FLORIDA BOARD OF PHARMACY
Rules Sub-Committee Agenda
June 27, 2019
Teleconference Call
1-888-585-9008
Public Number: 599196982
1:00 P.M.

Participants in this public meeting should be aware that these proceedings are being recorded and that an audio file of the meeting will be posted to the board's website.

Thursday, June 27, 2019 at 1:00 p.m.

I. Call to Order/Roll Call

II. HB 19 – Prescription Drug Importation Program

- i. CS/HB 19
- ii. Rule 64B16-28.100, F.A.C.
- iii. Draft Application – International Export Pharmacy Permit

III. Old Business/New Business

IV. Public Comment

V. Adjournment

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

INTERNATIONAL EXPORT PHARMACY PERMIT APPLICATION

XXXX 20XX

International Export Pharmacy Permit Application Information

An International Export Pharmacy Permit as authorized by Section 465.0157, *Florida Statutes* is required to participate as an exporter of prescription drugs into Florida.

Definition:

For the purposes of this application:

1. "International export pharmacy" means a pharmacy located outside of the United States which holds an active and unencumbered permit under chapter 465 to export prescription drugs into this state.
2. "Affiliated persons" means any person who has an ownership interest of 5% or greater in the pharmacy and any person who directly or indirectly manages, oversees, or controls the operation of the pharmacy."
3. "PDM" means the designated pharmacist that insures compliance with all requirements pertaining to International Export Drug Program licensees.
4. "Pharmacist" means a person who is licensed or otherwise authorized to practice pharmacy in the jurisdiction in which they are located.

Application Processing

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

Department of Health
Board of Pharmacy
P.O. Box 6330
Tallahassee, Florida 32314-6320

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

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

2. Along with the application, International Export Pharmacies must submit the following:

a. Proof of an active and unencumbered license or permit to operate a pharmacy in compliance with the laws of the jurisdiction in which the dispensing facility is located and from which the exported drugs shall be exported.

b. Documentation demonstrating such jurisdiction is in a country with which the United States has a current mutual recognition agreement, cooperative agreement, memorandum of understanding, or other federal mechanism recognizing the country's adherence to current good manufacturing practices for pharmaceutical products.

c. Submit the address, city, country, names, and titles of all principal corporate officers and the pharmacist who serves as the prescription department manager, as provided for in 64B16-27.450, F.A.C., for the prescription drugs exported into this state under the International Prescription Drug Importation Program.

d. Submit a written attestation by an owner or officer of the applicant and by the applicant's prescription department manager that:

- The attestor has read and understands the laws and rules governing the manufacture, distribution, and dispensing of prescription drugs in this state;
- A prescription drug shipped, mailed, or delivered into this state meets or exceeds this state's standards for safety and efficacy; and
- A prescription drug product shipped, mailed, or delivered into this state must not have been, or may not be, manufactured or distributed in violation of the laws and rules of the jurisdiction in which the applicant is located and from which the prescription drugs shall be exported.

e. Submit a current inspection report from an inspection conducted by the regulatory or licensing agency of the jurisdiction in which the applicant is located. The inspection report must reflect compliance with this section and is only valid if the inspection was conducted within **six (6) months** before the date of applying for an initial permit:

- If an applicant is unable to submit a current inspection report due to acceptable circumstances as stated in rule 64BXX-XX.XXX, the Department , or if an inspection has not been performed within the six (6) months before the date of applying for an initial permit, shall:
  - Conduct, or contract with an entity to conduct, an onsite inspection for which all costs shall be borne by the applicant;
  - Accept a satisfactory inspection report, as determined by rule 64BXX-XX.XXX, from an entity approved by the Board completed within six (6) months before the date of the application; or
  - Accept an inspection report from the United States Food and Drug Administration conducted pursuant to the federal Drug Quality and Security Act, Pu. L. No. 113-54 completed within six (6) months before the date of the application.

f. Submit documentation establishing that the applicant is in compliance with the financial responsibility and requirements as established in rule 64BXX-XX.XXX.

g. Submit documentation establishing the Prescription Department Manager's license as a pharmacist, or authorization to dispense prescription drugs in the jurisdiction where the applicant is located.

3. 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).

5. 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.

6. Policies and procedures – requires committee and board discussion.

FLORIDA BOARD OF PHARMACY
P.O. Box 6330 | Tallahassee, FL 32314
(850) 245-4474 | www.floridaspharmacy.gov

INTERNATIONAL EXPORT PHARMACY PERMIT APPLICATION

Please submit the application fee and unlicensed activity fee totaling $255 with your application.

Federal Employer Identification Number (FEIN)

1. Corporate Name | **Telephone Number**

2. Doing Business As (d/b/a) | **E-Mail Address (Optional)**

3. Mailing Address

City | State | Zip Code | Country

4. Physical Address of dispensing facility

City | State | Zip Code | Country

5. Prescription Department Manager (PDM) or equivalent

Name | License No. | Start Date

6. Contact Person | **Telephone Number**

7. DEA Registration Number (If applicable)

8. Date of last inspection: Day_____Month _____Year _____

Inspecting Authority_____

9. Was this inspection in compliance with section 456.0157, Florida statutes? (Attach a copy of the inspection report, the floor plan and your policies and procedures manual).

_____Yes _____No

10. Operating Hours

Monday-Friday: Open_____Close: _____

Saturday: Open_____Close: _____

Sunday: Open_____Close: _____

11. Ownership Information

a. Type of Ownership

_____Individual_____Corporation_____Partnership_____Other:_____

CORPORATIONS & LIMITED PARTNERSHIPS: INCLUDE A COPY OF THE ARTICLES OF INCORPORATION ON FILE WITH THE STATE WHERE THE FACILITY IS LOCATED.

b. List each principal, officer, agent, managing employee or affiliated person of the applicant.

Attach a separate sheet if necessary.

Name/Title	Date of Birth	Mailing Address, City State, Zip Code	% Ownership
	/ /		%
	/ /		%
	/ /		%

Questions 12 through 18 are required pursuant to Section 456.0635(2), *Florida Statutes*. Please explain any "yes" answered to the following questions on a separate sheet, providing as much detail as possible. Supporting documentation must include at a minimum the official charging document and the official judgment and sentence.

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 felony under Chapter 409, Chapter 817, or Chapter 893, Florida Statutes or a similar felony offense committed in another state or jurisdiction? (If "no", skip to question 15.)

Yes_____ No _____

If "yes", for the felonies of the first or second degree (or the equivalent level of felony in another state or jurisdiction), has it been more than 15 years from the date of the plea, sentence and completion of any subsequent probation?

Yes_____ No _____

If "yes", for the felonies of the third degree (or the equivalent level of felony in another state or jurisdiction), has it been more than 10 years from the date of the plea, sentence and completion of any subsequent probation? This question does not apply to felonies of the third degree under Section 893.13(6)(a), Florida Statutes or a similar felony offense committed in another state or jurisdiction.

Yes_____ No_____

If "yes", for the felonies of the third degree (or the equivalent level of felony in another state or jurisdiction) under Section 893.13(6)(a), Florida Statutes or a similar felony offense committed in another state or jurisdiction has it been more than 5 years from the date of the plea, sentence and completion of any subsequent probation?

Yes_____ No_____

If "yes", has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant successfully completed a drug court program that resulted in the plea for the felony offense being withdrawn or the charges dismissed?

Yes_____ No _____

13. 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 to a felony under 21 U.S.C. ss. 801-970 or 42 U.S.C. ss. 1395-1396 (relating to public health, welfare, Medicare and Medicaid issues)? (If "no", skip to question 16.)

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

If *"yes"*, is the date of application more than 15 years after the sentence and any subsequent period of probation ended?

Yes_____ No_____

14. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant ever been terminated for cause from the Florida Medicaid Program pursuant to Section 409.913, Florida Statutes? (If "no", skip to question 17.)

Yes_____ No _____

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

Yes_____ No _____

15. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant ever been terminated for cause, pursuant to the appeals procedures established by the state or from any other state Medicaid program? (If "no", skip to question 18)

Yes_____ No _____

If "yes", has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant been in good standing with a state Medicaid program for the most recent five years?

Yes_____ No _____

If "yes", did the termination occur at least 20 years prior to the date of this application?

Yes_____ No _____

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

Yes_____ No_____

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

Yes_____ No _____

State	Permit Type	Permit Number

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

Yes_____ No_____(If yes, please list them below, you may provide additional sheet)

Pharmacy Name	State	Status

19. Has any disciplinary action ever been taken against any license, permit or registration issued to the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant in this state or any other?

Yes_____ No_____(If yes, explain on a separate sheet providing accurate details and submit documentation from the licensing agency who took the disciplinary action)

20. Has any principal, officer, agent, managing employee, affiliated person of the applicant ever been convicted of a felony or misdemeanor, excluding minor traffic convictions?

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

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

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

22. Does the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant have any outstanding fines, liens or overpayments assessed by a final order of the department?

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

***If "yes",* does the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant have a repayment plan approved by the department?**

Yes_____ No _____

23. Has the applicant received an FDA Form 483 or Warning Letter following an inspection conducted by the FDA within the last 3 years?

Yes_____ No_____(If yes, please submit the Form 483 or Warning Letter, any corrective action plan, and supporting documentation demonstrating how the corrective action plan was implemented. Supporting documentation may include but is not limited to pictures, facility diagrams and updated policies and procedures.)

APPLICANT SIGNATURE PAGE

Florida law requires that applicants supplement their applications as needed to reflect any material change in any circumstances or conditions stated in the application that 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 of board.

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I, the undersigned, certify that the statements contained in this application are true, complete, and correct and I agree that said statements shall form the basis of my application. I do authorize the Florida Board of Pharmacy and the Department to make any investigations that they deem appropriate and to secure any additional information concerning the applicant or me. 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. I understand according to the Florida Board of Pharmacy Statutes that a Pharmacy Permit may be denied, revoked or suspended for presenting any false, fraudulent, or forged statement, certificate, diploma, or other thing, in connection with an application for a license or permit.

I, the undersigned, hereby acknowledge that providing false information in relation to this application, may result in denial of licensure, discipline, and/ or criminal penalties pursuant to sections: XXX.XX, XX.XXX, XXX.XX, XXX.XX and XXX.XX, *Florida Statutes*.

I, the undersigned, have completely reviewed and read the foregoing document and state that the facts stated in it are true.

SIGNATURE _____ TITLE_____DATE_____
Owner/Officer

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P.O. Box 6330 • Tallahassee, FL 32314-6320
Phone: (850) 245-4474
www.floridaspharmacy.gov

ATTESTATION

Section 465.0157 F.S., requires that applicants submit a written attestation by an owner or officer of the applicant and by the applicant's Prescription Department Manager (PDM).

I hereby attest:

1. *That I have read and understand the laws and rules governing the manufacture, distribution, and dispending of prescription drugs in the State of Florida;*
2. *That any prescription drug shipped, mailed, or delivered into the State of Florida from our facility meets or exceeds the State of Florida's standards for safety and efficacy; and*
3. *That any prescription drug product shipped, mailed, or delivered into this state has not been, and may not be, manufactured or distributed in violation of the laws and rules of jurisdiction in which the applicant is located and from the jurisdiction in which the applicant is located and from which the prescription drugs shall be exported.*

I declare that I have read the foregoing Attestation and that the facts stated in it are true.

SIGNATURE_____ TITLE_____ DATE_____
(Owner/Officer)

SIGNATURE_____ TITLE_____ DATE_____
(PDM)