

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 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" 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.

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.

BASIC PERMIT REQUIREMENTS (CONT.)

Section 499.01(2)(t), Florida Statutes

Health care clinic establishment permit.--Effective January 1, 2009, a health care clinic establishment permit is required for the purchase of a prescription drug by a place of business at one general physical location owned and operated by a professional corporation or professional limited liability company described in chapter 621, or a corporation that employs a veterinarian as a qualifying practitioner. For the purpose of this paragraph, the term "qualifying practitioner" means a licensed health care practitioner defined in s. 456.001 or a veterinarian licensed under chapter 474, who is authorized under the appropriate practice act to prescribe and administer a prescription drug.

1. An establishment must provide, as part of the application required under s. 499.012, designation of a qualifying practitioner who will be responsible for complying with all legal and regulatory requirements related to the purchase, recordkeeping, storage, and handling of the prescription drugs. In addition, the designated qualifying practitioner shall be the practitioner whose name, establishment address, and license number is used on all distribution documents for prescription drugs purchased or returned by the health care clinic establishment. Upon initial appointment of a qualifying practitioner, the qualifying practitioner and the health care clinic establishment shall notify the department on a form furnished by the department within 10 days after such employment. In addition, the qualifying practitioner and health care clinic establishment shall notify the department within 10 days after any subsequent change.

2. The health care clinic establishment must employ a qualifying practitioner at each establishment.

3. In addition to the remedies and penalties provided in this part, a violation of this chapter by the health care clinic establishment or qualifying practitioner constitutes grounds for discipline of the qualifying practitioner by the appropriate regulatory board.

4. 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.

5. A health care clinic establishment permit is not a pharmacy permit or otherwise subject to chapter 465. A health care clinic establishment that meets the criteria of a modified Class II institutional pharmacy under s. 465.019 is not eligible to be permitted under this paragraph.

6. This paragraph does not prohibit a qualifying practitioner from purchasing prescription drugs.

MISCELLANEOUS

Application Requirements

Complete and submit form DH-MQA 1033K (12/08) and remit with initial application fee of \$255.00.

Application requires designation of a qualifying practitioner.

Mailing Address

Mail application and fee to:
Department of Health
Drugs, Devices, and Cosmetics
P.O. Box 6320
Tallahassee, FL 32314-6320

Permit Renewal

The HCCE permit is valid for 2 years and shall be renewed biennially on the last day of the issue month.

Permit renewal fee is \$255.00.