

**DIVISION OF MEDICAL QUALITY ASSURANCE
BOARD OF PHARMACY
4052 BALD CYPRESS WAY, BIN #C-04
TALLAHASSEE, FLORIDA 32399-3254
(850) 245-4292**



**ANIMAL CONTROL PHARMACY PERMIT APPLICATION AND
INFORMATION**

JANUARY 2011



Dear Animal Control Pharmacy Permit Applicant,

Thank you for applying for an Animal Control Pharmacy permit 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 Board of Pharmacy (the board) 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..

Florida Statutes require a completed application and fees before your application can be reviewed. Please read these instructions carefully and fully before submitting the application. You should keep a copy of the completed application and all other materials sent to the board office for your records. When you mail the completed application and fees, use the address noted in the instructions and on the application form.

When your application arrives, your fees will be deposited and verified before the staff review can begin. You will receive a letter acknowledging receipt of your application. The staff will notify you within 30 days if any materials are incomplete.

If you need to communicate with the board staff, you are encouraged to email the board staff at mqa_pharmacy@doh.state.fl.us, or you may call us at (850) 245-4292. 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,

The Board of Pharmacy

OBTAINING AN ANIMAL CONTROL PHARMACY PERMIT OVERVIEW

Application Processing

Please read all application instructions before completing your application.

Please mail the application and the \$55.00 application fee (check or money order made payable to the FLORIDA DEPARTMENT OF HEALTH) to the following address:

Department of Health
Board of Pharmacy
P.O. Box 6320
Tallahassee, Florida 32314-6320

OR, use the following address if you are using express mail:

Department of Health
Board of Pharmacy
4052 Bald Cypress Way, Bin C-04
Tallahassee, FL 32399-3254

Within 30 days of receipt of your application and fees, the board office will notify you of the receipt of your application, any required documents, and your status. If the application is complete, you will be notified that an inspector will contact you to setup an inspection appointment. Please do not contact the board office concerning your inspection date, and allow 30 days for the inspector to contact you. If you have not been contacted by the inspector within 30 days, then notify the board. If your application is incomplete, you will be notified in writing of what is required to make your application complete.

Licensure Process

Upon completion of the inspection, the inspector will notify the board office as to whether the inspection was satisfactory or unsatisfactory. If the inspection was satisfactory, you will be issued a permit number within 30 days. **Please wait 30 days from your satisfactory inspection before checking on the status of your permit.** You may lookup your license number on our website at www.doh.state.fl.us/mqa under "Lookup Licensee." You may begin practicing pharmacy on your licensure date.

LAWS AND RULES

456.065, Florida Statutes, Unlicensed practice of a health care profession; intent; cease and desist notice; penalties; enforcement; citations; fees; allocation and disposition of moneys collected.--

(1) It is the intent of the Legislature that vigorous enforcement of licensure regulation for all health care professions is a state priority in order to protect Florida residents and visitors from the potentially serious and dangerous consequences of receiving medical and health care services from unlicensed persons whose professional education and training and other relevant qualifications have not been approved through the issuance of a license by the appropriate regulatory board or the department when there is no board. The unlicensed practice of a health care profession or the performance or delivery of medical or health care services to patients in this state without a valid, active license to practice that profession, regardless of the means of the performance or delivery of such services is strictly prohibited.

(2) The penalties for unlicensed practice of a health care profession shall include the following:

(a) When the department has probable cause to believe that any person not licensed by the department, or the appropriate regulatory board within the department, has violated any provision of this chapter or any statute that relates to the practice of a profession regulated by the department, or any rule adopted pursuant thereto, the department may issue and deliver to such person a notice to cease and desist from such violation. In addition, the department may issue and deliver a notice to cease and desist to any person who aids and abets the unlicensed practice of a profession by employing such unlicensed person. The issuance of a notice to cease and desist shall not constitute agency action for which a hearing under s. 120.569 and 120.57 may be sought. For the purpose of enforcing a cease and desist order, the department may file a proceeding in the name of the state seeking issuance of an injunction or a writ of mandamus against any person who violates any provisions of such order.

(b) In addition to the remedies under paragraph (a), the department may impose by citation an administrative penalty not to exceed \$5,000 per incident. The citation shall be issued to the subject and shall contain the subject's name and any other information the department determines to be necessary to identify the subject, a brief factual statement, the sections of the law allegedly violated, and the penalty imposed. If the subject does not dispute the matter in the citation with the department within 30 days after the citation is served, the citation shall become a final order of the department. The department may adopt rules to implement this section. The penalty shall be a fine of not less than \$500 nor more than \$5,000 as established by rule of the department. Each day that the unlicensed practice continues after issuance of a notice to cease and desist constitutes a separate violation. The department shall be entitled to recover the costs of investigation and prosecution in addition to the fine levied pursuant to the citation. Service of a citation may be made by personal service or by mail to the subject at the subject's last known address or place of practice. If the department is required to seek enforcement of the cease and desist or agency order, it shall be entitled to collect its attorney's fees and costs.

(c) In addition to or in lieu of any other administrative remedy, the department may seek the imposition of a civil penalty through the circuit court for any violation for which the department may issue a notice to cease and desist. The civil penalty shall be no less than \$500 and no more than \$5,000 for each offense. The court may also award to the prevailing party court costs and reasonable attorney fees and, in the event the department prevails, may also award reasonable costs of investigation and prosecution.

(d) In addition to the administrative and civil remedies under paragraphs (b) and (c) and in addition to the criminal violations and penalties listed in the individual health care practice acts:

1. It is a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084, to practice, attempt to practice, or offer to practice a health care profession without an active, valid Florida license to practice that profession. Practicing without an active, valid license also includes practicing on a suspended, revoked, or void license, but does not include practicing, attempting to practice, or offering to practice with an inactive or delinquent license for a period of up to 12 months which is addressed in subparagraph 3. Applying for employment for a position that requires a license without notifying the employer that the person does not currently possess a valid, active license to practice that profession shall be deemed to be an attempt or offer to practice that health care profession without a license.

Holding oneself out, regardless of the means of communication, as able to practice a health care profession or as able to provide services that require a health care license shall be deemed to be an attempt or offer to practice such profession without a license. The minimum penalty for violating this subparagraph shall be a fine of \$1,000 and a minimum mandatory period of incarceration of 1 year.

2. It is a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084, to practice a health care profession without an active, valid Florida license to practice that profession when such practice results in serious bodily injury. For purposes of this section, "serious bodily injury" means death; brain or spinal damage; disfigurement; fracture or dislocation of bones or joints; limitation of neurological, physical, or sensory function; or any condition that required subsequent surgical repair. The minimum penalty for violating this subparagraph shall be a fine of \$1,000 and a minimum mandatory period of incarceration of 1 year.

3. It is a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083, to practice, attempt to practice, or offer to practice a health care profession with an inactive or delinquent license for any period of time up to 12 months. However, practicing, attempting to practice, or offering to practice a health care profession when that person's license has been inactive or delinquent for a period of time of 12 months or more shall be a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084. The minimum penalty for violating this subparagraph shall be a term of imprisonment of 30 days and a fine of \$500.

(3) Because all enforcement costs should be covered by professions regulated by the department, the department shall impose, upon initial licensure and each licensure renewal, a special fee of \$5 per licensee to fund efforts to combat unlicensed activity. Such fee shall be in addition to all other fees collected from each licensee. The department shall make direct charges to the Medical Quality Assurance Trust Fund by profession. The department shall seek board advice regarding enforcement methods and strategies. The department shall directly credit the Medical Quality Assurance Trust Fund, by profession, with the revenues received from the department's efforts to enforce licensure provisions. The department shall include all financial and statistical data resulting from unlicensed activity enforcement as a separate category in the quarterly management report provided for in s. 456.025. For an unlicensed activity account, a balance which remains at the end of a renewal cycle may, with concurrence of the applicable board and the department, be transferred to the operating fund account of that profession. The department shall also use these funds to inform and educate consumers generally on the importance of using licensed health care practitioners.

(4) The provisions of this section apply only to health care professional practice acts administered by the department.

(5) Nothing herein shall be construed to limit or restrict the sale, use, or recommendation of the use of a dietary supplement, as defined by the Food, Drug, and Cosmetic Act, 21 U.S.C. s. 321, so long as the person selling, using, or recommending the dietary supplement does so in compliance with federal and state law.

History.--s. 73, ch. 97-261; s. 84, ch. 2000-160; s. 35, ch. 2000-318; s. 54, ch. 2001-277. Note.--Former s. 455.637.

CHAPTER 64B16-29
ANIMAL CONTROL SHELTER PERMITS

- 64B16-29.001 Definition
- 64B16-29.002 General Requirements
- 64B16-29.003 Drug Requirement
- 64B16-29.004 Records
- 64B16-29.0041 Record Maintenance Systems for Animal Shelter Permits
- 64B16-29.005 Storage

64B16-29.001 Definition.

An “animal control shelter” is a county or municipal animal control agency or Humane Society registered with the Secretary of State which holds a modified Class II Institutional Pharmacy permit issued by the Department of Health pursuant to certification of compliance with Rule 64B16-29.002, F.A.C., by the Board of Pharmacy. An animal control shelter is issued a pharmacy permit for the sole purpose of obtaining the drugs, sodium pentobarbital and sodium pentobarbital with lidocaine, for euthanization of animals within their lawful possession.

Specific Authority 465.005, 828.055 FS. Law Implemented 828.055 FS. History—New 10-17-79, Formerly 21S-14.01, Amended 4-24-88, Formerly 21S-14.001, 21S-29.001, 61F10-29.001, 59X-29.001.

64B16-29.002 General Requirements.

(1) Application for an Animal Control Shelter Pharmacy permit shall be made on Board of Pharmacy approved form DOH-MQA/PH/107 “Animal Control Pharmacy Permit Application and Information,” effective October 2009, which is incorporated by reference. To obtain an application, contact the Board of Pharmacy at 4052 Bald Cypress Way, Bin #C04, Tallahassee, FL 32399-3254, or (850) 488-0595, or download the application from the board’s website at <http://www.doh.state.fl.us/mqa/pharmacy>.

(a) The application fee for animal shelters applying for the Modified Class II Institutional permit shall be fifty dollars (\$50).

(b) The biennial permit renewal fee for animal shelters holding the Modified Class II Institutional permit shall be fifty dollars (\$50).

(2) The applicant shall apply to the Drug Enforcement Administration, United States Department of Justice, by the appropriate DEA form, for Registration as a practitioner, to be designated as “Animal Shelter” on the appropriate DEA form.

(3) The applicant shall be certified by the Board of Pharmacy to the Department as having met the requirements of this rule chapter prior to issuance of a permit. The certification process shall require prior inspection of the facility by authorized persons.

(4) The consultant pharmacist requirement of Section 465.019(5), F.S., is waived as being inapplicable to this special restricted permit.

(5) Authorized employees of the Department shall inspect animal control shelters not less than twice per year to determine compliance with this rule.

(6) Each animal control shelter permittee shall designate an on-site manager of the shelter. The on-site manager and permittee shall notify the Department within ten (10) days of any change in the on-site manager of the shelter.

Rulemaking Authority 465.005, 828.055 FS. Law Implemented 828.055 FS. History—New 10-17-79, Formerly 21S-14.02, Amended 4-24-88, Formerly 21S-14.002, Amended 10-1-92, Formerly 21S-29.002, Amended 7-18-94, Formerly 61F10-29.002, 59X-29.002, Amended 5-11-10.

64B16-29.003 Drug Requirement.

Animal control shelter permittees are restricted by law to purchase sodium pentobarbital and sodium pentobarbital with lidocaine only for the purpose of euthanizing animals. Federal Schedule II order forms (DEA-222) are required for the purchase of sodium pentobarbital.

Specific Authority 465.005, 828.055 FS. Law Implemented 828.055 FS. History—New 10-17-79, Formerly 21S-14.03, Amended 4-24-88, Formerly 21S-14.003, 21S-29.003, 61F10-29.003, 59X-29.003.

64B16-29.004 Records.

Animal control shelter permittees shall maintain records of purchases and administration of sodium pentobarbital and sodium pentobarbital with lidocaine for a period of not less than two (2) years. Records of administration shall contain:

- (1) The date of use;
- (2) Identification of the animal;
- (3) The amount of the drug used;
- (4) The signature of the person administering the drug;
- (5) The signature of the on-site manager certifying the accuracy of the administration of sodium pentobarbital and sodium pentobarbital with lidocaine not less than once per month; and
- (6) The signature of the on-site manager certifying to the accuracy of the records. These records are subject to audit by the Drug Enforcement Administration or authorized employees of the Department to determine adequacy, accuracy and validity of the record keeping.

Specific Authority 465.005, 828.055 FS. Law Implemented 828.055 FS. History--New 10-17-79, Formerly 21S-14.04, Amended 4-24-88, Formerly 21S-14.004, 21S-29.004, 61F10-29.004, 59X-29.004.

64B16-29.0041 Record Maintenance Systems for Animal Shelter Permits.

- (1) General requirements for records maintained in an electronic system.
 - (a) If a permitted animal shelter's data processing system is not in compliance with the Board's data processing requirements, the facility must maintain a manual recordkeeping system meeting the requirements of Rule 64B16-29.004, F.A.C.
 - (b) Requirements for back-up systems. The facility shall maintain a back-up copy of information stored in the data processing system using disk, tape, or other electronic back-up and up-date this back-up copy on a regular basis, at least monthly, to assure that data is not lost due to system failure.
 - (c) Change or discontinuance of a data processing system.
 1. Records of dispensed and returned medicinal drugs. A permitted animal shelter that changes or discontinues use of a data processing system must:
 - a. Transfer the records to the new data processing system; or
 - b. Purge the records to a printout which contains the same information as required on the audit trail printout as specified in Rule 64B16-29.004, F.A.C.
 2. Other records. A pharmacy that changes or discontinues use of a data processing system must:
 - a. Transfer the records to the new data processing system; or
 - b. Purge the records to a printout which contains all of the information required on the original document.
 3. Maintenance of purged records. Information purged from a data processing system must be maintained by the pharmacy for two years from the date of initial entry into the data processing system.
 - (d) Loss of data. The shelter manager for permitted animal shelters shall report to the Board in writing any significant loss of information from the data processing system within 10 days of discovery of the loss.
 - (2) The permitted animal shelter shall maintain a system(s) which can produce the information required in Rule 64B16-29.004, F.A.C., for the preceding two years. The information required in this paragraph shall be supplied by the permitted animal shelter within seven working days if requested.
 - (3) Failure to maintain records. Failure to provide records set out in this subsection, either on site or within 7 working days for whatever reason, constitutes failure to keep and maintain records.
 - (4) Data processing system downtime. In the event that a permitted animal shelter which uses a data processing system experiences system downtime, the permitted animal shelter must have an auxiliary procedure which will ensure that all data is retained.

Specific Authority 465.005, 465.0155, 465.022, 828.055 FS. Law Implemented 465.019, 465.022, 465.026, 893.07, 828.055 FS. History--New 3-31-05.

64B16-29.005 Storage.

Sodium pentobarbital and sodium pentobarbital with lidocaine shall be stored in a safe place. At a minimum, this shall require that the drugs be kept in a securely locked cabinet within a locked storage room. Schedule II order

forms are to be stored under the same conditions. Records of purchases of sodium pentobarbital and sodium pentobarbital with lidocaine shall be maintained in a separate file from the records of administration. The records of purchases and administration shall be maintained at the location.

Specific Authority 465.005, 828.055 FS. Law Implemented 828.055 FS. History--New 10-17-79, Formerly 21S-14.05, Amended 4-24-88, Formerly 21S-14.005, 21S-29.005, 61F10-29.005, 59X-29.005.



FLORIDA BOARD OF PHARMACY
 P.O. Box 6320 • Tallahassee, FL 32314-6320
 Phone: (850) 245-4292 www.doh.state.fl.us/mqa/pharmacy

APPLICATION FOR ANIMAL CONTROL PHARMACY PERMIT

Please type or print legibly.

1. Status of Application – Please choose one of the following:			
<input type="checkbox"/> New Establishment - \$55.00 Application Fee <input type="checkbox"/> Change of Ownership - \$55.00 Application Fee (A new permit number will be issued) Existing Permit Number _____ <input type="checkbox"/> Change of Location - \$50.00 Application Fee (Permit number will not change) Existing Permit Number _____ <input type="checkbox"/> To be amended - \$25.00 Application Fee (name change) <p style="text-align: center;"><i>NOTE: Permit fees include a \$5.00 unlicensed activity fee.</i></p>			
2. Current Permit Number		3. Phone Number	
4. Application Date			
5. Firm Name			
6. Doing Business As (d/b/a)			
7. Physical Address			
City	State		Zip
8. Current DEA Registration Number			
9. Ownership Information			
Type of Ownership: <input type="checkbox"/> Individual <input type="checkbox"/> Corporation <input type="checkbox"/> Partnership <input type="checkbox"/> Other: _____ Federal Employer Identification Number: _____ Taxpayer Identification Number: _____ Name of on-site Manager: _____ On-site Manager Contact Number: _____			
Please list all officers and Owners. Attach a separate sheet if necessary.			
Owner/Officer-Title	Home Address		Zip
10. Has the applicant, or any officer, member or partner ever been convicted of a felony or misdemeanor, excluding minor traffic convictions?			
Yes _____ No _____			

(You must include all misdemeanors and felonies, even if adjudication was withheld by the court, so that you would not have a record of conviction. Driving under the influence or driving while impaired is NOT a minor traffic offense for the purposes of this question.)

11. Are you currently registered or permitted in any other states? If yes, provide the state, permit type and permit number for each permit. Attach a separate sheet if necessary.

Yes _____ No _____

State	Permit Type	Permit Number

12. Has the applicant, or any officer, member or partner ever owned a pharmacy? If yes, provide the name of the pharmacy, the state where the pharmacy is located and the status of the pharmacy. Attach a separate sheet if necessary.

Yes _____ No _____

Pharmacy Name	State	Location

13. Has any disciplinary action ever been taken against any license, permit or registration issued to the applicant, or any officer, member or partner in this state or any other?

No _____ Yes _____ Explain: _____

ALL QUESTIONS MUST BE ANSWERED OR YOUR APPLICATION WILL BE RETURNED

Section 456.013(1), F.S., requires that applicants supplement their applications as needed to reflect any material change in any circumstances or conditions stated in the application, which takes place between the initial filing of the application and the final grant or denial of the license, which might affect the decision of the department.

The statements contained in this application are true, complete, and correct and I agree that said statements shall form the basis of my application and I do authorize the Florida Board of Pharmacy to make any investigations that they deem appropriate and to secure any additional information concerning me, and I further authorize them to furnish any information they may have or have in the future concerning me to any person, corporation, institution, association, board, or any municipal, county, state, or federal governmental agencies or units, and I understand according to the Florida Board of Pharmacy Statutes that a Pharmacist's license may be revoked or suspended for presenting any false, fraudulent, or forged statement, certificate, diploma, or other thing, in connection with an application for a license or permit, as set forth in Section 465.015(2)(a), F.S.

Providing false information may result in disciplinary action against my license or criminal penalties pursuant to sections 465.067, 775.082, 775.083, 775.084 and 465.018, F.S.

SIGNATURE _____ DATE _____
(Person responsible for drug security and record keeping)

NOTICE TO PERSON RESPONSIBLE FOR RECORD KEEPING AND SECURITY OF DRUGS: THE BOARD OF PHARMACY AMENDS THE PERMIT EACH TIME THERE IS A CHANGE IN THE PERSON RESPONSIBLE FOR RECORD KEEPING ACTIVITIES. PLEASE NOTIFY THE BOARD OFFICE IN WRITING WHENEVER SUCH A CHANGE OCCURS.

PHARMACY PERMIT APPLICATION CHECKLIST

Keep a copy of the completed application for your records.

It is recommended that you use the following checklist to help ensure that your application is complete. Failure to attach any required document, or to have required documentation sent to the Board, will result in an incomplete application. Final approval for inspection can not be granted until the application is complete. Faxed applications will not be accepted.

ANIMAL SHELTER PHARMACY PERMIT

- _____ **Application Completed (all questions answered)**
- _____ **Application signed**
- _____ **Onsite Manager listed**
- _____ **\$55.00 Fee Attached (Permit fee includes \$50 application fee and \$5.00 unlicensed activity fee)**
- _____ **Certificate of Status for the Corporation from the Secretary of State**
- _____ **Attestation for Business Taxable Assets if applicable**
- _____ **Bill of Sale is required for Change of Ownership**