

Final Order No. DOH-10-0668-DS-MQA  
FILED DATE - 3/9/2010  
Department of Health  
By: *Angela Barton*  
Deputy Agency Clerk

STATE OF FLORIDA  
DEPARTMENT OF HEALTH

IN RE:

PETITION FOR DECLARATORY  
STATEMENT BY HENRY SCHEIN, INC.,  
MEDLINE INDUSTRIES, INC.,  
CARDINAL HEALTH, INC.

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**SECOND AMENDED FINAL ORDER ON PETITION FOR  
DECLARATORY STATEMENT**

This matter came before the Department of Health, Drugs, Devices and Cosmetics Program (hereinafter referred to as the "Department") on February 15, 2009 for consideration of a Petition for Declaratory Statement (attached hereto) filed by the parties referenced above (hereinafter referred to as the "Petitioners") pursuant to Section 120.565, Florida Statutes and Chapter 28-105, Florida Administrative Code. The Petition asks questions related to the licensure and recordkeeping requirements of Section 499.01(2), (t) Florida Statutes (F.S.).

Having reviewed and discussed the Petition the Department made the following determinations:

**FINDINGS OF FACT**

1. The Petitioners are prescription drug wholesale distributors. They engage in the wholesale distribution of prescription drugs in Florida. Some, but not all of Petitioners' clients are business entities with federal employer tax identification numbers (FEIN's) that provide health care services in Florida. Petitioner Henry Schein, Inc. (Henry) has clients that provide veterinary services in Florida. Some, but not all of Henry's veterinary related clients also are business entities with federal employer tax identification numbers.

2. The definition of "establishment" for purposes of chapter 499 part I F.S. reads as follows:

*"Establishment" means a place of business at one general physical location.*

As described in paragraph 3. of the Petition, and in Section 499.01 (2), (t) F.S. a Health Care Clinic Establishment is described as *a place of business at one general physical location that provides health care or veterinary services, which is owned and operated by a business entity that has been issued a federal employer tax identification number.*

Section 499.01(2), (t) 4. F.S. reads in pertinent part: *The purchase of prescription drugs by the health care clinic establishment is prohibited during any period of time when the establishment does not comply with this paragraph.*

Section 499.01(2), (t) 6. F.S. reads in pertinent part: *This paragraph does not apply to the purchase of a prescription drug by a licensed practitioner under his or her license.*

3. Section 499.01(1), F. S. reads in pertinent part: *prior to operating, a permit is required for each person and establishment that intends to operate as: .....(t) a health care clinic establishment.*

Section 499.012 (4), (a) F.S. concerning application requirements for a health care clinic establishment permit reads in pertinent part: *an application for a permit must include: 4. the type of ownership or operation, such as a partnership, corporation, or sole proprietorship.*

4. Section 499.005 F.S. reads in pertinent part: *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;*

(15) *The sale or transfer of a prescription drug to a person that is not authorized under the law of the jurisdiction in which the person receives the drug to purchase or possess prescription drugs from the person selling or transferring the prescription drug;*

(21) *Failure to obtain a permit or registration, or operating without a valid permit when a permit or registration is required by this part for that activity.*

Section 499.0051(5), F.S. reads in pertinent part: *a person who knowingly sells or transfers to a person not authorized to purchase or prescribe prescription drugs, under the law of the jurisdiction in which the person receives the drug, a prescription drug in a wholesale distribution transaction commits a felony of the second degree....*

5. The definition of "distribute" or "distribution" as used in chapter 499 part I, F.S. is set forth at Section 499.003 (17), F.S. as follows: *means to sell, offer to sell; give away; transfer, whether by passage of title, physical movement, or both; deliver; offer to deliver. The term does mean to administer or dispense.*

6. The definition of wholesale distribution as used in chapter 499 part I F.S., subject to several exemptions not discussed herein is set forth at Section 499.003 (53) F.S. and reads as follows: *means distributions of prescription drugs to persons other than a consumer or patient....*

7. Section 499.01 (2), (d) F.S. reads as follows:

*The department may adopt rules for issuing a prescription drug wholesale distributor broker permit to a person who engages in the wholesale distribution of prescription drugs and does not take physical possession of any prescription drugs.*

8. Section 499.0121 (6), (a) F.S. reads in pertinent part:

*(a) Wholesale distributors must establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs.*

*These records must provide a complete audit trail from receipt to sale or other disposition, be readily retrievable for inspection, and include, at a minimum, the following information:*

- 1. The source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped;*
- 2. The name, principal address, and state license permit or registration number of the person authorized to purchase prescription drugs;*
- 3. The name, strength, dosage form, and quantity of the drugs received and distributed or disposed of;*
- 4. The dates of receipt and distribution or other disposition of the drugs; and*
- 5. Any financial documentation supporting the transaction.*

9. The Petition is adopted into this order and incorporated herein by reference. It does not contain a reference to sections 499.0121, 499.03 F.S., the Florida uniform commercial code, or to any federal law that might apply to the record keeping requirements for prescription drugs sold to or returned by a health care clinic establishment.

10. Section 499.003 (23) F.S., concerning the definition of a health care entity reads in pertinent part: *means a person, organization or business entity that provides diagnostic, medical, surgical, or dental treatment or care, or chronic or rehabilitative care.....*

Many, if not most of Petitioners, clients, as described in the Petition, provide one or more of these types of services at health care clinic establishments.

## CONCLUSIONS

1. The Department has jurisdiction over interpretation and enforcement of Chapter 499 Part I F. S. and rules adopted thereunder. Section 120.565 F. S. does not grant the Department authority to interpret a provision of the uniform commercial code within the context of a declaratory statement. Fla. Stat., 120.565 (2009); See, Fla. Stat., 672.101 et. seq. (2009).

2. Within the meaning of Section 499.01(2), (t) F.S. a health care clinic establishment is operated by a business entity. The business entity owner and operator of such an establishment is required to have the HCCE permit in order to purchase prescription drugs for use at the establishment, regardless of whose license number is provided on the distribution documentation. The business entity and operator are required by Section 499.01 (4), (a), 5. F.S. to be identified on the application for the HCCE permit. Fla. Stat., 499.01 (2), (t) 499.01(4),(a), 5. (2009).

3. The transactions described in the Petition are contractual and appear to be transactions in goods within the meaning of the uniform commercial code. Under the common law, passing of title between a seller and a buyer depends largely upon the intention of the parties. The intention of the seller as to which of two alleged purchasers is the actual purchaser depends on the seller's intentions as well as those of the alleged purchasers. Smith v. Baker, 206 So.2d 409 (Fla. 4<sup>th</sup> DCA 1968).

The question to be answered in determining whether an HCCE establishment is required to be permitted is whether the business entity operating the establishment is the purchaser of a prescription drug. These sales transactions are contractual in nature. They generally involve consideration in the form of an agreement to pay remuneration of some kind in exchange for prescription drugs. The fact that a practitioner's license number is used in audit trail documentation for a given transaction does not create a presumption, rebuttable or conclusive,

that the prescription drug is purchased by the practitioner within the meaning of Section 499.01(2), (t) F.S. Fla. Stat., 499.012(2), (t), (2009) (emphasis added). Accordingly, the fact that the HCCE business entity pays a Petitioner for a given prescription drug, does not create a presumption that the prescription drug is purchased by the entity. The answer to the "purchased by" question determines the answer to the "sold to" question, which is at issue in determining whether a wholesale distributor such as Petitioners is in violation of Section 499.005 (15) F.S. by selling a prescription drug to an unlicensed health care clinic establishment. It is determined by the intention of the parties that enter a purchase and sell agreement. The determination of the intent depends on the individual circumstances of each case and is not suitable for a policy statement wherein the agency describes a set of facts or specifies distribution document contents that create a presumption of the existence or absence of such intent. It must be determined on a case by case basis. As to a specific business arrangement for the purchase and sale of a prescription drug, the Petitioners prospectively are better able to determine, in the first instance, the nature of their intentions. Accordingly, in response to paragraph 10., second sentence of the Petition the Petitioners have the responsibility to comply with the law and not violate section 499.003 (15), F.S. by selling a prescription drug to a business entity that is not permitted at the establishment to which the sale is made. Fla. Stat., 499.005 (15), (2009).

4. The sales transactions described in the Petition, whether between the Petitioners and a health care practitioner or between the Petitioners and the owner and operator of a health care clinic establishment, are wholesale distributions. The Petitioners are operating as wholesale distributors within the meaning of Chapter 499 part I F.S.

5. Chapter 499 part I F.S. regulates the wholesale distribution of prescription drugs. Based on the "distribution" definition at Section 499.003 (17), F.S., it is possible to engage in a wholesale

distribution of a prescription drug by either selling it or transferring title to it as well as by transferring possession or otherwise delivering it to a person who is not the consumer of the drug. The health care clinic establishment permit is simply a statutory means for authorizing a person who is not a health care practitioner or veterinarian, through a wholesale distribution from persons such as the Petitioners, to purchase, receive, own and control a prescription drug. Fla. Stat., 499.003 (17), 499.003 (53), (54) (2009). See also, Fla. Stat., 499.03 (1), (b), (f) (2009).

6. Concerning the audit trail requirements for the transactions described in the Petition, the audit trail requirements of Section 499.01(2), (t) Florida Statutes read in conjunction with the audit trail requirements of Section 499.0121(6), F.S. indicate that both apply to a sale of a prescription drug to a health care clinic establishment by a wholesale distributor. Further, the provisions of section 64F-12.012 Florida Administrative Code (FAC), including section 64F-12.012 (2), (a) also apply. The documentation examples provided in paragraph 8. of the Petition do not comply with the Section 499.0121 (6), F.S., 64F-12.012 (1), (2) F.A.C. requirements for sales of prescription drugs to the owner or operator of a health care clinic establishment. Fla. Stat., 499.0121 (6), 499.01(2), (t); Fla. Admin. Code 64F-12.012 (as amended 8-6-06). Compare, 21 CFR 203.3, 203.20, 203.23, 205.3, 205.50 (concerning minimum federal documentation requirements for prescription drug returns by health care entities). The audit trail requirements of Section 499.01(2), (t) F.S. are in addition to the requirements of Section 499.0121 (6), F.S. and Section 64F-12.012 (2), F.A.C. The requirements of Section 499.0121 (6), (a) F.S. as well as those of Section 499.01 (2), (t) 1. F.S. apply to every sale of a prescription drug in Florida to a business entity that operates a health care clinic establishment required to be permitted under Section 499.012 (2), (t) F.S. Section 499.0121 (6), F.S., read in conjunction with section 64F-12.012 (1), (2) F.A.C. requires, in addition to other information, the business entity identity,

principal address and health care clinic establishment permit number to be provided in the audit trail documentation for every such sale. Fla. Stat., 499.012 (2), (t), 1., 499.0121 (6),(2009); Fla. Admin Code 64F-12.012 (1), (2) (as amended, 8-6-06).

7. Concerning paragraph 10. of the Petition, and the audit trail questions in sentence three, the inclusion by the Petitioners of the entities' name does not automatically preclude a practitioner working for an entity from personally purchasing drugs through the use of, or stated in another way "under his or her license." The last sentence to paragraph 10. is not answered because the Petitioners' circumstances are not stated with sufficient specificity.

8. Concerning paragraph 15. of the Petition, second sentence, the Petitioner's circumstances are not described with reasonable specificity; an answer will not be provided.

As to the third sentence the answer is: the use of the term "bill to" may be, depending on the intention of the parties, some evidence of the purchase of a prescription drug and the passing of title to the drug at the address. It might lead to further inquiry by the Department.

9. Unless a question is answered above the Petitioner's circumstances are not described with the particularity necessary for the Department to provide a definitive response to the Petition, without assuming missing facts and without engaging in broad policy making through the use of the declaratory statement. The purpose of a declaratory statement is to allow a Petitioner to select a proper course of action in advance, Chiles v. Department of State, Div. of Elections, 711 So. 2d 151, (Fla. 1<sup>st</sup> DCA 1998). It is not appropriate for seeking approval of conduct that has occurred in the past, Chiles, 711 So.2d at 151; nor is it appropriate in a situation where the legality of the past and future conduct of persons other than the Petitioner may be also necessarily implicated in the facts and subject matter of the opinion statement being sought by the Petitioner.

IT IS HEREBY ORDERED, that the Petition for Declaratory Statement is partially denied and partially granted. Except as stated otherwise above, the Petition is denied. This second amended final order is issued for the purpose of correcting clerical errors in the final order issued February 15, 2010 and the amended final order issued February 18, 2009. This order replaces the prior orders.

DONE AND ORDERED this 8 day of March 2010.



Rebecca R. Poston, R.Ph.  
Executive Director  
Drugs, Devices & Cosmetics Program

**NOTICE OF RIGHT TO JUDICIAL REVIEW**

A PARTY WHO IS ADVERSELY AFFECTED BY THIS FINAL ORDER IS ENTITLED TO JUDICIAL REVIEW PURSUANT TO SECTION 120.68, FLORIDA STATUTES. PROCEEDINGS ARE GOVERNED BY THE FLORIDA RULES OF APPELLATE PROCEDURE. SUCH PROCEEDINGS ARE COMMENCED BY FILING ONE COPY OF THE NOTICE OF APPEAL WITH THE AGENCY CLERK OF THE DEPARTMENT OF HEALTH AND A SECOND COPY, ACCOMPANIED BY FILING FEES PRESCRIBED BY LAW, WITH THE DISTRICT COURT OF APPEALS, FIRST DISTRICT, OR WITH THE DISTRICT COURT OF APPEAL IN THE APPELLATE DISTRICT WHERE THE PARTY RESIDES. THE NOTICE OF APPEAL MUST BE FILED WITHIN THIRTY (30) DAYS OF RENDITION OF THE ORDER TO BE REVIEWED.

**CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that a true and correct copy of the foregoing second amended FINAL ORDER has been furnished by postage paid first class U.S. mail to Edwin Bayo, Esquire at 1408 North Piedmont Way Tallahassee, Fl 32309 this 9<sup>th</sup> day of March, 2010.



Deputy Agency Clerk