DIVISION OF MEDICAL QUALITY ASSURANCE BOARD OF PHARMACY 4052 BALD CYPRESS WAY, BIN #C-04 TALLAHASSEE, FLORIDA 32399-3254 (850) 245-4474



CLASS III INSTITUTIONAL PHARMACY PERMIT APPLICATION AND INFORMATION

April 2023



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 call us at (850) 245-4474. 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 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.<u>Institutional Pharmacies that provide the same services as authorized for Class II Institutional Pharmacies.</u>

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 to 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. <u>Currently permitted Class II or Modified Class II Institutional Pharmacies.</u>

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.

As an alternative to issuance of a new Class III Institutional Pharmacy permit, an entity holding an active Class II or Modified Class II Institutional Pharmacy permit may have that permit reassociated as a Class III Institutional permit by completing form DOH/MQA/PH20. Re-association extinguishes the Class II/Modified Class II permit, and the existing permit number is re-associated to a Class III. Please see rule 64B16-28.750, F.A.C. and Form DOH/MQA/PH20 for more information.

3. <u>Central Distribution Facilities</u> 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 <u>will not receive</u> 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/livescanservice-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.

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

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. <u>Final approval for inspection cannot be granted until the application is complete.</u>

<u>INSTITU</u>	TIONAL 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 850-245-4474 http://www.floridaspharmacy.gov



APPLICATION

Application Type - Please choose	one of the follow	ving:		
New Establishment (\$255.00 fee Complete: Section A only, along with Iten	,	_		of Location (\$100.00 fee) Sections A and B <u>only</u> .
Change of Ownership (\$255.00 f Complete: Sections A and C <u>only</u> , along v	,	_		ansfer (no fee) Section A, pages 2-3 and Section D <u>only</u> .
Type of Facility - Please choose or	nly one of the fol	lowin	<u>g:</u>	
Current Class II Institutional pe	ermittee	_	Central D	Distribution Facility
Current Modified Class II Instit	utional permittee	-	No curre	nt Florida pharmacy permit(s)
Current Class III Institutional p	ermittee			
SECTION A.				
Please list your Federal Employe	r Identification N	umbe	r:	
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 A	applicant is affilia	ated	Existing Ph	narmacy Permit Number (If applicable)
6. Consultant Pharmacist of Reco	ord (COR) Inform	nation		
Name				License Number
Email Address ** (see note below)		Tele	phone Num	ber

7. Contact Person		Title	
Email Address ** (see note below)		Telephone Number	
		ou do not want your e-mail address released in respon- mail to our office. Instead contact the office by phone o	
8. Ownership Information			
a. Type of Ownership	CorporationP	artnershipOther	
		ip, or other business entity, you must include n file with the Florida Secretary of State's offic	
b. Are the applicants, officers,	directors, sharehold	ers, members and partners over the age of	f 18?
Yes No	_		
	blic Accountant for previo	n of business taxable assets in this state? ous tax year or Florida Corporate Income /Franch	•
Yes No			
interest of 5% or greater and a operation of the applicant including fingerprints and fees unless y only submit fingerprints for the file with DOH or AHCA and available.	iny person who, directuding officers and me ou answered yes to a e Consultant Pharma ailable to the Board of the % of Ownership	on. Each person listed below having an city or indirectly, manages, oversees, or combers of the board of directors must sub Bc. If 8c. is "Yes", please list the owners acist of Record. If 8c. is "Yes" and the profession of the requirement to submit the column does not add to 100%, please	controls the mit a set of below and rints are on e prints for provide an
Owner/Officer-Title	Date of Birth M	ailing Address, City, State, Zip Code	% of Ownership
	1 1		%
	1 1		%
	1 1		%
	sciplined, suspended,	st of 5% or more in a pharmacy or any oth revoked, or closed involuntarily within the the reason the entity was closed.	
Yes No	_		
	untarily relinquished	rest of 5% or more in a pharmacy or any or or closed voluntarily within the past 5 year on the entity was closed.	
Yes No			

following questions, explain on <u>a separate sheet</u> 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 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.)
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
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.)

17b. If response is "yes" are listed on the LEIE?	' to questi	on 17a, is the stu	dent Ioan default o	r delinquency the only reason you
Yes No				
applicant dispensed any prescription as defined believe that the purported includes a documented pestablish the diagnosis for the diagnosi	medicinal by s. 465.0 d prescrip patient eva or which a	drug based upor 03(14) or s. 893.0 tion is not based duation, including any drug is presc	n a communication 2 when the pharma upon a valid pract g history and a phy ribed and any othe	ree, or affiliated person of the that purports to be a cist knows or has reason to itioner-patient relationship that resical examination adequate to requirement established by hapter 464, or chapter 466?
Yes No				
19. Are you currently reg				states? (If yes, provide the state, y.)
Yes No State				
State		Permi	t Type	Permit Number
• •	(If yes, pro	vide the name of the	e pharmacy, the state v	Consultant Pharmacist of Record where the pharmacy is located and the
Yes No				
Individual's Name	Phar	macy Name	State	Status
21. Has any disciplinary a applicant, affiliated perso				rmit or registration issued to the pharmacist of record?
Yes No	_			
misdemeanor, excluding	minor traf	fic convictions?	You must include	been convicted of a felony or all misdemeanors and felonies, have a record of conviction.
Yes No				
23. Does the applicant, af overpayments assessed	•		•	any outstanding fines, liens or se answer <u>question #23a,</u>)
Yes No	_			

23a. Does the applicant, affiliated perso department?	n, partner, office	r, director have a re	payment plan approved by the
Yes No			
24. Is the applicant, affiliated persons, prosecution for a crime in any jurisdicti		s, or directors, und	er investigation or
Yes No			
25. Is the applicant, affiliated persons, administrative action by the licensing a subdivisions?			
Yes No			
SECTION B. Please complete for	or Change of	Location only.	
1. Current Practice Location Address			
City	State		Zip
E-Mail Address** (see note below)		Telephone Number	er
2. New Practice Location Address			
City	State		Zip
E-Mail Address** (see note below)		Telephone Number	er
Please provide your existing Pharmacy	Permit Number:		
Please provide your existing federal DE	A Number (If ap	plicable):	
** <u>NOTE:</u> Under Florida law, email addresses are p records request, do not provide an email address o			
SECTION C. Please complete for	or Change of	Ownership onl	<u>γ</u> .
1. Are you changing physical locations	s with this chang	e of ownership?	
Yes No	NOTE: If yes, ple	ease complete Section	n B above.
2. Please provide date when business	transaction for t	he change of owne	rship will be completed?
Date:			
3. Do you have a signed letter from bot permit license should be transferred?	——————————————————————————————————————		•
Yes No			

SECTION D. Please complete for Stock Transfer of Ownership Interests only.
Please provide the date when the transfer of ownership interest took place?
Date:
2. Did your company's FEIN change as a result of the transfer of ownership interest referenced in Section D, Question 1 above?
Yes No NOTE: If yes, please complete Section C above and include necessary fee.
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 chang 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 sai statements shall form the basis of my application and I do authorize the Florida Board of Pharmacy to make an 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 providin 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 <u>will not receive</u> 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 (MM/DD/YYYY)	e of Birth:	
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 S		

Keep this form for your records.



To:

Florida Board of Pharmacy

<u>Item #1- Consultant Pharmacist of Record</u> <u>Designation and Privacy Statement Acknowledgement</u>

To: Florida Board of Pharm Post Office Box 6320 Tallahassee, FL 32314- (850) 245-4474 - phone (850) 921-5389 - fax MQAPharmPDMAffiliate	6320 @flhealth.gov	File #: (if known): License #: (if applicable):
	Pharmacist of Record (COR)	Designation
Applicant/Pharmacy Name:		
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Applicant/Pharmacy Mailing	Address:	
City	State	Zip
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Incoming COR Name:		License#:
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Date Beginning as COR:	Incoming COR Signature	10
	r (TCN) – related to Livescan Fingerpr regarding Livescan Fingerprints go to:	



Item #2- Affiliate/Owner Privacy Statement Acknowledgement

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

Affiliate / Owner Name:			File # (required		
			i non (requirem		
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 go to: http://fihealthsource.gov/bgs-faqs **					
NOTE: Under Florida law, email addresses are public records. If you do not want your e-mail addressed in response to a public records request, do not provide an email address or send electro mail to our office. Instead contact the office by phone or in writing.					



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?