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

INSTITUTIONAL PHARMACY PERMIT APPLICATION AND INFORMATION

November 2012

DH-MQA, 1215, 11/12
Rule 64B16-28.100, F.A.C.

Dear Florida Pharmacy Permit Applicant,

Thank you for applying for a 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 at 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,

The Florida Board of Pharmacy

DH-MQA, 1215, 11/12
Rule 64B16-28.100, F.A.C.

Institutional Pharmacy Permit Application Information

Whether opening a new establishment, changing locations, or changing owners, a pharmacy permit is required prior to operating in the State of Florida. The permit application must be completed and returned to the Florida Board of Pharmacy with the required fee of $255.00. The application MUST have the original signatures of the owner or officer of the establishment and the Consultant Pharmacist of Record.

Chapter 465, F.S., requires all institutional pharmacies to be under the professional supervision of the consultant pharmacist of record licensed in the State of Florida. A Florida licensed pharmacist shall perform compounding and dispensing of medicinal drugs.

There are three types of Institutional Pharmacy Permit applicants. Please read the description below. Check which permit type you are applying for on the application.

1. Institutional Class I Pharmacy – An Institutional Class I pharmacy is an institutional pharmacy in which all medicinal drugs are administered from individual prescription containers to the individual patient and in which medicinal drugs are not dispensed on the premises. No medicinal drugs may be dispensed in a Class I Institutional pharmacy. A Special- Closed System Pharmacy Permit, Special Parenteral and Enteral Pharmacy Permit, or Community Pharmacy Permit provide the individual patient prescriptions

2. Institutional Class II Pharmacy Permit – An Institutional Class II pharmacy is an institutional pharmacy that employs the services of a registered pharmacist or pharmacists who, in practicing institutional pharmacy, provide dispensing and consulting services on the premises to patients of that institution, for use on the premises of that institution. An Institutional Class II pharmacy is required be open sufficient hours to meet the needs of the hospital facility.

The consultant pharmacist of record shall be responsible for establishing written policy and procedure manual for the implementation of the general requirements set forth in Rule 64B16-28.702, F.A.C.

An Institutional Class II Pharmacy may elect to participate in the Cancer Drug Donation Program. If you are applying for this permit and would like to participate, please answer ”yes” on question 20 of the application and attach a Notice of Participation to your application. For more information about the Cancer Drug Donation Program, and for a copy of the Notice of Participation, please visit the program’s website at www.doh.state.fl.us/mqa/ddc/cancer.

3. Modified Institutional Class II Pharmacy Permits

Modified Institutional Class II pharmacies are those institutional pharmacies in short-term, primary care treatment centers that meet all the requirements for a Class II permit, except space and equipment requirements. Modified Class II Institutional pharmacies are designated as Type “A”, Type “B” and Type “C” according to the type of specialized pharmaceutical delivery system utilized. Please review Rule 64B16-28.702, Florida Administrative Code for specific requirements.

Application Processing

Please read all application instructions before completing your application.

1) Please mail the application and the $255.00 application fee and fingerprint fees (cashiers check or money order) made payable to the FLORIDA DEPARTMENT OF HEALTH) to the following address:

Florida 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:

Florida 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 the inspector has not contacted you 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.

2) Submit fingerprint results.

Failure to submit fingerprints will delay your application. All officers, officers and prescription department managers are required to submit a set of fingerprints unless the corporation is exempt under the Section 465.022, Florida Statutes for corporations having more than $100 million of business taxable assets in this state. These corporations are only required to have the prescription department manager or consultant of record to submit fingerprints. The statute allows the prescription department manager for a corporation having more than $100 million of business taxable assets in this state to submit results from AHCA if the results were also available to the Department and are within one year of the receipt date of the application. If the manager prints were submitted to DOH within one year of the date of the application they are not required to submit them over.

Applicants can use any Livescan vendor that has been approved by the Florida Department of Law Enforcement to submit their fingerprints to the department. Please ensure that the Originating Agency Identification (ORI) number is provided to the vendor when you submit your fingerprints. If you do not provide an ORI number or if you provide an incorrect ORI number to the vendor, the Board of Pharmacy will not receive your fingerprint results. The applicant is fully responsible for selecting the vendor and ensuring submission of the prints to the Department.

1. How do I find a Livescan vendor in order to submit my fingerprints to the department?
The Department of Health accepts electronic fingerprinting service offered by Livescan device vendors that are approved by the Florida Department of Law Enforcement and listed at their site. You can view the vendor options and contact information at www.doh.state.fl.us/mqa/pharmacy, select Apply for a License, select Pharmacy Permit Information, select Livescan vendor list.

2. What information must I provide to the Livescan vendor I choose?

a) If you are an applicant seeking a license for any profession regulated by the Department of Health, which requires a criminal background search as a condition of licensure, you must provide accurate demographic information at the time your fingerprints are taken, ***including your Social Security number***. The Department will not be able to process a submission that does not include your Social Security number

b) You must provide the correct ORI number.

3. Where do I get the ORI number to submit to the vendor?

The ORI number for the pharmacy profession is EDOH4680Z

3) Attestation for Business Taxable Assets

If the applicant has more than $100 million dollars of business taxable assets in this state, please submit a formal opinion letter from a Certified Public Accountant duly licensed in the state of your principal place of business affirming the corporation has more than $100 million of business taxable assets in this state for the previous tax year. In lieu of submitting a formal opinion letter from a Certified Public Accountant, the applicant may submit its Florida Corporate Income/Franchise and Emergency Excise Tax Return (Form F-1120, Effective 01/09).

4) Institutional Class II Pharmacy Permit Applicants and Modified Institutional Class II Pharmacy Applicants complete and submit with application answers to the applicable questions below:

Institutional Class II Pharmacy Permit Applicants Complete the Following Questions.

The Consultant Pharmacist of Record is responsible for developing and maintaining a current policy and procedure manual. The permittee must make available the policy and procedure manual to the appropriate state or federal agencies upon inspection. Do not send the policy and procedure manual to the board office. The board office will approve the policy and procedure manual based upon answers submitted for the following questions, where applicable, by using excerpts or summaries from the policy and procedure manual.

1) List the following:
Firm Name:
Doing business as (d/b/a):
Telephone number:
Address:
Permit number (if already licensed as an institutional pharmacy):

2) Explain the practice setting of the proposed facility.

3) What are the objectives and purpose of the permittee? Give detailed explanation of the services of the facility scope and practice.

4) What are the experience, qualifications, special education, and/or training of the compounding pharmacist? Please provide a resume.

5) Address the ratio of supportive personnel to each pharmacist. How will the supportive personnel be utilized? Include a job description for any such supportive personnel.

6) Describe the drug delivery system. Begin with the ordering of medications and track your procedures up to delivery to the patient. If utilizing remote medication order processing and the pharmacist is not an employee of the institution, describe the pharmacist and institution's responsibility.

7) What categories of parenteral/enteral products will be prepared (i.e. IV, enteral, irrigating, and oncology products)? Include sample labels.

8) What is the policy regarding the delivery of parenteral/enteral products to the patient? Describe methods used and trace the path the product takes from the time it leaves the permittee until it reaches the patient. Describe how products are protected from extreme temperature conditions.

9) Address the policy and procedure, special equipment and special techniques to dispense sterile preparations for parenteral therapy/nutrition. If this type of dispensing will not be performed, please state so accordingly.

10) Address the policy and procedure, special equipment and special techniques to dispense sterile jejunostomy feeding/sterile irrigation solutions. If this type of dispensing will not be performed, please state so accordingly.

11) Address the policy and procedure, special equipment and special techniques to dispense cytotoxic or anti-neoplastic agents. If this type of dispensing will not be performed, please state so accordingly.

12) What is the procedure for the annual review and updating of the policy and procedure manual?

13) Include the layout/floor plan of the pharmacy. The drawing must include the dimensions of the clean room and the pharmacy, location of the hood, sink and other equipment. The drawing must also show the location of the clean room relative to other pharmacy and storage areas.

14) Include a sample copy of a patient profile.

15) Address the use of aseptic techniques.

16) Describe the Quality Assurance Program.

17) Describe with detail the policy and procedure for patient education, including the personnel involved.

18) Address the policy and procedure for handling waste and returns.

19) Describe the type of certified laminar flow hood(s) used and the frequency of certification.

20) Describe the refrigerator/freezer to be used.

21) Describe appropriate waste containers for:

    a. Used needles and syringes.

    b. Cytotoxic waste including disposable apparel used in preparation.

22) Address the following supplies to be used: gloves, mask, gowns, needles, syringes, disinfectant cleaning agents, clean towels, hand-washing materials with bactericidal properties, vacuum containers/transfer sets, and spill kits for cytotoxic agent spills.

23) Address the following references to be used:

a. Chapters 465 and 893, F.S., and Rule Title

64B16,F.A.C.

b. Authoritative Therapeutic Reference.

c. Handbook of injectable drugs by American Society of Health-System Pharmacists.

24) Occupational Safety and Health Administration guidelines for safe handling of cytotoxic drugs.

Modified Institutional Class II Pharmacy Permit Applicants Complete the Following Questions

Modified Institutional Class II pharmacies are those institutional pharmacies in short-term, primary care treatment centers that meet all the requirements for a Class II permit, except space and equipment requirements. Modified Class II Institutional pharmacies are designated as Type "A", Type "B" and Type "C" according to the type of specialized pharmaceutical delivery system utilized. Please review Rule 64B16-28.702, Florida Administrative Code for specific requirements.

Chapter 465.019, F.S., requires the permit holder to be under the control and supervision of a Consultant Pharmacist licensed in the State of Florida. The Consultant Pharmacist of Record is responsible for developing and maintaining a current policy and procedure manual. The permittee must make available the policy and procedure manual to the appropriate state or federal agencies upon inspection. Do not send the policy and procedure manual to the board office. The board office will approve the policy and procedure manual based upon answers submitted for the following questions, where applicable, by using excerpts or summaries from the policy and procedure manual.

1) List the following:
Firm Name:
Doing business as (d/b/a):
Telephone number:
Address:
Consultant pharmacist of record:

2) Describe the purpose of the establishment. What sector of the community are you serving?

3) Is this is an inpatient facility? If so, how many beds are housed in the facility? What is the average length of stay?

4) List the drug formulary to be used.

5) Include a diagram of pharmacy storage space and a description of drug security measures.

6) Describe the consultant pharmacist of record's responsibilities.

7) Under whose DEA registration will controlled substances be ordered?

8) Describe the drug delivery system. Begin with the ordering of medications and track your procedures up to delivery to the patient.

9) Include a statement that perpetual inventory records will be maintained for controlled substances and injectable inventory.

10) Include a statement to the effect that no drugs will be dispensed from the facility.

If compounding sterile preparations, please answer the additional questions below.

11) If compounding sterile preparations, describe compliance with Rule 64B16-27.797, F.A.C.

12) What categories of parenteral/enteral products will be prepared (i.e. IV, enteral, irrigating, and oncology products)? Include sample labels.

13) What is the policy regarding the delivery of parenteral/enteral products to the patient? Describe methods used and trace the path the product takes from the time it leaves the permittee until it reaches the patient. Describe how this product is protected from extreme temperature conditions.

14) Address the policy and procedure, special equipment and special techniques to dispense sterile preparations for parenteral therapy/nutrition. If this type of dispensing will not be performed, please state so accordingly.

15) Address the policy and procedure, special equipment and special techniques to dispense sterile jejunostomy feeding/sterile irrigation solutions. If this type of dispensing will not be performed, please state so accordingly.

16) Address the policy and procedure, special equipment and special techniques to dispense cytotoxic or anti-neoplastic agents. If this type of dispensing will not be performed, please state so accordingly.

17) What is the procedure for the annual review and updating of the policy and procedure manual?

18) Include the layout/floor plan of the pharmacy. The drawing must include the dimensions of the clean room and the pharmacy, location of the hood, sink and other equipment. The drawing must also show the location of the clean room relative to other pharmacy and storage areas.

19) Include a sample copy of a patient profile.

20) Address the use of aseptic techniques.

21) Describe the Quality Assurance Program.

22) Describe with detail the policy and procedure for patient education, including the personnel involved.

23) Address the policy and procedure for handling waste and returns.

24) Describe the type of certified laminar flow hood(s) to be used and the frequency of certification.

25) Describe the refrigerator/freezer to be used.

26) Describe appropriate waste containers for:

a. Used needles and syringes.
b. Cytotoxic waste including disposable apparel used in preparation.

27) Address the following supplies to be used: gloves, mask, gowns, needles, syringes, disinfectant cleaning agents, clean towels, hand-washing materials with bactericidal properties, vacuum containers/transfer sets, and spill kits for cytotoxic agent spills.

28) Address the following references to be used:

a. Chapters 465 and 893, F.S., and Title 64B16, F.A.C. b.
Authoritative Therapeutic Reference.
c. Handbook of Injectable D rugs by American Society of Health-System Pharmacists.
d. Occupational Safety and Health Administration guidelines for safe handling of cytotoxic drugs.

Licensure Process

Once the application is deemed complete, the board staff authorizes an inspection. Upon completion of the inspection, the inspector notifies the board office as to whether the inspection was satisfactory or unsatisfactory. If the inspection is satisfactory, a permit number is issued within 10 days. **Please wait 10 days from your satisfactory inspection before checking on the status of your permit**. **You may lookup your license number on our website at http://www.doh.state.fl.us/mqa under "Lookup Licensee."**

Drug Enforcement Administration (DEA)

The DEA will not issue a registration until the Florida Board of Pharmacy has issued a pharmacy permit. The Board is responsible for notifying the DEA when the pharmacy permit is issued.

If controlled substances will be involved in your pharmacy practice, you must make an Application for Registration under the Controlled Substance Act of 1970 with the DEA. If possible, you are encouraged to use the on-line form system provided by the DEA. Information is available by visiting their website at http://www.DEAdiversion.usdoj.gov. DEA Form 224 may be obtained in paper form by writing to:

Drug Enforcement Administration
Attn: ODR
PO Box 2639
Springfield, VA 22152-2639

Form 224 should be completed and mailed via U.S. Postal service to the address listed on the form.

Contact DEA at 1-800-667-9752 or 954-306-4654 for information on change of location or change of name.

If your pharmacy does change locations, you are required to have a pharmacy inspection prior to operating in the new location.

IMPORTANT NOTICE: The department or board shall deny an application for a pharmacy permit if the applicant or an affiliated person, partner, officer, director, or prescription department manager or consultant pharmacist of record of the applicant:

(a)Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under chapter 409, chapter 817, or chapter 893, or a similar felony offense committed in another state or jurisdiction, since July 1, 2009.
(b)Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under 21 U.S.C. ss. 801-970 or 42 U.S.C. ss. 1395-1396 since July 1, 2009.
(c) Has been terminated for cause from the Florida Medicaid program pursuant to s. 409.913, unless the applicant has been in good standing with the Florida Medicaid program for the most recent 5-year period.
(d)Has been terminated for cause, pursuant to the appeals procedures established by the state, from any other state Medicaid program, unless the applicant has been in good standing with a state Medicaid program for the most recent 5-year period and the termination occurred at least 20 years before the date of the application.
(e) Has obtained a permit by misrepresentation or fraud.
(f) Has attempted to procure, or has procured, a permit for any other person by making, or causing to be made, any false representation.
(g) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to the practice of, or the ability to practice, the profession of pharmacy.
(h) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to health care fraud.
(i) Is currently listed on the United States Department of Health and Human Services Office of Inspector General's List of Excluded Individuals and Entities.
(j) Has dispensed any medicinal drug based upon a communication that purports to be a prescription as defined by s. 465.003(14) or s. 893.02 when the pharmacist knows or has reason to believe that the purported prescription is not based upon a valid practitioner-patient relationship that includes a documented patient evaluation, including history and a physical examination adequate to establish the diagnosis for which any drug is prescribed and any other requirement established by board rule under chapter 458, chapter 459, chapter 461, chapter 463, chapter 464, or chapter 466.

If applicable to you, please provide the documentation to the Florida Board of Pharmacy.

PRE-INSPECTION CHECKLIST

_____ Is there an adequate sink in workable condition that is easily accessible to the prescription counter that will be available during the hours when the prescription department is normally open for business pursuant to Rule 64B16-28.102, F.A.C.?

_____ Is the pharmacy department equipped an area suitable for private patient counseling if applying for a community pharmacy permit pursuant to Rule 64B16-28.1035, F.A.C.?

_____ Are all required signs displayed?

- o Daily operating hours pursuant to Rule 64B16-28.1081, F.A.C.
- o "Consult your pharmacist regarding the availability of a less expensive generically equivalent drug and the requirements of Florida law" pursuant to Section 465.025(7), F.S.
- o Prescription Department Closed pursuant to Rule 64B16-28.109, F.A.C.
- o Pharmacist meal breaks pursuant to Rule 64B16-27.1001(6), F.A.C.
- o Patient Consultation Area pursuant to Rule 64B16-28.1035, F.A.C.

_____ If compounding sterile preparations, is your pharmacy compliant with Standards for Compounding Sterile Preparations pursuant to Rule 64B16-27.797, F.A.C?

_____ If participating in the Cancer Drug Donation Program, check question #25 on the application and submit a Notice of Participation form with the application.

FLORIDA BOARD OF PHARMACY
P.O. Box 6320
Tallahassee, FL 32314-6320
Telephone (850) 488-0595
http://www.doh.state.fl.us/mqa/pharmacy

INSTITUTIONAL PHARMACY PERMIT APPLICATION

Application Type – Please choose one of the following:

____ New Establishment $255 fee
____ Change of Location $100 fee _____(existing permit number)
____ Change of Ownership (a new permit number will be issued) $255 _____(existing permit number)

Type of Institutional Pharmacy Permit - Please choose one of the following:
____ Institutional Class I ____ Institutional Class II ____ Modified Institutional Class II ____A ____B ____C

Federal Employer Identification Number: _____

1. Corporate Name	**Telephone Number**
2. Doing Business As (d/b/a)	**E-Mail Address**

3. Mailing Address

City	**State**	**Zip Code**

4. Physical Address

City	**State**	**Zip Code**

5. Consultant Pharmacist of Record

Name	**License No.**	**Start Date**	**Signature**

6. Contact Person	**Telephone Number**
7. DEA Registration Number	**8. Date ready for inspection (must be within 90 days of the date of the application) _____**

9. Please provide the name, address, telephone number, and permit number of your prescription drug wholesale distributor.

Name	**Telephone Number**	**Permit Number**	
Street Address	**City**	**State**	**Zip**

10. Pharmacy Technician Ratio 2:1 or 3:1 (Optional)

Rule 64B16-27.410, *Florida Administrative Code*, provides that the consultant pharmacist of record be required to submit a request and receive approval from the Board of Pharmacy prior to practicing with either a 2:1 or 3:1 ratio of supervision.

If you would like to apply for the Pharmacy Technician 2:1 or 3:1 ratio, you may do so by checking the appropriate selection below. Selecting an option below serves as your official notification to the board office that you are requesting approval to practice with a 2:1 or 3:1 ratio. The board will provide notice of application approval or denial.

_____ 2:1 Ratio _____ 3:1 Ratio

11. Operating Hours

Prescription Department Hours

Monday-Friday: Open _____ Close:

Saturday: Open: _____ Close:

Sunday: Open: _____ Close: _____

12. Ownership Information

12a. Type of Ownership: ____Individual _____Corporation _____Partnership

_____Other: _____

NOTE: IF CORPORATION OR LIMITED PARTNERSHIP YOU MUST INCLUDE WITH YOUR APPLICATION A COPY OF THE ARTICLES OF INCORPORATION ON FILE WITH THE FLORIDA SECRETARY OF STATE'S OFFICE

12b. Are the applicants, officers, directors, shareholders, members and partners over the age of 18?

Yes _____ No _____

12c. Does the corporation have more than $100 million of business taxable assets in this state?

Yes _____ No_____

If yes, provide attestation from Certified Public Accountant for previous tax year or Florida Corporate Income/Franchise and Emergency Excise Tax Return (F-1120). If no, continue to 12d.

12d. List all the owners and officers of the corporation. Each person listed below having an ownership interest of 5 percent or greater and any person who, directly or indirectly, manages, oversees, or controls the operation of the applicant including officers and members of the board of directors must submit a set of fingerprints and fees unless you answered yes to 12c. If 12c is yes please list the owners below and only submit fingerprint cards for the Consultant and the representative who is signing this application. If the representative has prints on file with DOH or AHCA you may provide proof and the requirements to submit prints for this person is met.

Attach a separate sheet if necessary.

Owner/Officer-Title	Date of Birth	Mailing Address, City, State, Zip Code	% of Ownership
	/ /		%
	/ /		%
	/ /		%
	/ /		%
	/ /		%
	/ /		%
	/ /		%

13. Has anyone listed in 12.d has an ownership interest of 5% or more in a pharmacy or any other business permit which was disciplined, suspended, revoked, or closed involuntarily within the past 5 years?

Yes_____ No_____

14. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under Chapter 409, F.S. (relating to social and economic assistance), Chapter 817, F.S. (relating to fraudulent practices), Chapter 893, F.S. (relating to drug abuse prevention and control) or a similar felony offense(s) in another state or jurisdiction? (If you responded "no", skip to #15.)

Yes _____ No _____

14a. If "yes" to 14, for the felonies of the first or second degree, has it been more than 15 years from the date of the plea, sentence and completion of any subsequent probation?

Yes _____ No _____

14b. If "yes" to 14, for the felonies of the third degree, has it been more than 10 years from the date of the plea, sentence and completion of any subsequent probation? (This question does not apply to felonies of the third degree under Section 893.13(6)(a), Florida Statutes).

Yes _____ No _____

14c. If "yes" to 14, for the felonies of the third degree under Section 893.13(6)(a), Florida Statutes, has it been more than 5 years from the date of the plea, sentence and completion of any subsequent probation?

Yes _____ No _____

14d. If "yes" to 14, has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant successfully completed a drug court program that resulted in the plea for the felony offense being withdrawn or the charges dismissed? (If "yes", please provide supporting documentation).

Yes_____ No _____

15. I have been provided and read the statement from the Florida Department of Law Enforcement regarding the sharing, retention, privacy and right to challenge incorrect criminal history records and the "Privacy Statement" document from the Federal Bureau of Investigation.

Yes_____ No_____

16. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under 21 U.S.C. ss. 801-970 (relating to controlled substances) or 42 U.S.C. ss. 1395-1396 since July 1, 2009 (relating to public health, welfare, Medicare and Medicaid issues)?

Yes _____ No_____

16a. If "yes" to 16, has it been more than 15 years before the date of application since the sentence and any subsequent period of probation for such conviction or plea ended?

Yes _____ No_____

17. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant ever been terminated for cause from the Florida Medicaid Program pursuant to Section 409.913, Florida Statutes? (If no, do not answer 18.)

Yes _____ No _____ (If yes, explain on a separate sheet providing accurate details)

18. If the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant has been terminated, has the applicant been reinstated and in good standing with the Florida Medicaid Program for the most recent five years?

Yes _____ No _____ (If yes, explain on a separate sheet providing accurate details)

19. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant ever been terminated for cause, pursuant to the appeals procedures established by the state or federal government, from any other state Medicaid program or the federal Medicare program? (If no, do not answer 20 and 21.)

Yes _____ No _____ (If yes, explain on a separate sheet providing accurate details)

20. Has the applicant been in good standing with a state Medicaid program or the federal Medicare program for the most recent five years?

Yes _____ No _____ (If yes, explain on a separate sheet providing accurate details)

21. Did the termination occur at least 20 years prior to the date of this application?

Yes _____ No _____ (If yes, explain on a separate sheet providing accurate details)

22. Is the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant currently listed on the United States Department of Health and Human Services Office of inspector General's List of Excluded Individuals and Entities?

Yes _____ No _____

23. 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

DH-MQA, 1215, 11/12
Rule 64B16-28.100, F.A.C.

24. Has the applicant, affiliated persons, partners, officer, directors, or consultant pharmacist of record 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 _____(If yes, explain on a separate sheet providing accurate details)

Pharmacy Name	State	Status

25. Has any disciplinary action ever been taken against any license, permit or registration issued to the applicant, affiliated persons, partners, officers, directors or consultant pharmacist of record in this state or any other?

Yes _____ No _____ (If yes, explain on a separate sheet providing accurate details)

26. Is there any other permit issued by the Department of Health located at the physical location address on this application?

Yes _____ No _____ (If yes, explain on a separate sheet providing accurate details)

27. If compounding sterile preparations, is your establishment Rule 64B16-27.797, F.A.C. compliant?

Yes _____ No _____

28. Is the policy and procedure manual for preventing controlled substances dispensing based on fraudulent representation or invalid practitioner-patient relationship available for inspection by DOH?

Yes _____ No_____

29. Does the applicant, affiliated person, partner, officer, director have any outstanding fines, liens or overpayments assessed by a final order of the department?

Yes_____ No_____ (If yes, explain on a separate sheet providing accurate details)

ALL QUESTIONS MUST BE ANSWERED OR YOUR APPLICATION WILL BE RETURNED

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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.

I certify that 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 Pharmacy Permit 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.

Under penalty of perjury I have read the foregoing document and that the facts stated in it are true. I recognize that providing false information may result in disciplinary action against my license or criminal penalties.

SIGNATURE _____ TITLE _____ DATE_____

Owner/Officer

.

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.

INSTITUTIONAL PHARMACY PERMITS

_____ **Application Completed (all questions answered)**

_____ **Application signed**

_____ **Pharmacy Manager or Consultant Listed with Signature**

_____ **$255.00 Fee Attached (Permit fee includes $250 application fee and $5.00 unlicensed activity fee)**

_____ **Certificate of Status for the Corporation from the Secretary of State**

_____ **Fingerprints have been submitted via livescan for all officers and owners and the consultant or record.**

_____ **Attach Proof from AHCA that the fingerprints are on file if applicable**

_____ **Attestation for Business Taxable Assets of $100 million if applicable**

_____ **Bill of Sale is required for Change of Ownership**

Electronic Fingerprinting

Take this form with you to the Live Scan service provider. Please check the service provider's requirements to see if you need to bring any additional items.

- Background screening results are obtained from the Florida Department of Law Enforcement and the Federal Bureau of Investigation by submitting to a fingerprint scan using the livescan method;
- You can find a Livescan service provider at: http://www.doh.state.fl.us/mqa/background.html;
- Failure to submit background screening will delay your application;
- Applicants may use any Livescan service provider approved by the Florida Department of Law Enforcement to submit their background screening to the department;
- If you do not provide the correct Originating Agency Identification (ORI) number to the livescan service provider the Board office will not receive your background screening results;
- You must provide accurate demographic information to the livescan service provider at the time your fingerprints are taken, ***including your Social Security number (SSN)***;
- If you do not have a SSN you will need to contact the Board office for a fingerprint card then return the card to the Board office;
- The ORI number for the Board of Pharmacy is EDOH4680Z
- Typically background screening results submitted through a Livescan service provider are received by the Board within 24-72 hours of being processed.
- If you obtain your livescan from a service provider who does not capture your photo you may be required to be reprinted by another agency in the future.

Name:_____ Social Security Number: _____

Aliases:_____

Date of Birth: _____ Place of Birth: _____

(MM/DD/YYYY)

Citizenship: _____ Race: _____ (W-White/Latino(a); B-Black; A-Asian; NA-Native American; U-Unknown)

Sex: _____ Weight: _____ Height: _____

(M=Male; F=Female)

Eye Color:_____ Hair Color: _____

Address: _____ Apt. Number: _____

City:_____ State: _____ Zip Code: _____

Transaction Control Number (TCN#):_____

(This will be provided to you by the Live Scan Service provider.)

Keep this form for your records.

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FLORIDA DEPARTMENT OF LAW ENFORCEMENT

NOTICE FOR APPLICANTS SUBMITTING FINGERPRINTS WHERE CRIMINAL RECORD RESULTS WILL BECOME PART OF THE CARE PROVIDER BACKGROUND SCREENING CLEARINGHOUSE

NOTICE OF:

- **SHARING OF CRIMINAL HISTORY RECORD INFORMATION WITH SPECIFIED AGENCIES,**
- **RETENTION OF FINGERPRINTS,**
- **PRIVACY POLICY, AND**
- **RIGHT TO CHALLENGE AN INCORRECT CRIMINAL HISTORY RECORD**

This notice is to inform you that when you submit a set of fingerprints to the Florida Department of Law Enforcement (FDLE) for the purpose of conducting a search for any Florida and national criminal history records that may pertain to you, the results of that search will be returned to the Care Provider Background Screening Clearinghouse. By submitting fingerprints, you are authorizing the dissemination of any state and national criminal history record that may pertain to you to the Specified Agency or Agencies from which you are seeking approval to be employed, licensed, work under contract, or to serve as a volunteer, pursuant to the National Child Protection Act of 1993, as amended, and Section 943.0542, Florida Statutes. "Specified agency" means the Department of Health, the Department of Children and Family Services, the Division of Vocational Rehabilitation within the Department of Education, the Agency for Health Care Administration, the Department of Elder Affairs, the Department of Juvenile Justice, and the Agency for Persons with Disabilities when these agencies are conducting state and national criminal history background screening on persons who provide care for children or persons who are elderly or disabled. The fingerprints submitted will be retained by FDLE and the Clearinghouse will be notified if FDLE receives Florida arrest information on you.

Your Social Security Number (SSN) is needed to keep records accurate because other people may have the same name and birth date. Disclosure of your SSN is imperative for the performance of the Clearinghouse agencies' duties in distinguishing your identity from that of other persons whose identification information may be the same as or similar to yours.

Licensing and employing agencies are allowed to release a copy of the state and national criminal record information to a person who requests a copy of his or her own record if the identification of the record was based on submission of the person's fingerprints. Therefore, if you wish to review your record, you may request that the agency that is screening the record provide you with a copy. After you have reviewed the criminal history record, if you believe it is incomplete or inaccurate, you may conduct a personal review as provided in s. 943.056, F.S., and Rule 11C8.001, F.A.C. If national information is believed to be in error, the FBI should be contacted at 304-625-2000. You can receive any national criminal history record that may pertain to you directly from the FBI, pursuant to 28 CFR Sections 16.30-16.34. You have the right to obtain a prompt determination as to the validity of your challenge before a final decision is made about your status as an employee, volunteer, contractor, or subcontractor.

Until the criminal history background check is completed, you may be denied unsupervised access to children, the elderly, or persons with disabilities.

The FBI's Privacy Statement follows on a separate page and contains additional information.

US Department of Justice, Federal Bureau of Investigation,

Criminal Justice Information Services Division

Privacy Statement

Authority: The FBI's acquisition, preservation and exchange of information requested by this form is generally authorized under 28 U.S.C. 534. Depending on the nature of your application, supplemental authorities include numerous Federal statutes, hundreds of State statutes pursuant to Pub.L.92-544, Presidential executive orders, regulations and/or orders of the Attorney General of the United States, or other authorized authorities. Examples include, but are not limited to: 5 U.S.C. 9101; Pub.L.94-29; Pub.L.101-604; and Executive Orders 10450 and 12968. Providing the requested information is voluntary; however, failure to furnish the information may affect timely completion of approval of your application.

Social Security Account Number (SSAN): Your SSAN is needed to keep records accurate because other people may have the same name and birth date. Pursuant to the Federal Privacy Act of 1974 (5 USC 552a), the requesting agency is responsible for informing you whether disclosure is mandatory or voluntary, by what statutory or other authority your SSAN is solicited, and what uses will be made of it. Executive Order 9397 also asks Federal Agencies to use this number to help identify individuals in agency records.

Principal Purpose: Certain determinations, such as employment, security, licensing and adoption, may be predicated on fingerprint based checks. Your fingerprints and other information contained on (and along with) this form may be submitted to the requesting agency, the agency conducting the application investigation, and/or FBI for the purpose of comparing the submitted information to available records in order to identify other information that may be pertinent to the application. During the processing of this application, and for as long hereafter as my be relevant to the activity for which this application is being submitted, the FBI(may disclose any potentially pertinent information to the requesting agency and/or to the agency conducting the investigation. The FBI may also retain the submitted information in the FBI's permanent collection of fingerprints and related information, where it will be subject to comparisons against other submissions received by the FBI. Depending on the nature of your application, the requesting agency and/or the agency conducting the application investigation may also retain the fingerprints and other submitted information for other authorized purposes of such agency(ies).

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Routine Uses: The fingerprints and information reported on this form may be disclosed pursuant to your consent, and may also be disclosed by the FBI without your consent as permitted by the Federal Privacy Act of 1974 (5 USC 552a(b)) and all applicable routine uses as many be published at any time in the Federal Register, including the routine uses for the FBI Fingerprint Identification Records System (Justice, FBI-009) and the FBI's Blanket Routine Uses (Justice/FBI-BRU). Routine uses include, but are not limited to, disclosures to: appropriate governmental authorities responsible for civil or criminal law enforcement counterintelligence, national security or public safety matters to which the information may be relevant; to State and local governmental agencies and nongovernmental entities for application processing as authorized by Federal and State legislation, executive order, or regulation, including employment, security, licensing, and adoption checks; and as otherwise authorized by law , treaty, executive order, regulation, or other lawful authority. If other agencies are involved in processing the application, they may have additional routine uses.

Additional Information: The requesting agency and/or the agency conducting the application investigation will provide you additional information pertinent to the specific circumstances of this application, which may include identification of other authorities, purposes, uses, and consequences of not providing requested information. In addition, any such agency in the Federal Executive Branch has also published notice.

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