The inability to offer these services affects Petitioner's ability to offer Florida hospitals access to its services, and affects its ability to participate in the supply chain through existing wholesale channels. Enabling the repackaging services described in this petition will help improve hospital efficiency and provide an infrastructure that allows for better patient care.

20. If Petitioner is required to receive and provide Florida-compliant pedigrees, Petitioner will incur substantial costs in reviewing and preparing those pedigrees.

Discussion

21. The provisions in the DQSA clearly permit Petitioner to repackage and re-distribute drugs that have been purchased by a hospital, provided that the repackaging is done for use by that hospital or other health care entity and other health care entities that are under

common control, if ownership of the drug remains with the hospital or other health care entity at all times.

22. Section 499.005(21)(a), *Florida Statutes*, would prohibit activities that are clearly allowed by the DQSA.

23. When it passed the DQSA, Congress intended for Florida laws to be preempted, effective November 27, 2013, to the extent that they "continue in effect inconsistent requirements relating to paper or electronic records or any other requirements 'which are inconsistent with . . . requirements applicable under section 503(e) as amended by [the] Act,' including wholesale distribution exceptions contained therein." See Letter from the Honorable Robert E. Latta to Reginald Dixon, Dated Feb. 19, 2014 (attached as Exhibit A) (footnote omitted).

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

Questions Presented

25. Safecor respectfully requests a declaratory statement regarding the following questions:

a. If Safecor receives, for purposes of repackaging, finished pharmaceutical products that have been purchased by a public or private hospital or other health care entity and distributed to Safecor by or at the direction of the health care entity, whether Safecor may transfer those repackaged drugs to the public or private hospitals' or health care entities' locations in Florida which are under common control with the hospital or other health care entity that

originally purchased the products, if ownership of the drug remains with the hospital or other health care entity at all times.

b. Whether any of the transfers of drugs, as described in subsection (a) above, would require Safecor to receive or provide a Florida-compliant pedigree paper.

Wherefore, Petitioner requests that the Department issue an order declaring whether Safecor's proposed repackaging activities, as described above, are permissible in Florida.

Respectfully submitted this 12th day of March, 2014.

HOLLAND & KNIGHT LLP

Shannon Hartsfield Salimone
Florida Bar No. 0055130
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Tallahassee, Florida 32302
Phone (850)224-7000
Facsimile (850)224-8832
Email: Shannon.salimone@hklaw.com
ATTORNEYS FOR PETITIONER

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 12th day of March, 2014.

Shannon Salimone

Exhibit A

(See Attachment)

ROBERT E. LATTA
5TH DISTRICT, OHIO

ASSISTANT MAJORITY WHIP

CO-CHAIRMAN
CONGRESSIONAL SPORTSMEN'S CAUCUS

COMMITTEE ON
ENERGY AND COMMERCE
SUBCOMMITTEE ON
COMMUNICATIONS AND TECHNOLOGY
VICE CHAIRMAN

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February 19, 2014

Reginald Dixon, Executive Director
Division of Drugs Devices and Cosmetics
Florida Department of Business and Professional Regulation
1940 N. Monroe St.
Tallahassee, FL 32399-1047

Dear Mr. Dixon,

It is my understanding that some State licensing entities have raised questions as to the effective date of certain provisions included in the Drug Quality and Security Act (DQSA or the Act) (P.L. 113-54) that expressly preempt State rules governing the traceability of products throughout the drug supply chain. As the primary sponsor of the drug distribution supply chain portion of the legislation, I am writing to clarify the Act's provisions in this regard.

Since Congress began working on this issue many years ago, our intent has always been to create a uniform, nationwide system to track and trace drug products throughout the supply chain. From the outset, it is essential to the successful development of such a system to clearly define the different stakeholders in the supply chain and their related requirements.

The DQSA contains provisions that have expressly preempted certain State laws and regulations from the date of enactment, November 27, 2013. Specifically:

> "Beginning on the date of enactment of the [DQSA], 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."[1]

[1] Drug Quality and Security Act, Pub. L. No. 113-54, 127 Stat. 587, 638-639 (2013).

Accordingly, State definitions of a "wholesale distributor," and/or any related exemptions inconsistent with Section 581 of the Act, were expressly preempted on November 27, 2013. In addition, a State cannot establish or continue in effect inconsistent requirements relating to paper or electronic records or any other requirements "which are inconsistent with . . . requirements applicable under section 503(e) as amended by [the] Act,"[2] including the wholesale distribution exceptions contained therein.

I appreciate State efforts to protect supply chain security, but it is important that they do not conflict with the DQSA. I look forward to working with States to ensure prompt implementation of this Act. Should you have any questions, please contact my Legislative Director, Allison Witt, at (202) 225-6405.

Sincerely,

Robert E. Latta
Member of Congress

REL/ahw

Cc: Robert Jernigan, Compliance and Enforcement Manager, Assistant General Counsel, Florida Department of Health

[2] *Id.* at 639.