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STATE OF FLORIDA

DEPARTMENT OF HEALTH  
DRUGS, DEVICES AND COSMETICS PROGRAM

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**PETITION FOR DECLARATORY STATEMENT OR IN  
THE ALTERNATIVE PETITION FOR RULEMAKING  
BEFORE THE DEPARTMENT OF HEALTH, DRUGS,  
DEVICES AND COSMETICS PROGRAM ADDRESSING  
§499.01(2)(t), FLORIDA STATUTES, ON BEHALF OF  
HENRY SCHEIN, INC.; MEDLINE INDUSTRIES, INC.;  
and CARDINAL HEALTH, INC.**

**PETITION FOR DECLARATORY STATEMENT**

COMES NOW Petitioners, Henry Schein, Inc.; Medline Industries, Inc., and Cardinal Health, Inc. by and through undersigned legal counsel and pursuant to §120.565, Florida Statutes, and Rule 28-105.002, Florida Administrative Code, hereby petition the Department of Health, Drugs, Devices and Cosmetics Program (Hereinafter "DDC") for a Declaratory Statement regarding the responsibilities of a licensed prescription drug wholesale distributor regarding the Health Care Clinic Establishment (HCCE) Permit. In support thereof, Petitioners states as follows:

1. Petitioner Henry Schein, Inc. is located at 135 Duryea Road, Melville, New York 11747, (631) 843-5546. Petitioner Medline Industries, Inc. is located at One Medline Place, Mundelein, Illinois 60060, (847) 837-2759. Petitioner Cardinal Health, Inc. is located at 700 Cardinal Place, Dublin, Ohio 43017, (614) 757-5000. For purposes of this proceeding, Petitioners' addresses, phone numbers and fax numbers will be those of the undersigned counsel.

2. Petitioners are licensed prescription drug wholesale distributors. They supply practitioners providing health care services in Florida. Petitioner

Henry Schein additionally supplies providers of veterinary services in Florida. Most of Petitioners' clients operate as business entities that have been issued a federal employee tax identification number.

3. Historically, Petitioners have included the name and license number of the practitioner ordering the prescription drugs, as well as the name and address of the business entity on all shipping documents which may include packing slips, invoices or other billing documents.

4. Section 499.01(2)(t), F.S., created the HCCE permit. This statute provides, *inter alia*, that an HCCE permit "is required for the purchase of a prescription drug by 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."

5. Subsection 499.01(2)(t)6., F.S., provides "[t]his paragraph does not apply to the purchase of a prescription drug by a licensed practitioner under his or her license."

6. On several occasions, Petitioners have been informed by clients that the HCCE permit is not required because they are already providing the Petitioners with the name and license number of the practitioner, and are electing to purchase the drugs under the practitioner's own license.

7. These clients provide Petitioner with a licensed practitioner's name and license number, to be used and included in any shipping, invoicing and billing documents. However, these clients also wish to have the shipping,

invoicing and billing documents reflect the name of the corporate entity they practice under, in addition to the name and license number of the practitioner. They further wish to pay any such invoices with a check drawn on the account of the corporate entity.

8. As an example, Petitioners have received orders from, or have been asked to invoice:

John Doe, DDS, DN 005432  
ABC Dental Group, P.A.  
123 Main Street  
Anytown, FL 33033

or:

ABC Dental Group, P.A.  
John Doe, DDS, DN 005432  
123 Main Street  
Anytown, FL 33033

9. Petitioners would first conduct due diligence to ascertain that Dr. Doe is currently licensed and that he has a valid DEA number (if appropriate), as a precondition to any sale. In addition, Petitioners would include Dr. Doe's name and license number in all invoices and billing documents.

10. Petitioners are uncertain of their obligations as licensed prescription drug wholesale distributors under the HCCE statute. Specifically, Petitioners are seeking clarification as to their responsibility, if any, to inquire into the business structure of any practitioner's practice to determine if the practice has obtained (or is required to obtain) an HCCE permit. Petitioners are uncertain whether the inclusion of the entities' name on the order, invoice, shipping, or billing documents automatically precludes a practitioner working for such an entity to purchase drugs "under his or her license." Petitioners are further uncertain

whether it is allowable to list both the practitioner's name and license number and the name of the business entity on the invoice, whether the entity has an HCCE permit or not.

11. Petitioners are further uncertain as to whether receiving payment by check drawn on the account of a corporation employing such a practitioner will result in a presumption by the DDC that the drugs were not purchased "under" the practitioner's license. Petitioners are uncertain as to the DDC's interpretation of what constitutes purchasing prescription drugs "under" the practitioner's license.

12. Section 499.01(2)(t)1., F.S., does not require that the practice provide an HCCE permit number when ordering prescription drugs. Instead, the statute requires that the "designated qualifying practitioner" shall be the practitioner whose name, establishment address, and license number is used on all distribution documents. Therefore, the paperwork received by Petitioners contains the same information it has historically contained. Petitioners are uncertain whether such information (which Petitioners verify as stated in paragraph 8) will be considered by the DDC as adequate licensure information.

13. Petitioners aver that this statute, enacted during the 2008 session and amended in 2009, has been the subject of various interpretations, both formal and informal, by the DDC. As an example, attached to this Petition and marked as Exhibit A are copies of a "quick reference guide" and a "Dear Wholesaler" letter issued by the DDC. The letter indicates that the HCCE permit is available as an "alternative to the purchase of prescription drugs under a

practitioner's personal license." Furthermore, question 2 of the "frequently asked questions" in the quick reference guide indicates that practitioners in a group practice may administer drugs purchased by another member of the group practice at that establishment. Presumably, this question relates to a group practice that does not have an HCCE permit.

14. Petitioners also aver that staff of the DDC have stated, at public meetings on this subject, that the DDC "does not care who pays for the drugs" so long as the drugs are sold/transferred to an authorized recipient.

15. Petitioners further aver that it is commonplace in the community that a practitioner may have multiple practice locations, or that a customer may request that all invoices be "billed to" or "remitted to" a different address than the "ship to" address. Petitioners are seeking clarification as to whether it may have any additional obligation under the HCCE statute, such as, for example, ensuring that the licensed practitioner's name and license number is included in the "bill to" address. Petitioners also seek clarification on whether DDC interprets the use of specific words on the shipping and billing documents such as "bill to" and "remit to" as indicative of ownership and thus requiring a license.

16. Petitioners are subject to regulation by the DDC, and may be subject to significant penalties for selling prescription drugs to unauthorized persons or failing to create and maintain documentation sufficient to establish a proper audit trail. Petitioners need guidance as to their obligations under the new law to inquire about the existence (or need for) an HCCE permit when they have received and verified the licensure of a practitioner who is qualified to purchase,

receive and store prescription drugs at that address. Petitioners respectfully submit that they have an actual, present, and practical need to receive the requested declaratory statement.

WHEREFORE, Petitioners respectfully request, pursuant to §120.565, Florida Statutes, that the Department of Health, Drugs, Devices and Cosmetics Program, issue a Declaratory Judgment clarifying Petitioner's obligations as requested in this Petition.

### **ALTERNATIVE PETITION FOR RULEMAKING**

In the event that the Department of Health, Drugs, Devices and Cosmetics Program (Hereinafter "DDC") declines to issue a Declaratory Statement, Petitioners hereby file this Petition for Rulemaking pursuant to §120.54(7), Florida Statutes and Rule 28-103.006, Florida Administrative Code. In support thereof, Petitioners state as follows:

17. Petitioners reaver the allegations contained in paragraphs 1 through 15 above.

18. Section 499.0121, F.S., authorizes the Department of Health to adopt rules regarding the establishment and maintenance of prescription drug distribution records. Pursuant to this authority, the Department has adopted Rule 64F-12.012, F.A.C.

19. Petitioner requests the amendment of rule, 64F-12.012, F.A.C., entitled "Records of Drugs, Cosmetics and Devices." Petitioner specifically requests the creation of a new paragraph (2)(g) which would state:

(g) Health Care Clinic Establishment (HCCE) Permit. An HCCE permit is required for the purchase of a prescription drug by 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 wishes to purchase and own prescription drugs in the business entity's name. An HCCE permit is not required for a practitioner to purchase prescription drugs under his/her personal license. A practitioner working at a place of business owned by a business entity may purchase drugs under his/her personal license. In order to document that the distribution of prescription drugs was made to a practitioner under her/his license, the order, invoice, shipping or other billing document must contain the name and license number of the practitioner. If, in addition to the practitioner's name and license number, the practitioner also wishes to have the business entity's name on such documents for delivery or convenience purposes, then the wholesale distributor must obtain a written statement signed by the practitioner that attests to the fact that the practitioner is electing to purchase drugs under his/her own license. So long as the requirements of this paragraph are met, payment by the business entity will not be deemed to constitute a transfer of title to the prescription drugs.

20. Petitioners respectfully submit that the proposed rule is consistent with the Legislative intent expressed in §499.01(2)(t)6., Florida Statutes that the HCCE permit “does not apply to the purchase of a prescription drug by a licensed practitioner under his or her license.” Petitioners further submit that the Department has the authority to promulgate the requested rule pursuant to §499.0121, Florida Statutes.

21. Petitioners further submit that the proposed rule is consistent with the DDC's pronouncements in the “quick reference guide” and “Dear Wholesaler” letter referenced in paragraph 12.

22. Petitioners have a substantial interest in the action requested. The proposed rule would clarify address the ability of practitioners purchasing prescription drugs under the authority of their own license, whether working independently or for a business entity.

WHEREFORE, Petitioner respectfully requests that the Department of Health initiate rulemaking pursuant to Section 120.54, F.S., for the purpose of amending rule 64F-12.012 as requested in this Petition.

Respectfully submitted, this 17 day of November, 2009.

A handwritten signature in black ink, appearing to read "Edwin M.", with a long horizontal flourish extending to the right.

Edwin A. Bayó  
Fla. Bar No. 327727  
Metzger, Grossman, Furlow & Bayó, L.L.C.  
1408 N. Piedmont Way  
Tallahassee, FL 32309  
(850)385-1314/fax(850)385-4240

On behalf of Petitioners



# DRUGS, DEVICES & COSMETICS PROGRAM

## HEALTH CARE CLINIC ESTABLISHMENT PERMIT

# QUICK REFERENCE GUIDE

### BASIC PERMIT REQUIREMENTS

#### **Health Care Clinic Establishment (HCCE) Permit -**

Effective January 1, 2009, the Drugs Devices and Cosmetics Program will begin issuing HCCE permits, in accordance with section 499.01(2)(t), *Florida Statutes* (F.S.)

#### **Who needs an HCCE permit?**

An HCCE permit is required for the purchase of a prescription (Rx) drug by a place of business at one general location owned and operated by a professional corporation or a professional limited liability company described in chapter 621, F.S., or a corporation that employs a veterinarian as a qualifying practitioner, and wishes to purchase and own prescription drugs in the business entity's name.

#### **What is a "qualifying practitioner?"**

- A "qualifying practitioner" (QP) is a licensed health care practitioner defined in s. 456.001, F.S., or a veterinarian licensed under chapter 474, F.S., who is authorized under the appropriate practice act to prescribe and administer a prescription drug.
- The following licensees may be designated as a QP:
  1. Medical Doctor (M.D.)
  2. Osteopathic Physician (D.O.)
  3. Physician Assistant (P.A.)
  4. Advanced Registered Nurse Practitioner (ARNP)
  5. Optometrist (O.D.)
  6. Podiatric Physician (D.P.M.)
  7. Dentist (D.D.S., D.M.D.)
  8. Veterinarian (D.V.M.)
  9. Chiropractic Physician (DC)
- The QP is responsible for ensuring compliance with all legal and regulatory requirements related to the purchase, recordkeeping, storage, and handling of prescription drugs.
- A violation of Chapter 499, F.S., by the HCCE or Designated Qualifying Practitioner constitutes grounds for discipline of the Designated Qualifying Practitioner by the appropriate regulatory board.
- The HCCE must employ a QP at each establishment.

### BASIC PERMIT REQUIREMENTS (CONT.)

#### **Qualified Practitioner Changes**

- The initial appointment of a qualifying practitioner will be made on the HCCE permit application.
- The qualifying practitioner and HCCE must notify the department within ten (10) days of any subsequent change in the qualifying practitioner.

### APPLICATION INSTRUCTIONS

#### **Application Requirements**

- Complete and submit form DH-MQA 2360 (12/08) and remit with \$255.00 application fee.
- Must designate a qualifying practitioner.
- An inspection is not required with initial application.

#### **Address for Mailing Application**

Department of Health  
Division of Medical Quality Assurance  
P.O. Box 6320  
Tallahassee, FL 32314-6320

#### **Renewal**

The HCCE permit is valid for 2 years.  
Permit renewal fee is \$255.00.

### FREQUENTLY ASKED QUESTIONS

#### **Q1 - Is the HCCE permit required for a "sole practitioner" to purchase Rx drugs?**

A1 - The HCCE permit is not required for a practitioner to purchase Rx drugs under his/her personal license.

#### **Q2 - Can practitioners in a group practice administer drugs purchased by another practitioner in the group practice?**

A2 - The Department does not intend to enforce an interpretation of the law that would prohibit the use of Rx drugs by practitioners at an establishment in a group practice that were purchased by another member of the group practice at that establishment.

#### **Q3 - Can a HCCE permit transfer Rx drugs to other practice locations?**

A3 - Drugs purchased by this permit are for use at the licensed establishment.

#### **Q4 - Does an "S" corporation qualify for the HCCE permit?**

A4 - An "S" corporation that employs a veterinarian as a Qualifying Practitioner may qualify for the HCCE permit.

### FREQUENTLY ASKED QUESTIONS (CONT.)

#### **Q4 - Does an "S" corporation qualify for the HCCE permit?**

A4 - An "S" corporation that employs a veterinarian as a Qualifying Practitioner may qualify for the HCCE permit.

#### **Q5 - Who are authorized sources from which a HCCE permit may purchase Rx drugs.**

A5 - All sources of Rx drugs must be licensed by the Department of Health to distribute Rx drugs. See list below:

1. Prescription Drug Manufacturer
2. Prescription Drug Repackager
3. Prescription Drug Wholesale Distributor
4. Non-Resident Prescription Drug Manufacturer
5. Out of State Prescription Drug Wholesaler Distributor
6. Compressed Medical Gas Manufacturer
7. Compressed Medical Gas Wholesaler
8. Veterinary Prescription Drug Wholesale Distributor
9. Limited Prescription Drug Veterinary Wholesale Distributor

#### **Q6 - Are there any restrictions on the type of drugs that can be purchased by a HCCE?**

A7 - A HCCE permit may only purchase Rx drugs that the Designated Qualifying Practitioner is authorized to prescribe.

#### **Q7 - Which business organizations do not qualify for the HCCE permit to purchase of Rx drugs in the business name?**

A7 - There are several forms of business structures that do not qualify for the HCCE permit. Below is a list of examples.

- Limited Liability Partnerships
- Not for Profit Corporations
- Sole Proprietor operating under a Fictitious Name

#### **Q8 - What is the difference in the HCCE permit issued by the Department of Health and the Health Care Clinic license issued by the Agency for Health Care Administration (AHCA)?**

A8 - The HCCE permit issued by the Department of Health is authorized to purchase Rx Drugs. A Health Care Clinic licensed by AHCA under the Health Care Clinic Act (section 400.990-400.995, Florida Statutes) is not authorized to purchase Rx drugs.

#### **Q9 - Can a HCCE continue to purchase Rx drugs if the QP resigns?**

A9 - No. The purchase of Rx drugs by a HCCE is prohibited during any time the HCCE does not have a QP.

Dear Wholesaler:

On January 1, 2009, the Florida Department of Health will begin issuing a new permit called the Health Care Clinic Establishment (HCCE) permit. The purpose of this letter is to provide you, as the suppliers of prescription drugs to Florida's health care providers, an overview of the permit and explanation of the Department's process in issuing this new permit.

Health care practitioners or veterinarians who are purchasing prescription drugs through the use of their personal professional license number are **not** required to obtain the HCCE permit. The HCCE permit is available as an **alternative** to the purchase of prescription drugs under a practitioner's personal license. It authorizes a professional corporation or professional limited liability company under Chapter 621, Florida Statutes (F.S.), to purchase prescription drugs. It also authorizes the purchase of prescription drugs by corporations that employ veterinarians.

The Department recognizes many distributors have traditionally included on their invoices the name and license number of the practitioner purchasing the drug, along with the name of the clinic. Section 499.01(2)(t), F.S., requires both the name and license number of the HCCE establishment and the name and license number of the Qualifying Practitioner to be on the distribution document. The Department understands that distributors may have to make recordkeeping changes to comply with these new requirements.

We are receiving large numbers of HCCE applications from businesses that have chosen to purchase prescription drugs in the name of their business organization. Our staff is dedicated to processing applications as quickly as possible to insure that there is no disruption in the distribution of prescription drugs to practitioners while enacting the new law.

Additional information about the new permit, including the permit application and Quick Reference Guide containing frequently asked questions (FAQs), is available at the Drugs, Devices and Cosmetics Program website [www.doh.state.fl.us/pharmacy](http://www.doh.state.fl.us/pharmacy). You may also call our designated phone line for the HCCE permit at 850-245-4227.

Sincerely,

Rebecca Poston, R.Ph.  
Executive Director