



Charlie Crist
Governor

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

December 18, 2008

Dear Health Care Clinic Establishment Permit Applicant:

Thank you for your interest in the Health Care Clinic Establishment permit.

Health care practitioners or veterinarians who are personally purchasing prescription drugs through the use of their professional license number need not apply. This permit authorizes the purchase of prescription drugs by a professional corporation or professional limited liability company. It also authorizes the purchase of prescription drugs by corporations that employ veterinarians.

As part of the application, 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. A "qualifying practitioner" is a medical doctor, doctor of osteopathic medicine, physician assistant, advanced registered nurse practitioner, optometrist, doctor of podiatric medicine, dentist, chiropractor in limited circumstances, and veterinarian who are authorized under the appropriate practice act to prescribe and administer prescription drugs.

Enclosed are the Health Care Clinic Establishment permit application, Quick Reference Guide, and the Change in Designated Qualifying Practitioner form. The Quick Reference Guide will address a number of your questions; however, if you have additional questions or need additional information, please visit our website at www.doh.state.fl.us/pharmacy. If you need to communicate with the program staff, you are encouraged to email the program office at mqa_DDC@doh.state.fl.us, or you may call us at (850) 488-0595 or (850) 245-4227. We are committed to providing prompt and reliable information and processing your application as quickly as possible.

Sincerely,

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

Rebecca R. Poston, R.Ph.
Executive Director

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 (F.A.C.)? 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 (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.



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.