AGENDA

Florida Board of Pharmacy * Rules Subcommittee Meeting
Class III Institutional Pharmacy Permit Discussion

May 24, 2018 – 4:00 p.m.

Conference Call Number: (888) 670-3525
Conference Code Number: 5134896685

Board Members:
Richard Montgomery, BPharm, MBA – Chair

Board Staff:
C. Erica White, MBA, JD – Executive Director
Robert DiFiore, RPh - Pharmaceutical Program Manager – Bureau of Enforcement

Committee Members:

- Dominic Bracero, MBA – Pharmacy Director, Florida Hospital, Central Fill Facility
- Heather Fuller, MBA, PharmD, MPharm, – Division Director of Pharmacy Services, North Florida - HCA
- Michael Magee, MS, RPh, FASHP – Vice-President of Pharmacy, BayCare Health System
- Thomas Johns, PharmD – Director of Pharmacy Services – University of Florida Health/Gainesville Campus

Board Counsel:
David Flynn, Assistant Attorney General
Lawrence Harris, Assistant Attorney General

Note: Participants in this public meeting should be aware that these proceedings are being recorded.

1. **Call to Order**
   (*Facilitator – Richard Montgomery)*
2. **Review of April 19, 2018 minutes**
   (*Facilitator – Richard Montgomery)*
3. **Overview of Draft Rule 64B16-28.750, F.A.C. - Class III Institutional Pharmacies**
   (*Facilitator – Lawrence Harris*)
4. **Overview of Draft Class III Institutional Pharmacy Permit application**
   (*Facilitator – Lawrence Harris*)
5. **Overview of Change of Permit Association Form (proposed)**
   (*Facilitator – C. Erica White*)
6. **Old Business/ New Business**
   (*Facilitator – Richard Montgomery)*
7. **Public Comment**
8. **Adjourn**

TAB #2

FLORIDA | Board of Pharmacy
Rules Subcommittee Meeting
Class III Institutional Pharmacy Permit Discussion

DRAFT
April 19, 2018 – 9:00 a.m.

Best Western Gateway Grand Hotel and Conference Center
*4200 NW 97th Boulevard * Gainesville, FL 32606*
(352) 331-3336

Richard Montgomery, BPharm, MBA
Chair, Class III Institutional Pharmacy Permit Rules Subcommittee

C. Erica White, MBA, JD
Executive Director

Thursday, April 19, 2018

Those present for all or part of the Class III Institutional Pharmacy Permit Rules Subcommittee Discussion included the following:

BOARD MEMBERS PRESENT:

- Richard Montgomery, BPharm, MBA, Chair

COMMITTEE MEMBERS PRESENT:

- Dominic Bracero, MBA – Pharmacy Director, Florida Hospital, Central Fill Facility
- Heather Fuller, MBA, PharmD, MPharm, – Division Director of Pharmacy Services, North Florida - HCA
- Michael Magee, MS, RPh, FASHP – Vice-President of Pharmacy, BayCare Health System
- Thomas Johns, PharmD – Director of Pharmacy Services – University of Florida Health/Gainesville Campus

BOARD COUNSEL:

- David Flynn, Assistant Attorney General
- Lawrence Harris, Assistant Attorney General

STAFF PRESENT:

- C. Erica White, MBA, JD, Executive Director
- Robert DiFiore, RPh, Pharmaceutical Program Manager – Department of Health, Division of Medical Quality Assurance - Bureau of Enforcement

AUDIO from this meeting may can be found online: http://floridaspharmacy.gov/

The Subcommittee Discussion convened at approximately 9:01 a.m.

Introductions

Mr. Montgomery thanked everyone for being part of this brainstorming session, and facilitated the introductions of subcommittee members.

Overview of Rule Drafting

(*Facilitator – Lawrence Harris*)

Mr. Harris provided an overview of the rule drafting and rulemaking process. To the extent that rulemaking is required to implement or interpret the statute as changed by HB 675, this is what the subcommittee is going to focus on. This working group will come up with draft rules to bring back to the Full Board for voting.

The goal is to present to the Board the proposed rules from the subcommittee at the June 2018 meeting of the Board of Pharmacy, and after following the necessary publishing and public comments timeframes, Mr. Harris is hopeful that the rules implementing HB 675, would be published around the end of September 2018.

Review of Legislation/ Drafting of Permit Application
(*Facilitator – Richard Montgomery*)

Mr. Montgomery provided a review of the HB 675 legislation. The authority that Institutional Pharmacies were given in HB 675, in addition to the normal duties of dispensing, distributing, compounding, and filling prescriptions, includes the ability to prepackage of drug products instead of repackaging the drug products. Also conducting other pharmaceutical services for entities under common control, and the term "common control" is defined in the legislation. Provide medications and pharmaceutical services to an entity which holds a health care clinic establishment permit. This legislation helps align Florida with the federal government requirements. Also, it creates a permit for a central distribution facility, so under a Class III you can provide all pharmaceuticals to affiliated Class III institutions. Also, additional changes were made to Chapter 499, F.S., the Florida Drug and Cosmetic Act, which is administered by the Florida Department of Business and Professional Regulation. The effective date is July 1, 2018.

Dr. Johns stated that the legislation extends what each pharmacy facility is able to do, to include distribution. Mr. Flynn stated that this legislation allows a Class III to do everything a Class II Institutional Pharmacy can do, but now add distribution to those existing duties. Mr. Montgomery stated that there are no changes to FDA or FTC rules, this legislation just allows licensees to move product without permitting. The Trace and Trace stops at the front door of the pharmacy.

Mr. Magee stated this legislation extends the walls of the hospital. In the prepackage /repackage world, the hospital practice has been done under the guidance of USP for years. This is not changing, it is just going to be done in a health system instead of just a hospital – under a Class III. It is not reselling, but just being done under the common practices – repackage is not for resell, but for further distribution within the same entity. Dr. Johns said that in pharmacies under the Class II Institutional Pharmacies, perform these activities on a regular basis, and have been doing so under the context of existing regulations.

Mr. Magee explained the difference between Class II and Class III Institutional Pharmacies – the new developments in this legislation is the component related to central fill. Most common license associated with health systems are Modified Class 2B Institutional Pharmacies. Mr. DiFiore stated that Modified Class 2C Institutional Pharmacies are occasional, and Modified Class 2A Institutional Pharmacies are rare – from a permitting perspective. Mr. Montgomery stated that we have to figure out how to "marry up" these common entities under a Class III Permit.

Mr. Montgomery stated that this legislation only allows a Class III Institutional Pharmacy to receive product, but nothing else will change. The legislation will just allow a central fill or central hub pharmacy to able to move the necessary drugs, and also repackage those drugs centrally and move them without having a restrictive wholesale distribution license. Mr. Bracero stated that currently a Modified Class 2B Institutional Pharmacy cannot currently move product under the current legislation, and the rules should be written to allow this type of facility to be able to obtain the Class III license. Ms. White suggested that perhaps one way to facilitate the transition under the new legislation is to write the rules to allow a Modified Class 2B Institutional Pharmacy to relinquish their license and then be issued a new Class III license.

Dr. Johns described the current state of permitting in Florida. It is quite a complicated process, and the ultimate goal is to simplify the process of regulating this area. Dr. Johns is the Consultant of Record (COR) for a large Class II Institutional Pharmacy Permit – University of Florida Shands Teaching Hospital and Clinics, Inc. There are several permits associated with the under this permit:

- SSCP (Special Sterile Compounding Permit - does not anticipate this permit will change under this legislation)
- SLC (Special Limited Community Permit - does not anticipate this permit will change under this legislation)
- Four (4) COMM (Community Pharmacy Permits - does not anticipate these permits will change under this legislation)
- SPE (Special P/E Permit - does not anticipate this permit will change under this legislation)
- Series of Ten (10) Modified Class 2B Institutional Pharmacies (does anticipate these permits will change under this legislation)
    - 2 Free Standing Emergency Departments;
    - Ambulatory Wound Care Center;
    - Surgery Centers;
    - Endoscopy Centers; and
    - Dialysis Centers

Dr. Johns' vision for this legislation would be to "convert" the Modified Class 2B Institutional Pharmacies to Class III Pharmacies. Also to "convert" the main Class II Institutional Pharmacy to a Class III Pharmacy, and by doing so it allows distribution between all of the entities which are in the Class III network under common control. In additional to what Dr. Johns described above, the central fill pharmacy would also be classified as a Class III to allow for distribution to all other Class III Pharmacies in the network.

Dr. Johns also mentioned that since this legislation is a modernization of the Institutional Pharmacy permits, what types of places in the future will want a Class II Institutional Pharmacy license? It may be some small critical access hospitals or some smaller rural hospitals that are not part of a network, but the majority of the Institutional permits going forward will be Class III's.

Lunch

The lunch break was skipped in order for participants to continue with completing the agenda.

Drafting of Rules (Break included)
(*Facilitator – Richard Montgomery*)

Mr. Harris asked for clarification for what "Other Pharmaceutical Services" language (looking at page 3 of 15, new Section 21, line 67) meant in the legislation. Mr. Magee responded and said that what the industry was perceiving (i.e. – BayCare) was that there might be other activities being conducted in the central distribution warehouse, which are not related to distribution. For example, BayCare has a transition of care program where pharmacist contact patients after discharge to make that they know how to take their medications properly. These pharmacists are housed at the central distribution facility. Also, there is a community benefit program, where anyone can call the central distribution facility to obtain help if they are having difficulty with

access to medications. Also centralized contracting is being performed at the BayCare central hub facility as well.

Mr. Harris also recommended that there be some kind of standard for the prepackaged drugs – whatever the current standard about the minimum requirements for the preparation for prepackaged drug products. Mr. Harris also discussed other rules within the Florida Administrative Code which required conforming changes as a result of this legislation (Chapter 64B16-28.501, F.A.C., 64B16-28.502, 64B16-28.602, F.A.C., 64B16-28.6021, F.A.C., 64B16-28.603,F.A.C., 64B16-28.604,F.A.C., 64B16-28.605,F.A.C., 64B16-28.606,F.A.C., and 64B16-28.810,F.A.C.)

7. **Summary –** Mr. Harris will get a draft Institutional Pharmacy permit form out to the committee, and Mr. Montgomery asked all committee members to review it and get back to Mr. Harris with their comments. Mr. Montgomery also asked all committee members to look through their policy and procedure manuals identify standards which could be used for benchmark purposes.

The Board Office will coordinate the next conference call of the committee around mid-May 2018. The committee members thanked Mr. Montgomery for coordinating the discussion on this topic, and he thanked the committee members for participating in the meeting.

8. **Public Comment**

Public comment was provided and taken by the committee throughout the discussion.

The Subcommittee Discussion convened at approximately 1:15 p.m.

TAB #3

REVISED DRAFT LANGUAGE - 15 MAY 2018

64B16-28.750 Class III Institutional Pharmacies.

(1)(a) Class III Institutional Pharmacies are those Institutional Pharmacies authorized by section 465.019(2)(d), F.S. All Class III Institutional Pharmacies must be affiliated with a hospital. An Institutional Pharmacy may hold only a Class III Institutional Pharmacy Permit, or may hold a Class III Institutional Permit in conjunction with other permits authorized by Florida statute or administrative rule.

(b) A Class III Institutional Permit may be issued as an initial permit; ~~In addition~~ to existing Class II or Modified Class II Institutional Pharmacy Permittees; or ~~, Class III Institutional Pharmacy permits may be issued~~ to Central Distribution Facilities under common control with a hospital.

(2) Applicants for a Class III Institutional Pharmacy permit must complete an application for a permit using an original Form DH-MQA XXX , "Class III Institutional Pharmacy Permit Application and Information," Rev 06/18, which is incorporated by reference herein and is available at http://www.flrules.org/Gateway/reference.asp?No=Ref- . Applicants for an Institutional Pharmacy Permit must designate a consultant pharmacist of record as required by Section 465.019, F.S. and Rule 64B16-28.501, F.A.C.

(3) A copy of the permittee's policy and procedure manual as provided herein shall accompany the permit application. The original policy and procedure manual shall be kept within the Class III Institutional Pharmacy and shall be available for inspection by the Department of Health or authorized representative of the Board.

(4)(a) The policy and procedure manual of facilities which are issued a Class III Institutional Permit shall, at a minimum, include the following:

1. The process for designation of the consultant pharmacist responsible for pharmaceutical services, including maintenance of drug records required by law and drug handling procedures.

2. Safe practices for the preparation, dispensing, prepackaging, distribution, and transportation of medicinal drugs and prepackaged drug products.

3. Provisions for maintaining records to monitor the movement, dispensing, distribution, and transportation of medicinal drugs and prepackaged drug products.

4. Provisions for maintaining records of pharmacy staff responsible for each step in the preparation, dispensing, prepackaging, transportation, and distribution of medicinal drugs and prepackaged drug products.

5. Identification of medicinal drugs and prepackaged drug products that may not be safely distributed among Class III Institutional Pharmacies and health care establishment permittees.

6. If an Institutional Formulary system is to be adopted and used, the policies and procedures for the development and approval of the system.

7. The establishment of a Pharmacy Services Committee which shall meet at least annually.

8. Provisions for the secure ordering, storage and recordkeeping of all medicinal drugs at the facility.

9. Provisions for the utilization of a perpetual inventory system for all controlled substances.

10. Provisions to ensure prepackaged drug products are not adulterated and are free of contamination or cross-contamination.

11. Provisions to ensure medicinal drugs and prepackaged drug products are transported according to manufacturer's recommended guidelines for storage and transportation, including exposure to light, heat, etc.

12. Provisions regarding compliance with all state and Federal laws, regulations, and rules regarding controlled substances, including ordering, inventory and anti-diversion mechanisms.

13. Provisions regarding the labeling of medicinal drugs and prepackaged drug products, including, if applicable, labels related to transfers between Class III pharmacies, transportation requirements, or safe handling/hazardous precautions.

(b) The Class III Institutional Pharmacy's policies and procedures shall be based upon authoritative literature, studies, and materials generally accepted and commonly relied upon by the Pharmacy and

pharmaceutical professions, which must be identified in the policies and procedures.

(c) In addition to the policies and procedures manual, the Class III Institutional Pharmacy shall create and maintain documentation of: the hospital with which the permittee is affiliated; all other entities eligible to hold a Class III Institutional Pharmacy Permit under common control with the permittee; all health care clinic establishments under common control with the permittee; and the way/manner in which the permittee and other entities are under common control. Such documentation shall be maintained by the permittee and shall be available for review by a Department Inspector or authorized agent of the Board.

(d) Pursuant to section 465.022(4), F.S., each applicant must attach to the application the applicant's written policies and procedures for preventing controlled substance dispensing based on fraudulent representations or invalid practitioner-patient relationships. The policy and procedure manual shall contain, at a minimum, the following:

1. Provisions to identify and guard against invalid practitioner-patient relationships.
2. Provisions to guard against filling fraudulent prescriptions for controlled substances.
3. Provisions to identify prescriptions that are communicated or transmitted legally.
4. Provisions to identify the characteristics of a forged or altered prescription.

(5) As required by Rule 64B16-28.100(1)(c), F.A.C., prior to issuance of a Class III Institutional Pharmacy Permit, the applicant must pass an on-site inspection. For applicants who currently hold Institutional Class II or Modified Class II permits, the on-site inspection required for issuance of the Class III permit shall be coordinated, to the extent practicable, with any other inspections required or recently conducted, and in no event, shall reset or disrupt the permittee's existing inspection schedule.

(6) Each applicant must comply with the fingerprinting requirements of section 465.022, F.S., unless the applicant qualifies for the statutory exception for corporations having more than $100 million of business taxable assets in Florida. Electronic fingerprint information ("EFI") that has been submitted to the Florida Agency for Health Care Administration may be accessible by the Florida Department of Health for a period of sixty (60) months. If the Department is able to access EFI from AHCA, applicants will not be required to resubmit EFI for additional or new applications submitted during this time period. After sixty (60) months, new electronic fingerprint information must be submitted as part of all applications, unless the applicant is a corporation having more than $100 million of business taxable assets in Florida.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.019(2)(d), 465.022 FS. History–New _____

TAB #4

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

CLASS III INSTITUTIONAL PHARMACY PERMIT APPLICATION AND INFORMATION

June 2018

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 info@floridaspharmacy.gov 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 Board of Pharmacy

CLASS III INSTITUTIONAL PHARMACY PERMIT APPLICATION INFORMATION

A Class III Institutional Pharmacy permit is required prior to performing any of the activities enumerated in section 465.019(2)(d)1., F.S., including operating a central distribution facility and preparing prepackaged drug products and performing other pharmaceutical services for entities under common control. A Class III Institutional Pharmacy must be affiliated with a hospital. 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 (COR). A Class III Institutional Pharmacy permit may be issued to entities already holding other permits from the Board, including Class II and Modified Class II Institutional pharmacy permits.

There are three ~~two~~ classes of entities which may be issued Class III Institutional Pharmacy Permits. Please read the description below. Check which permit type you are applying for on the application.

1. Institutional Pharmacies that provide the same services as authorized for Class II Institutional Pharmacies.

Institutional Class II Pharmacies employ 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.

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.

2. Currently permitted Class II or Modified Class II Institutional Pharmacies.

Pharmacies currently permitted as Class II or Modified Class II Institutional Pharmacies may apply for a Class III Institutional Pharmacy permit. If issued a Class III Institutional Pharmacy permit, these existing permittees may continue to hold both a Class II/Modified Class II Institutional Pharmacy Permit and a Class III Institutional Pharmacy Permit, or may choose to relinquish any existing permit(s) and hold only a Class III Institutional Pharmacy permit.

3. Central Distribution Facilities are facilities under common control with a hospital that has been issued a Class III Institutional Pharmacy permit. Central Distribution Facilities dispense, distribute, compound, and fill prescriptions; prepare prepackaged drug products for entities under common control with the hospital and the Central Distribution Facility; and conduct other pharmaceutical services for entities under common control.

Section 465.022(4), Florida Statutes, also provides that an application for a pharmacy permit must include the applicant's written policies and procedures for preventing controlled substance dispensing based on fraudulent representations or invalid practitioner-patient relationships. The policy and procedure manual shall contain the procedures implemented to minimize the dispensing of controlled substances based on fraudulent representations as follows:

1. Provisions to identify and guard against invalid practitioner-patient relationships.
2. Provisions to guard against filling fraudulent prescriptions for controlled substances.

3. Provisions to identify prescriptions that are communicated or transmitted legally.
4. Provisions to identify the characteristics of a forged or altered prescription.

Application Processing

Please read all application instructions before completing your application.

1) Mail Application.

Please mail the application and the $255.00 application fee (cashier's check or money order made payable to the FLORIDA DEPARTMENT OF HEALTH) to the following address:

Application & Fees:
Department of Health
Board of Pharmacy
P.O. Box 6320
Tallahassee, Florida 32314-6320

Express Mail ONLY
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 set up an inspection appointment. 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 owners, officers, and Consultant Pharmacists of Record (CORs) are required to submit a set of fingerprints unless the corporation is exempt under 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 COR to submit fingerprints.

Electronic fingerprint information ("EFI") that has been submitted to the Florida Agency for Health Care Administration may be accessible by the Florida Department of Health for a period of sixty (60) months. If the Department is able to access EFI from AHCA, applicants will not be required to resubmit EFI for additional or new applications submitted during this time period. After sixty (60) months, new electronic fingerprint information must be submitted as part of all applications. **Note: If your officer, owner, or Consultant Pharmacist of Record has already been fingerprinted at the time you are completing this Institutional Pharmacy permit application, please ensure to provide the Transaction Control Number (TCN), if known, with the requested information in the application.**

Applicants may 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.

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:

http://www.floridahealth.gov/licensing-and-regulation/background-screening/livescan-service-providers.html

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

- 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.
- You must provide the correct ORI number.

Where do I get the ORI number to submit to the vendor?
The ORI number for the pharmacy profession is **EDOH4680Z**.

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).

3) Privacy Statement and Attestation

In order for the Board of Pharmacy Office to receive your Livescan electronic fingerprinting results, you must affirm that you have been provided with and read the attached statement from the Florida Department of Law Enforcement regarding the sharing, retention, and right to challenge incorrect criminal history records, and the "Privacy Statement" document from the Federal Bureau of Investigation. The appropriate form(s) to provide this affirmation are included within Items #1 and #2 of the application.

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 7 - 14 days from your satisfactory inspection before checking on the status of your permit**.

You may look up your license number on our website at http://www.flhealthsource.com/ under "Verify a License."

Drug Enforcement Administration (DEA)

Please note that the DEA will not issue a registration until the Florida Board of Pharmacy has issued a pharmacy permit. More information is available by visiting the DEA website at http://www.DEAdiversion.usdoj.gov, or by contacting them at (800)667-9752.

IMPORTANT NOTICE: Pursuant to Section 465.022(5), F.S., the Department or Board shall deny an application for a pharmacy permit if the applicant or an affiliated person, partner,

officer, director, or consultant pharmacist of record of the applicant:

(a) Has obtained a permit by misrepresentation or fraud.

(b) Has attempted to procure, or has procured, a permit for any other person by making, or causing to be made, any false representation.

(c) 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.

(d) 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.

(e) 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.

(f) 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.

(g) 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.

(h) 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.

(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.

For felonies in which the defendant entered a plea of guilty or nolo contendere in an agreement with the court to enter a pretrial intervention or drug diversion program, the department shall deny the application if upon final resolution of the case the licensee has failed to successfully complete the program.

<u>If applicable to you, please provide the documentation to the Florida Board of Pharmacy.</u>

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 cannot be granted until the application is complete.

INSTITUTIONAL PHARMACY PERMIT

_____ All Application Questions Answered?

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

_____ Articles of Incorporation paperwork from the Secretary of State provided?

_____ COR Designation and Privacy Statement Acknowledgement provided (Application Item #1)?

_____ Affiliate/Owner Privacy Statement Acknowledgement provided for each affiliate/owner (Application Item #2)?

_____ Answers to Policy and Procedure Questions provided for applicants (Application Item #3)?

_____ Applicant/Affiliate/Owner supplemental documents provided for explaining any previous ownership, disciplinary actions, voluntary relinquishments and/or criminal activity?

_____ Applicant/Affiliate/Owner pharmacy permit questions answered and supplemental documents provided?

_____ Policies and Procedures for preventing controlled substance dispensing based on fraudulent representations or invalid practitioner-patient relationships submitted?

_____ Policies and Procedures for items identified in section 465.019(2)(d)2.a.- e., F.S. submitted?

FLORIDA BOARD OF PHARMACY
P.O. Box 6320
Tallahassee, FL 32314-6320
850-245-4292
http://www.floridaspharmacy.gov

CLASS III INSTITUTIONAL PHARMACY PERMIT

APPLICATION

Type of Facility – Please choose only one of the following:	
____Current Class II Institutional permittee	____Central Distribution Facility
____Current Modified Class II Institutional permittee	____No current Florida pharmacy permit(s)

SECTION A.

Please list your Federal Employer Identification Number:

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

3. Mailing Address

City	**State**	**Zip**

4. Physical Address

City	**State**	**Zip**

5. Name of Hospital with which Applicant is affiliated.

6. Consultant Pharmacist of Record (COR) Information

Name	**License Number**

Email Address ** (see note below)	**Telephone Number**
7. Contact Person	**Title**
Email Address ** (see note below)	**Telephone Number**

NOTE: Under Florida law, email addresses are public records. If you do not want your e-mail address released in response to a public records request, do not provide an email address or send electronic mail to our office. Instead contact the office by phone or in writing.

8. Ownership Information

a Type of Ownership _____Corporation _____Partnership _____Other

NOTE: If the applicant is a corporation, limited partnership, or other business entity, you must include with your application a copy of the Articles of Incorporation on file with the Florida Secretary of State's office.

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

Yes _____ No_____

c. Does the corporation have more than $100 million of business taxable assets in this state? *If yes, provide attestation from Certified Public Accountant for previous tax year or Florida Corporate Income /Franchise and Emergency Excise Tax Return (F-1120).*

Yes _____ No_____

d. List all the owners and officers of the corporation. Each person listed below having an ownership interest of 5% 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 8c. If 8c. is "Yes", please list the owners below and only submit fingerprints for the Consultant Pharmacist of Record. If 8c. is "Yes" and the prints are on file with DOH or AHCA and available to the Board of Pharmacy, the requirement to submit the prints for this person is met. Also, if the % of Ownership column does not add to 100%, please provide an explanation. *Attach a separate sheet if necessary.*

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

9. Has anyone listed in 8d. 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? *If yes, please provide a signed statement disclosing the reason the entity was closed.*

Yes_____ No_____

9a. Has anyone listed in 8d. had an ownership interest of 5% or more in a pharmacy or any other business permit which was voluntarily relinquished or closed voluntarily within the past 5 years? *If yes, please provide a signed statement disclosing the reason the entity was closed.*

Yes _____ No _____

Pursuant to Section 465.022(5), the questions 10 – 18 are being asked. If you answer "Yes" to any of the following questions, explain on a separate sheet providing accurate details and submit copies of supporting documentation.

10. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant obtained a permit by misrepresentation or fraud?

Yes _____ No_____

11. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant attempted to procure, or has procured, a permit for any other person by making, or causing to be made, any false representation?

Yes _____ No _____

12. 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 crime in any jurisdiction which relates to the practice of, or the ability to practice, the profession of pharmacy?

Yes _____ No_____

13. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant ever 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?

Yes_____ No_____

14. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant ever 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?

Yes _____ No_____

15. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant 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?

Yes _____ No _____

16. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant 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?

Yes _____ No _____

17. 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 Human Services Office of Inspector General's List of Excluded Individuals and Entities? *(If yes, please submit proof.)*

Yes _____ No _____

18. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant 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?

Yes _____ No _____

19. Are you currently registered or permitted in Florida or 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

20. 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 _____

Individual's Name	Pharmacy Name	State	Status

21. 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?

Yes _____ No _____

22. Has the applicant, affiliated person, partner, officer, or director ever been convicted of a felony or misdemeanor, excluding minor traffic convictions? 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.

Yes _____ No _____

23. Does the applicant, affiliated person, partner, officer, director have any outstanding fines, liens or overpayments assessed by a final order of the department? *(If yes, please answer question #23a.)*

Yes _____ No _____

23a. Does the applicant, affiliated person, partner, officer, director have a repayment plan approved by the department?
Yes _____ No _____
24. Is the applicant, affiliated persons, partners, officers, or directors, under investigation or prosecution for a crime in any jurisdiction?
Yes _____ No_____
25. Is the applicant, affiliated persons, partners, officers, or directors, under investigation or pending administrative action by the licensing authority of any jurisdiction, including its agencies and subdivisions?
Yes _____ No_____

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.

I swear and affirm 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 item, 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 _____ DATE_____
(Owner or officer of establishment)

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).

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.

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.floridahealth.gov/licensing-and-regulation/background-screening/livescan-service-providers.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)***;
- 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:_____ SSN#: _____ - ____ - _____

Aliases:_____

Address: _____ Apt. Number: _____

City:_____ State: _____Zip Code: _____

Date of Birth: _____/_____/_____ Place of Birth: _____
(MM/DD/YYYY)

Weight: _____ Height: _____ Eye Color:_____ Hair Color: _____

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

Sex: _____
(M=Male; F=Female)

Citizenship: _____

Transaction Control Number (TCN#):_____
(*This will be provided to you by the Live Scan Service provider*.)

Keep this form for your records.

Item #1- Consultant Pharmacist of Record Designation and Privacy Statement Acknowledgement

To: **Florida Board of Pharmacy**
Post Office Box 6320
Tallahassee, FL 32314-6320
(850) 245-4292- phone
(850) 413-6982 - fax
MQAPharmPDMAffiliate@flhealth.gov

File #: (if known)**:**
License #: (if applicable)**:**

Section A. Consultant Pharmacist of Record (COR) Designation

Applicant/Pharmacy Name:		
Applicant/Pharmacy Mailing Address:		
City	**State**	**Zip**
Incoming COR Name:		**License#:**
		PU
Date Beginning as COR:	**Incoming COR Signature**	

Transaction Control Number (TCN) – related to Livescan Fingerprints *(optional, if known)***:**
** For more information regarding Livescan Fingerprints to: http://flhealthsource.gov/bgs-faqs**

****OPTIONAL: Only provide following information if there is an Outgoing COR at current pharmacy****

Outgoing COR Name:	**License#:**
	PU
Date Ending as COR:	**Outgoing COR Signature** *(optional)*

Section B. Incoming COR Privacy Statement Acknowledgement

Note: Acknowledgment should be completed by same person listed in Section A above as Incoming COR.

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."

Date:	**Incoming COR Signature**

Item #2- Affiliate/Owner Privacy Statement Acknowledgement

To be completed by EACH Affiliate/Owner listed in the application.

To: **Florida Board of Pharmacy, Post Office Box 6320, Tallahassee, FL 32314-6320**
(850) 245-4292- phone * (850) 413-6982 – fax * MQAPharmPDMAffiliate@flhealth.gov

From:

Affiliate / Owner Name:		**File # (required):**
Applicant Name:		
Affiliate/Owner Mailing Address:		
City	**State**	**Zip**
Affiliate/Owner E-Mail ** (see note below)	**Affiliate/Owner Telephone Number**	
Affiliate/Owner Transaction Control Number (TCN) *(optional, if known)*: ** For more information regarding Livescan Fingerprints to: http://flhealthsource.gov/bgs-faqs**		
NOTE: Under Florida law, email addresses are public records. If you do not want your e-mail address released in response to a public records request, do not provide an email address or send electronic mail to our office. Instead contact the office by phone or in writing.		

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."

_____ _____

Affiliate/Owner Signature (Required) **Date (of signature)**

Policy and Procedure Questions

To be completed by Class III Institutional Pharmacy Permit Applicants

The Consultant Pharmacist of Record is responsible for developing and maintaining a current policy and procedure manual. A copy of the permittee's policy and procedure manual as provided herein shall accompany the permit application. The original policy and procedure manual shall be kept within the Class III Institutional Pharmacy and shall be available for inspection by the Department of Health. 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 facility.

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

4) Describe the process for designation of the consultant pharmacist responsible for pharmaceutical services.

5) Describe practices and procedures for the preparation, dispensing, prepackaging, distribution, and transportation of medicinal drugs and prepackaged drug products.

6) Describe practices and procedures for maintaining records to monitor the movement, dispensing, distribution, and transportation of medicinal drugs and prepackaged drug products.

7) Describe practices and procedures for maintaining records of pharmacy staff responsible for each step in the preparation, dispensing, prepackaging, transportation, and distribution of medicinal drugs and prepackaged drug products.

8) Describe practices and procedures for identification of medicinal drugs and prepackaged drug products that may not be safely distributed among Class III Institutional Pharmacies and Health Care Establishment Permits under common control.

9) If an Institutional Formulary system is to be adopted and used, describe the policies and procedures for the development and approval of the system.

10) Describe practices and procedures for the establishment of a Pharmacy Services Committee which shall meet at least annually.

11) Describe practices and procedures for the secure ordering, storage and recordkeeping of all medicinal drugs at the facility.

12) Describe practices and procedures for the utilization of a perpetual inventory system for all controlled substances.

13) Describe practices and procedures to ensure prepackaged drug products are not adulterated and are free of contamination or cross-contamination.

14) Describe practices and procedures to ensure medicinal drugs and prepackaged drug products are transported according to manufacturer's recommended guidelines for storage and transportation, including exposure to light, heat, etc.

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

16) Describe the Quality Assurance Program.

17) Provide a statement regarding legal compliance, regulations, and authoritative literature to be used by the Consultant Pharmacist of Record to ensure the permittee's compliance with the laws and rules governing the practice and operation of the permittee and the preparation, dispensing, prepackaging, distribution, and transportation of medicinal drugs and prepackaged drug products, to include:
    a. Chapters 465 and 893, F.S., and Rule Title 64B16,F.A.C.
    b. Relevant Federal laws and regulations;
    c. Authoritative (peer reviewed) literature, reports or studies.

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

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

TAB #5

Change of Permit Association – Class III Pharmacy

Section 465.019(2)(d), F.S., provides that "Class III institutional pharmacies" are those institutional pharmacies, including central distribution facilities, affiliated with a hospital that provide the same services that are authorized by a Class II institutional pharmacy permit. Rule 64B16-28.750, F.A.C., provides that all Class III Institutional Pharmacies must be affiliated with a hospital.

This request for a change of permit association allows a Class II Institutional Pharmacy, who currently holds an **active** pharmacy permit, to change its pharmacy permit association from a Class II Institutional Pharmacy association to a Class III Pharmacy association. Rule 64B16-28.2021(1), F.A.C., provides that a pharmacy permit is not transferable. If there is any change in the identity (i.e. – change in the entity's Federal Employer Identification Number) of the business entity which holds the current pharmacy permit, a new application must be completed and a new permit obtained.

Application Type – Please choose one of the following:	
___ Change of Permit Association ($255.00 fee) **Complete: Section A only.**	___ Change of Location ($100.00 fee) **Complete: Sections A and B.**
Pharmacy Permit Type – Please choose only one of the following:	
____Institutional Class II	Modified Institutional Class II A ___Class II B____ Class II C___

SECTION A. Please complete for all Application Types

Please provide your existing Pharmacy Permit Number:	
Please list your Federal Employer Identification Number:	
Please provide your existing Federal DEA Number:	
1. Will your company's FEIN change as a result of this Change of Permit Association?	
Yes_____ No _____ *NOTE: If yes, please stop and obtain a Change of Ownership form.*	
2. Corporate Name	**Telephone Number**
3. Doing Business As (d/b/a)	**E-Mail Address**** (see note below)
4. Mailing Address	
City	**State** / **Zip**
5. Physical Address	
City	**State** / **Zip**
6. Consultant Pharmacist of Record (COR) Information	
Name	**License Number**
Email Address ** (see note below)	**Telephone Number**

NOTE: Under Florida law, email addresses are public records. If you do not want your e-mail released in response to a public records request, do not provide an email or send e-mail to our office. Instead contact the office by phone or in writing..

SECTION B. Please complete for Change of Location.

1. Current Practice Location Address

City	**State**	**Zip**

E-Mail Address** (see note below)	**Telephone Number**

2. New Practice Location Address

City	**State**	**Zip**

E-Mail Address** (see note below)	**Telephone Number**

NOTE: Under Florida law, email addresses are public records. If you do not want your e-mail released in response to a public records request, do not provide an email or send e-mail to our office. Instead contact the office by phone or in writing.

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.

I swear and affirm 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 item, 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 _____ DATE_____
(Owner or officer of establishment)

Policy and Procedure Questions

To be completed by Class III Institutional Pharmacy Permit Applicants

The Consultant Pharmacist of Record is responsible for developing and maintaining a current policy and procedure manual. A copy of the permittee's policy and procedure manual as provided herein shall accompany the permit application. The original policy and procedure manual shall be kept within the Class III Institutional Pharmacy and shall be available for inspection by the Department of Health. 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 facility.

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

4) Describe the process for designation of the consultant pharmacist responsible for pharmaceutical services.

5) Describe practices and procedures for the preparation, dispensing, prepackaging, distribution, and transportation of medicinal drugs and prepackaged drug products.

6) Describe practices and procedures for maintaining records to monitor the movement, dispensing, distribution, and transportation of medicinal drugs and prepackaged drug products.

7) Describe practices and procedures for maintaining records of pharmacy staff responsible for each step in the preparation, dispensing, prepackaging, transportation, and distribution of medicinal drugs and prepackaged drug products.

8) Describe practices and procedures for identification of medicinal drugs and prepackaged drug products that may not be safely distributed among Class III Institutional Pharmacies and Health Care Establishment Permits under common control.

9) If an Institutional Formulary system is to be adopted and used, describe the policies and procedures for the development and approval of the system.

10) Describe practices and procedures for the establishment of a Pharmacy Services Committee which shall meet at least annually.

11) Describe practices and procedures for the secure ordering, storage and recordkeeping of all medicinal drugs at the facility.

12) Describe practices and procedures for the utilization of a perpetual inventory system for all controlled substances.

13) Describe practices and procedures to ensure prepackaged drug products are not adulterated and are free of contamination or cross-contamination.

14) Describe practices and procedures to ensure medicinal drugs and prepackaged drug products are transported according to manufacturer's recommended guidelines for storage and transportation, including exposure to light, heat, etc.

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

16) Describe the Quality Assurance Program.

17) Provide a statement regarding legal compliance, regulations, and authoritative literature to be used by the Consultant Pharmacist of Record to ensure the permittee's compliance with the laws and rules governing the practice and operation of the permittee and the preparation, dispensing, prepackaging, distribution, and transportation of medicinal drugs and prepackaged drug products, to include:
    a. Chapters 465 and 893, F.S., and Rule Title 64B16,F.A.C.
    b. Relevant Federal laws and regulations;
    c. Authoritative (peer reviewed) literature, reports or studies.

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

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