



Charlie Crist
Governor

Ana M. Viamonte Ros, M.D., M.P.H.
State Surgeon General

Dear Health Care Clinic Establishment Permit Applicant:

Thank you for applying for permitting as a Health Care Clinic Establishment in the State of Florida. The information in this packet has been designed to provide the essential information required to process your application in a timely manner. Your assistance in providing all required information will enable the Florida Drugs, Devices and Cosmetics Program staff to process your application as soon as possible. You are encouraged to apply as early as possible, to avoid delays due to a large volume of applicants.

On May 1, 2008, the Florida Legislature passed HB 7049. In addition to substantially reorganizing Chapter 499, Part I, Florida Statutes, the bill created two new permits under Drugs, Devices, and Cosmetics Program. One of the new permits is called a "Health Care Clinic Establishment Permit."

Effective January 1, 2009, a health care clinic establishment permit will be required for the purchase of prescription drugs by a group practice (place of business at one general physical location owned and operated by a professional corporation or professional limited liability company described in chapter 621 F.S., or a corporation that employs a veterinarian as a qualifying practitioner) that wishes to purchase and own prescription drugs. Under current law, health care practitioners in a group practice setting must individually order their own prescription drugs for dispensing or administering to their own patients under their own license number.

As part of the application required under section 499.012, F.S., the establishment will be required to designate 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. For the purposes of this section, a "qualifying practitioner" is 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.

Additionally, the designated qualifying practitioner must be the practitioner whose name, establishment address, and license number is used on all distribution documents for the prescription drugs purchased or returned by the health care clinic establishment. The qualifying practitioner and health care clinic establishment are responsible for notifying the department within 10 days of any changes to their designated qualifying practitioner.

Enclosed are the Health Care Clinic Establishment permit application, application instruction/reference, and the Change in Qualifying Practitioner form. If you need to communicate with the program staff, you are encouraged to email the program staff at mqa_DDC@doh.state.fl.us, or you may call us at (850) 245-4292. Phone calls are returned within 24 hours and emails are responded to within 48 hours during normal business hours. Our staff is committed to providing prompt and reliable information to our customers. Many procedures have been streamlined to expedite the processing of applications; we certainly welcome your comments on how our services may be improved.

Sincerely,

A handwritten signature in dark ink that reads "Rebecca R. Poston".

Rebecca R. Poston, R.Ph.
Executive Director

APPLICATION FOR A HEALTH CARE CLINIC ESTABLISHMENT PERMIT



Florida Department of Health
Drugs, Devices and Cosmetics Program
P.O. Box 6320
Tallahassee, Florida 32314-6320
(850) 245-4292

APPLICATION TO BE TYPED OR PRINTED WITH INK

This application form provides information as required by the Florida Drug and Cosmetic Act, Chapter 499, Florida Statutes. Only a completed application signed by the authorized representative of the applicant will be processed. Additional information may be required for an application to be considered complete. This application must be filled out in its entirety. Failure to do so will result in a delay in the permitting process, and may result in denial of this application.

SUBMIT \$255.00 FEE WITH APPLICATION

1 PROVIDE FEDERAL TAX IDENTIFICATION NUMBER (FEID#) If you do not have an FEID#, call 1-800-829-1040		
2 PROVIDE CORPORATE OR LEGAL NAME OF BUSINESS ENTITY		
3 DOING BUSINESS AS (name in which you are doing business and the name in which permit will be issued - this name shall be reflected on sales invoices and shipping documents)		
4 MAILING ADDRESS (if different from physical location; this is where the renewal application and other official information will be sent by the department)		
6 CITY	7 STATE	8 ZIP
		5 SUITE NUMBER
9 COUNTY	10 AREA CODE & TELEPHONE NUMBER	
11 PHYSICAL ADDRESS (physical location of establishment - this address shall be reflected on sales invoices and shipping documents)		
13 CITY	14 STATE	15 ZIP
		12 SUITE NUMBER
16 WHO SHOULD THE DEPARTMENT CONTACT WITH QUESTIONS REGARDING THIS APPLICATION?		
NAME (Last, First, MI)	AREA CODE & TELEPHONE NUMBER	POSITION/TITLE
ADDRESS		
CITY	STATE	ZIP CODE
*EMAIL ADDRESS		FACSIMILE NUMBER (fax)
17 DESIGNATED QUALIFYING PRACTITIONER (an individual employed at the establishment who will be responsible for all legal and regulatory requirements and will be contacted in case of an emergency)		
NAME (Last, First, MI)		
RESIDENCE ADDRESS		
CITY	STATE	ZIP CODE
SIGNATURE OF DESIGNATED QUALIFYING PRACTITIONER		*EMAIL ADDRESS
		LICENSE # WITH PREFIX AREA CODE & TELEPHONE NUMBER
18 BUSINESS OPERATING HOURS		
M	AM TO PM	AM TO PM
TU	AM TO PM	AM TO PM
W	AM TO PM	AM TO PM
TH	AM TO PM	AM TO PM
F	AM TO PM	AM TO PM
*19 PROVIDE AN EMAIL ADDRESS WHERE REGULATORY UPDATES CAN BE SENT		
*20 FACSIMILE NUMBER WHERE REGULATORY UPDATES CAN BE SENT		
*Requested		

21 MARK AN "X" ON THE LINE FOR THE TYPE OF OWNERSHIP. (Mark only ONE in this section and provide all necessary information):

NOTE: ONLY VETERINARIANS MAY SELECT PUBLICLY OR CLOSELY HELD CORPORATION

A PUBLICLY HELD CORPORATION (traded on a stock exchange)
CLOSELY HELD CORPORATION

IF THE APPLICANT IS INCORPORATED IN FLORIDA PLEASE PROVIDE A COPY OF THE ARTICLES OF INCORPORATION AS THAT TERM IS DEFINED AT SECTION 607.01401 (1), F.S.

IF THE APPLICANT IS NOT INCORPORATED IN FLORIDA PLEASE PROVIDE A CERTIFICATE OF AUTHORITY ISSUED BY THE OFFICE OF THE FLORIDA DEPARTMENT OF STATE, THAT AUTHORIZES THE APPLICANT TO TRANSACT BUSINESS IN THE STATE OF FLORIDA.

LIST STATE OF INCORPORATION _____ (state abbreviation)

LIST THE REGISTERED AGENT OF CORPORATION _____

LIST THE FIVE MOST SENIOR CORPORATE OFFICERS (i.e., CEO/COO, President, V.P., Sec., Treas.): (use additional sheet if necessary)

NAME (Last, First, MI)	Date of Birth	POSITION/TITLE	Ownership
_____	____/____/____	_____	____% if applicable
_____	____/____/____	_____	____% if applicable
_____	____/____/____	_____	____% if applicable
_____	____/____/____	_____	____% if applicable
_____	____/____/____	_____	____% if applicable

B PROFESSIONAL LIMITED LIABILITY COMPANY (LLC) AS DESCRIBED IN CHAPTER 621 F.S.

PROVIDE A COPY OF THE ARTICLES OF ORGANIZATION AS THAT TERM IS DEFINED AT SECTION 608.402(2), F.S.

LIST THE REGISTERED AGENT OF THE LLC: _____

LIST THE NAME AND ADDRESS OF EACH MEMBER (Use an additional sheet if necessary)

NAME (Last, First, MI)	ADDRESS	CITY	STATE	% OF OWNERSHIP
_____	_____	_____	_____	____% if applicable
_____	_____	_____	_____	____% if applicable
_____	_____	_____	_____	____% if applicable
_____	_____	_____	_____	____% if applicable
_____	_____	_____	_____	____% if applicable

C PROFESSIONAL CORPORATION AS DESCRIBED IN CHAPTER 621, F.S.

PLEASE PROVIDE A COPY OF THE ARTICLES OF INCORPORATION AS THAT TERM IS DEFINED AT SECTION 607.01401(1), F.S.

LIST THE REGISTERED AGENT OF THE CORPORATION _____

ARE ALL CORPORATE OFFICERS EIGHTEEN (18) YEARS OF AGE OR OLDER? ☐ YES ☐ NO

LIST THE FIVE MOST SENIOR CORPORATE OFFICERS (i.e., CEO/COO, President, V.P., Sec., Treas.): (use additional sheet if necessary)

NAME (Last, First, MI)	Date of Birth	POSITION/TITLE	Ownership
_____	____/____/____	_____	____% if applicable
_____	____/____/____	_____	____% if applicable
_____	____/____/____	_____	____% if applicable
_____	____/____/____	_____	____% if applicable
_____	____/____/____	_____	____% if applicable

22 IS THIS NEW APPLICATION RELATED TO A CHANGE OF OWNERSHIP? If yes, provide change of ownership documentation. ☐ YES ☐ NO

If yes, please include the permit number of the current holder. Permit Number: _____

23 DO YOU UNDERSTAND THAT A HEALTH CARE CLINIC ESTABLISHMENT AND THE DESIGNATED QUALIFYING PRACTITIONER ARE REQUIRED TO COMPLY WITH THE PROVISIONS OF CHAPTER 499, F.S. AND RULE 64F-12, FLORIDA ADMINISTRATIVE CODE? ☐ YES ☐ NO

24 HAS THE APPLICANT, OWNER(S), MANAGER(S)-IN-CHARGE, ANY OFFICER(S), OR DESIGNATED QUALIFYING PRACTITIONER:

- A. BEEN FINED OR DISCIPLINED BY A REGULATORY AGENCY IN ANY STATE (INCLUDING FLORIDA) FOR ANY OFFENSE THAT WOULD CONSTITUTE A VIOLATION OF CHAPTERS 456, 465, 474, 499, 893 F.S., RELATED TO THE DISTRIBUTION, POSSESSION, ADMINISTRATION OR DISPENSING OF PRESCRIPTION DRUGS? ☐ YES ☐ NO
- B. EVER ENTERED A PLEA TO, BEEN CONVICTED OR FOUND GUILTY OF, ANY FELONY UNDER A FEDERAL, STATE (INCLUDING FLORIDA), OR LOCAL LAW RELATED TO THE DISTRIBUTION, POSSESSION, ADMINISTRATION OR DISPENSING OF PRESCRIPTION DRUGS? INCLUDE ALL CASES WHERE A GUILTY, NOLO CONTENDERE OR NO CONTEST PLEA WAS ENTERED, WHETHER OR NOT ADJUDICATION WAS WITHHELD. ☐ YES ☐ NO
- C. HAD ANY CURRENT OR PREVIOUS PERMIT OR LICENSE SUSPENDED OR REVOKED WHICH WAS ISSUED BY A FEDERAL, STATE OR LOCAL GOVERNMENTAL AGENCY RELATING TO THE MANUFACTURING, DISTRIBUTING, PRESCRIBING, DISPENSING, OR ADMINISTERING OF PRESCRIPTION DRUGS? ☐ YES ☐ NO
- D. BEEN DENIED A PERMIT OR LICENSE IN ANY STATE (INCLUDING FLORIDA) RELATED TO AN ACTIVITY REGULATED UNDER CHAPTERS 465, 499, 893, F.S.? ☐ YES ☐ NO

IDENTIFY BY NAME, DATE OF BIRTH, ADDRESS AND POSITION WITH THE COMPANY, ANY PERSON THAT IS THE SUBJECT OF A "YES" RESPONSE TO ANY OF THE QUESTIONS A. THROUGH D. IMMEDIATELY ABOVE. FOR ALL CRIMINAL CASES, PROVIDE COURT CHARGING DOCUMENTS AND FINAL DISPOSITION DOCUMENTS, INCLUDING ANY JUDGMENT, SENTENCE OR PLEA DOCUMENTS. PROVIDE A COPY OF ANY ORDER THAT FINED, DISCIPLINED, REVOKED, SUSPENDED, OR DENIED ANY LICENSE / PERMIT TO MANUFACTURER OR DISTRIBUTE DRUGS, DEVICES OR COSMETICS ISSUED BY ANY GOVERNMENT AGENCY. PROVIDE A DETAILED EXPLANATION OF THE CIRCUMSTANCES INVOLVED WITH EACH "YES" RESPONSE TO ANY OF THE QUESTIONS A. THROUGH D. IMMEDIATELY ABOVE.

AFFIDAVIT: I, _____, ON BEHALF OF THE APPLICANT BUSINESS,
(Print Name)
DO SOLEMNLY SWEAR OR AFFIRM THAT THE INFORMATION SUBMITTED TO THE DEPARTMENT
ON THIS APPLICATION AND ANY ATTACHMENTS THERETO ARE TRUE AND CORRECT.

Signature of Owner or Company Officer

Title

Date

If signed by someone other than an owner or officer identified in question #21, you must submit a letter for the signer to bind the applicant.

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 2360 (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.



DRUGS, DEVICES, AND COSMETICS PROGRAM
4052 Bald Cypress Way, Bin C-04 • Tallahassee, FL 32399
Phone: (850) 245-4292 • Fax: (850) 413-6982
www.doh.state.fl.us/pharmacy/drugs

CHANGE OF DESIGNATED QUALIFYING PRACTITIONER FORM

Section 499.01(2)(t), *Florida Statutes* (F.S.), requires the Health Care Clinic Establishment and Qualifying Practitioner to notify the Department of Health within **10 days** of any change in the Qualifying Practitioner. A qualifying practitioner means a licensed health care practitioner defined in Section 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.

This section must be completed by the Incoming Qualifying Practitioner

QUALIFYING PRACTITIONER NAME: _____
Print Qualifying Practitioner Name
QUALIFYING PRACTITIONER SIGNATURE: _____
Signature
QUALIFYING PRACTITIONER LICENSE NUMBER WITH PREFIX: _____
DATE BEGINNING AS QUALIFYING PRACTITIONER: ____/____/____

This section must be completed by the Outgoing Qualifying Practitioner

QUALIFYING PRACTITIONER NAME: _____
Print Qualifying Practitioner Name
QUALIFYING PRACTITIONER SIGNATURE: _____
Signature
QUALIFYING PRACTITIONER LICENSE NUMBER WITH PREFIX: _____
DATE ENDING AS QUALIFYING PRACTITIONER: ____/____/____

This section must be completed by the Health Care Clinic Establishment

HEALTH CARE CLINIC ESTABLISHMENT NAME: _____
Print Establishment Name
HEALTH CARE CLINIC ESTABLISHMENT PERMIT NUMBER: _____
SIGNATURE: _____ DATE: _____
PRINT NAME: _____ POSITION: _____

Please return the signed form to Drugs, Devices and Cosmetics Program, 4052 Bald Cypress Way, Bin C-04, Tallahassee, FL 32399-3254 ATTN: Permitting. Please be aware that failure to provide this information may affect the establishment's ability to purchase prescription drugs.

If you have any questions, you may contact our office at (850) 245-4292.