

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



**COMMUNITY PHARMACY PERMIT APPLICATION AND
INFORMATION**

August 2012



Dear Florida Pharmacy Permit Applicant,

Thank you for applying for a pharmacy permit in the State of Florida. The information in this packet has been designed to provide the essential information required to process your application in a timely manner. Your assistance in providing all required information will enable the Florida Board of Pharmacy (the board) staff to process your application as soon as possible. You are encouraged to apply as early as possible, to avoid delays due to a large volume of applicants.

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

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

If you need to communicate with the board staff, you are encouraged to email the board staff at mqa_pharmacy@doh.state.fl.us, or you may 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

Community Pharmacy Permit Application Information

Whether opening a new establishment, changing locations, or changing owners, a pharmacy permit is required prior to operating in the State of Florida. The permit application must be completed and returned to the Florida Board of Pharmacy with the required fee of \$255.00. The application **MUST** have the original signatures of the owner or officer of the establishment and the Prescription Department Manager (PDM). If compounding sterile preparations, submit an additional application on Form DH-MQA 1220, "Special-Enteral and Parenteral Permit," and pay additional permitting fee.

A community pharmacy provides outpatient pharmacy services, and is open for a minimum of 40 hours per week unless reduced hours have been approved by the Board. Section 465.018, *Florida Statutes* (F.S.), requires a permit holder to designate a pharmacist licensed in the State of Florida as the manager of the prescription department. The Prescription Department Manager (PDM) is responsible for maintaining all drug records, providing for the security of the prescription department and following other such rules as relates to the practice of pharmacy. **Rule 64B16-27.104(5), F.A.C., mandates that a pharmacist may not be registered as the pharmacy manager for more than one pharmacy.**

The PDM is responsible for developing and maintaining a current policy and procedure manual. The permittee must make available the policy and procedure manual to the appropriate state or federal agencies upon inspection. Do not send the policy and procedure manual to the board office.

Application Processing

Please read all application instructions before completing your application.

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

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

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

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

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

2) Submit fingerprint results.

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

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

1. **How do I find a Livescan vendor in order to submit my fingerprints to the department?**

The Department of Health accepts electronic fingerprinting service offered by Livescan device vendors that are approved by the Florida Department of Law Enforcement and listed at their site. You can view the vendor options and contact information at www.doh.state.fl.us/mqa/pharmacy, select Apply for a License, select Pharmacy Permit Information, select Livescan vendor list.

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

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

b) You must provide the correct ORI number.

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

The ORI number for the pharmacy profession is FL924190Z

3) Attestation for Business Taxable Assets

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

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 30 days. **Please wait 30 days from your satisfactory inspection before checking on the status of your permit.** You may lookup your license number on our website at <http://www.doh.state.fl.us/mqa> under "Lookup Licensee."

Drug Enforcement Administration (DEA)

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

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

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

Mail completed DEA Form 224 via U.S. Postal service to the address listed on the form.

DEA applications are not required for a change of location or change of name. However, if your pharmacy does change locations, you are required to have a pharmacy inspection prior to operating in the new location and the inspector will contact the board office and the DEA to notify them of the change.

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

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

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

PRE-INSPECTION CHECKLIST

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

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

_____ Are all required signs displayed?

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

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

You may download a copy of the inspection form from the website at http://doh.state.fl.us/mqa/enforcement/359_Comm_Pharm.pdf



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

COMMUNITY PHARMACY PERMIT APPLICATION

Application Type – Please choose one of the following:

- New Establishment \$255 fee Additional Permit Type \$255 fee _____ (existing permit number)
- Change of Location \$100 fee _____ (existing permit number)
- Change of Ownership (a new permit number will be issued) \$255 _____ (existing permit number)

Will the Pharmacy Dispense Schedule II and/or III Controlled Substances? Yes No

Will the Pharmacy act as a Central Fill Pharmacy? Yes No

Please list your Federal Employer Identification Number: _____

1. Corporate Name	Telephone Number
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2. Doing Business As (d/b/a)	E-Mail Address
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3. Mailing Address	
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City	State	Zip
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4. Physical Address	
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City	State	Zip
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City	State	Zip
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City	State	Zip
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City	State	Zip
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City	State	Zip
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City	State	Zip
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City	State	Zip
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5. List the Prescription Department Manager (PDM)	
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Name	License No.	Start Date	PDM Signature
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6. Contact Person	Telephone Number
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7. DEA Registration Number	8. Date ready for inspection (within 90 days)
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9. Please provide the name, address, telephone number, and permit number of your prescription drug wholesale distributor. (write pending if not known)	
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Name	Telephone Number	Permit Number
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Name	Telephone Number	Permit Number
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Street Address	City	State	Zip
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Street Address	City	State	Zip
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10. Pharmacy Technician Ratio 2:1 or 3:1 (Optional)	
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Rule 64B16-27.410, *Florida Administrative Code*, provides that the prescription department manager or consultant pharmacist of record is required to submit a written request and receive approval from the Board of Pharmacy prior to the pharmacy allowing a pharmacist to supervise more than one registered pharmacy technician. If you would like to apply for the Registered Pharmacy Technician 2:1 or 3:1 ratio, you may do so by checking the appropriate selection below. Selecting an option below serves as your written request to the board office for approval to practice with a 2:1 or 3:1 ratio.

_____ 2:1 Ratio _____ 3:1 Ratio

(please attach a brief description of the workflow needs that include the operating hours of the pharmacy, number of pharmacist, registered interns and registered pharmacy technicians employed to justify the ratio request)

11. Operating Hours

Store/Facility Hours

Monday-Friday: Open: _____ Close: _____
Saturday: Open: _____ Close: _____
Sunday: Open: _____ Close: _____

Prescription Department Hours

Monday-Friday: Open: _____ Close: _____
Saturday: Open: _____ Close: _____
Sunday: Open: _____ Close: _____

12. Ownership Information

a. Type of Ownership: _____ Individual _____ Corporation _____ Partnership
_____ Other: _____

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

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?

Yes _____ No _____ If yes, provide attestation from Certified Public Accountant for previous tax year or Florida Corporate Income/Franchise and Emergency Excise Tax Return (F-1120)

d. List all the owners and officers of the corporation. Each person listed below having an ownership interest of 5 percent or greater and any person who, directly or indirectly, manages, oversees, or controls the operation of the applicant including officers and members of the board of directors must submit a set of fingerprints and fees unless you answered yes to 12c. If 12c is yes please list the owners below and only submit fingerprints for the Prescription Department Manager or Consultant Pharmacist of Record. If 12c 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. Attach a separate sheet if necessary.

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

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

Yes _____ No _____ If yes, please provide a signed affidavit disclosing the reason the entity was closed.

13a. Has anyone listed in 12.d 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?

Yes _____ No _____ If yes, please provide a signed affidavit disclosing the reason the entity was closed.

14. Has anyone listed in 12.d ever obtained a pharmacy permit by misrepresentation or fraud or 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 _____ If yes, please provide documents concerning this conviction.

Pursuant to Section 456.0635(2) and 465.022(5), Florida Statutes, questions 15 through 22 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.
15. 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 to, regardless of adjudication, a felony under Chapter 409, F.S. (relating to social and economic assistance), Chapter 817, F.S. (relating to fraudulent practices), Chapter 893, F.S. (relating to drug abuse prevention and control) or a similar felony offense(s) in another state or jurisdiction? (If you responded “no”, skip to #16.)
Yes _____ No _____
15a. If “yes” to 15, for the felonies of the first or second degree, has it been more than 15 years from the date of the plea, sentence and completion of any subsequent probation?
Yes _____ No _____
15b. If “yes” to 15, for the felonies of the third degree, has it been more than 10 years from the date of the plea, sentence and completion of any subsequent probation? (This question does not apply to felonies of the third degree under Section 893.13(6)(a), Florida Statutes).
Yes _____ No _____
15c. If “yes” to 15, for the felonies of the third degree under Section 893.13(6)(a), Florida Statutes, has it been more than 5 years from the date of the plea, sentence and completion of any subsequent probation?
Yes _____ No _____
15d. If “yes” to 15, has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant successfully completed a drug court program that resulted in the plea for the felony offense being withdrawn or the charges dismissed? (If “yes”, please provide supporting documentation).
Yes _____ No _____
16. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication to a felony under 21 U.S.C. ss.801-970 or 42 U.S.C. ss. 1395-1396 since July 1, 2009?
Yes _____ No _____ (If yes, explain on a separate sheet providing accurate details)
17. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant ever been terminated for cause from the Florida Medicaid Program pursuant to Section 409.913, Florida Statutes? (If no, do not answer 18)
Yes _____ No _____ (If yes, explain on a separate sheet providing accurate details)
18. If the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant has been terminated, has the applicant been reinstated and in good standing with the Florida Medicaid Program for the most recent five years?
Yes _____ No _____ (If yes, explain on a separate sheet providing accurate details)
19. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant ever been terminated for cause, pursuant to the appeals procedures established by the state or federal government, from any other state Medicaid program or the federal Medicare program? (If no, do not answer 20 and 21)
Yes _____ No _____ If yes, please provide documents concerning this conviction.

20. 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, explain on a separate sheet providing accurate details)

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

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

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

Yes _____ No _____ (If yes please submit proof)

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

Yes _____ No _____

State	Permit Type	Permit Number

24. Has the applicant, affiliated person, partner, officer, director ever owned a pharmacy? If yes, provide the name of the pharmacy, the state where the pharmacy is located and the status of the pharmacy. Attach a separate sheet if necessary.

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

Pharmacy Name	State	Status

25. Has any disciplinary action ever been taken against any license, permit or registration issued to the applicant, affiliated person, partner, officer, director, or prescription department manager?

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

26. Has the applicant, or any officer, member or partner ever been convicted of a felony or misdemeanor, excluding minor traffic convictions?

Yes _____ No _____ (You must include all misdemeanors and felonies, even if adjudication was withheld by the court, so that you would not have a record of conviction. Driving under the influence or driving while impaired is NOT a minor traffic offense for the purposes of this question.)

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

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

28. 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 28d.

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

28d. Does the applicant, affiliated person, partner, officer, director have a repayment plan approved by the department?

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

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

No _____ Yes _____

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 certify that the statements contained in this application are true, complete, and correct and I agree that said statements shall form the basis of my application and I do authorize the Florida Board of Pharmacy to make any investigations that they deem appropriate and to secure any additional information concerning me, and I further authorize them to furnish any information they may have or have in the future concerning me to any person, corporation, institution, association, board, or any municipal, county, state, or federal governmental agencies or units, and I understand according to the Florida Board of Pharmacy Statutes that a Pharmacy Permit may be revoked or suspended for presenting any false, fraudulent, or forged statement, certificate, diploma, or other 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)

PHARMACY PERMIT APPLICATION CHECKLIST

Keep a copy of the completed application for your records.

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

COMMUNITY PHARMACY PERMIT

- Application Completed (all questions answered)**
- Application signed**
- Pharmacy Manager Signature**
- \$255.00 Fee Attached (Permit fee includes \$250 application fee and \$5.00 unlicensed activity fee)**
- Articles of Incorporation from the Secretary of State**
- Fingerprints have been submitted via livescan for all officers and owners and the prescription department manager**
- Attach Proof from AHCA that the fingerprints are on file if applicable from the last year**
- Attestation for Business Taxable Assets of \$100 million if applicable**
- Bill of Sale is required for Change of Ownership**