

### **AGENDA**

## Florida Board of Pharmacy - Rules Committee Meeting October 2, 2017 - 1:00 p.m.

Rosen Plaza Hotel \* 9700 International Drive \* Orlando, FL 32819 \* (407)996-9700

#### **Committee Members:**

Jeffrey Mesaros, PharmD, JD – Chair Goar Alvarez, PharmD David Bisaillon Jeenu Philip, BPharm

#### **Board Staff**

C. Erica White, MBA, JD - Executive Director Irene Lake, Program Operations Administrator Jessica Hollingsworth - Gov. Analyst II

#### **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. Rule 64B16-27.830, F.A.C. Standards of Practice Drug Therapy Management
- 2. **Rule 64B26-27.831, F.A.C.** Standards of Practice for the Filling of Controlled Substance Prescriptions; Electronic Prescribing; Mandatory Continuing Education
- 3. **Rule 64B16-27.410, F.A.C.** Registered Pharmacy Technician to Pharmacist Ratio Reference September 19, 2017 JAPC Letter regarding Rule 64B16-27.1001, F.AC.
- 4. **Rule 64B16-27.1001, F.A.C.** Delegation to and Supervision of Pharmacy Technicians; Responsibility of Supervising Pharmacist
- 5. **Discussion of Board Rules:** 
  - Related to and during Emergency situations, Declaration of Emergency, etc; including the ability to add provisions to current rules
  - Lift provisions and examine potential rules that may have posed barriers to access or care for possible amendments.
- 6. Rule 64B16-28.100, F.A.C., and Amendments to Pharmacy Permit Applications:
  - Community Pharmacy Permit DH MQA 1214
  - Institutional Pharmacy Permit DH MQA 1215
  - Special Pharmacy Permit DH MQA 1220
  - Special Sterile Compounding Pharmacy Permit DH MQA 1270
  - Nuclear Pharmacy Permit DH MQA 1218
  - Internet Pharmacy Permit DH MQA 1216
- 7. Old Business / New Business
- 8. **Public Comment**
- 9. **Adjourn**



# **TAB #1**

#### 64B16-27.830 Standards of Practice - Drug Therapy Management.

- (1) "Prescriber Care Plan" means an individualized assessment of a patient and orders for specific drugs, laboratory tests, and other pharmaceutical services intended to be dispensed or executed by a pharmacist. The Prescriber Care Plan shall be written by a physician licensed pursuant to Chapter 458, 459, 461, or 466, F.S., or similar statutory provision in another jurisdiction, and may be transmitted by any means of communication. The Prescriber Care Plan shall specify the conditions under which a pharmacist shall order laboratory tests, interpret laboratory values ordered for a patient, execute drug therapy orders for a patient, and notify the physician.
  - (2) "Drug Therapy Management" means any act or service by a pharmacist in compliance with orders in a Prescriber Care Plan.
- (3) A pharmacist may provide Drug Therapy Management services for a patient, incidental to the dispensing of medicinal drugs or as a part of consulting concerning therapeutic values of medicinal drugs or as part of managing and monitoring the patient's drug therapy. A pharmacist who provides Drug Therapy Management services for a patient shall comply with orders in a Prescriber Care Plan, insofar as they specify:
  - (a) Drug therapy to be initially dispensed to the patient by the pharmacist; or
  - (b) Laboratory values or tests to be ordered, monitored and interpreted by the pharmacist; or
- (c) The conditions under which the duly licensed practitioner authorizes the execution of subsequent orders concerning the drug therapy for the patient; or
  - (d) The conditions under which the pharmacist shall contact or notify the physician.
- (4) A pharmacist who provides Drug Therapy Management services shall do so only under the auspices of a pharmacy permit that provides the following:
  - (a) A transferable patient care record that includes:
- 1. A Prescriber Care Plan that includes a section noted as "orders" from a duly licensed physician for each patient for whom a pharmacist provides Drug Therapy Management services;
  - 2. Progress notes; and
- (b) A pharmaceutical care area that is private, distinct, and partitioned from any area in which activities other than patient care activities occur, and in which the pharmacist and patient may sit down during the provision of Drug Therapy Management services; and
- (c) A continuous quality improvement program that includes standards and procedures to identify, evaluate, and constantly improve Drug Therapy Management services provided by a pharmacist.

Specific Authority 465.005, 465.0155 FS. Law Implemented 465.003(13), 465.0155, 465.022(1)(b) FS. History-New 4-4-00.



# **TAB #2**

# 64B16-27.831 Standards of Practice for the Filling of Controlled Substance Prescriptions; Electronic Prescribing; Mandatory Continuing Education.

The Board of Pharmacy recognizes that it is important for the patients of the State of Florida to be able to fill valid prescriptions for controlled substances. In filling these prescriptions, the Board does not expect pharmacists to take any specific action beyond exercising sound professional judgment. Pharmacists should not fear disciplinary action from the Board or other regulatory or enforcement agencies for dispensing controlled substances for a legitimate medical purpose in the usual course of professional practice. Every patient's situation is unique and prescriptions for controlled substances shall be reviewed with each patient's unique situation in mind. Pharmacists shall attempt to work with the patient and the prescriber to assist in determining the validity of the prescription.

- (1) Definitions: For purposes of this rule the following definitions shall apply:
- (a) Valid Prescription. A prescription is valid when it is based on a practitioner-patient relationship and when it has been issued for a legitimate medical purpose.
- (b) Invalid Prescription. A prescription is invalid if the pharmacist knows or has reason to know that the prescription was not issued for a legitimate medical purpose.
- (c) Validating a Prescription. Validating a prescription means the process implemented by the pharmacist to determine that the prescription was issued for a legitimate medical purpose.
- (2) General Standards for Validating a Prescription: Each prescription may require a different validation process and no singular process can fit each situation that may be presented to the pharmacist. There are circumstances that may cause a pharmacist to question the validity of a prescription for a controlled substance; however, a concern with the validity of a prescription does not mean the prescription shall not be filled. Rather, when a pharmacist is presented with a prescription for a controlled substance, the pharmacist shall attempt to determine the validity of the prescription and shall attempt to resolve any concerns about the validity of the prescription by exercising his or her independent professional judgment.
- (a) When validating a prescription, neither a person nor a licensee shall interfere with the exercise of the pharmacist's independent professional judgment.
- (b) When validating a prescription, the pharmacist shall ensure that all communication with the patient is not overheard by others.
- (c) When validating a prescription, if at any time the pharmacist determines that in his or her professional judgment, concerns with the validity of the prescription cannot be resolved, the pharmacist shall refuse to fill or dispense the prescription.
  - (3) Minimum Standards Before Refusing to Fill a Prescription.
- (a) Before a pharmacist can refuse to fill a prescription based solely upon a concern with the validity of the prescription, the pharmacist shall attempt to resolve those concerns and shall attempt to validate the prescription by performing the following:
- 1. Initiate communication with the patient or the patient's representative to acquire information relevant to the concern with the validity of the prescription;
- 2. Initiate communication with the prescriber or the prescriber's agent to acquire information relevant to the pharmacist's concern with the validity of the prescription.
- (b) In lieu of either subparagraph 1. or 2., but not both, the pharmacist may elect to access the Prescription Drug Monitoring Program's Database to acquire information relevant to the pharmacist's concern with the validity of the prescription.
- (c) In the event that a pharmacist is unable to comply with paragraph (a) due to a refusal to cooperate with the pharmacist, the minimum standards for refusing to fill a prescription shall not be required.
- (4) Duty to Report: If a pharmacist has reason to believe that a prescriber is involved in the diversion of controlled substances, the pharmacist shall report such prescriber to the Department of Health.
- (5) Electronic Prescriptions: All controlled substances listed in Schedule II through V may be electronically prescribed pursuant to the provisions of Section 456.42(2), F.S. (2015), and pursuant to applicable federal law. For more information related to the federal requirements, access http://www.deadiversion.usdoj.gov/ecomm/index.html.
- (6) Mandatory Continuing Education: All pharmacists shall complete a Board-approved 2-hour continuing education course on the Validation of Prescriptions for Controlled Substances. The course content shall include the following:
  - (a) Ensuring access to controlled substances for all patients with a valid prescription;
  - (b) Use of the Prescription Drug Monitoring Program's Database;
  - (c) Assessment of prescriptions for appropriate therapeutic value;

- (d) Detection of prescriptions not based on a legitimate medical purpose; and,
- (e) The laws and rules related to the prescribing and dispensing of controlled substances. All licensed pharmacists shall complete the required course during the biennium ending on September 30, 2017. A 2-hour course shall be taken every biennium thereafter. The course shall count towards the mandatory 30 hours of CE required for licensure renewal. All newly licensed pharmacists must complete the required course before the end of the first biennial renewal period.
- (7) Summary Record: Every pharmacy permit holder shall maintain a computerized record of controlled substance prescriptions dispensed. A hard copy printout summary of such record, covering the previous 60 day period, shall be made available within 72 hours following a request for it by any law enforcement personnel entitled to request such summary under authority of Section 893.07(4), F.S. Such summary shall include information from which it is possible to determine the volume and identity of controlled substances being dispensed under the prescription of a specific prescriber, and the volume and identity of controlled substances being dispensed to a specific patient.

Rulemaking Authority 456.013, 465.005, 465.0155, 465.009, 465.022(12) FS. Law Implemented 456.013, 456.42, 456.43, 465.0155, 465.003, 465.009, 465.016(1)(i), (s), 465.017, 465.022(12), 893.04 FS. History–New 8-29-02, Amended 2-24-03, 11-18-07, 12-24-15.

# 64B16-27.831 Standards of Practice for the Filling of Controlled Substance Prescriptions; Electronic Prescribing; Mandatory Continuing Education.

The Board of Pharmacy recognizes that it is important for the patients of the State of Florida to be able to fill valid prescriptions for controlled substances. In filling these prescriptions, the Board does not expect pharmacists to take any specific action beyond exercising sound professional judgment. Pharmacists should not fear disciplinary action from the Board or other regulatory or enforcement agencies for dispensing controlled substances for a legitimate medical purpose in the usual course of professional practice. Every patient's situation is unique and prescriptions for controlled substances shall be reviewed with each patient's unique situation in mind. Pharmacists shall attempt to work with the patient and the prescriber to assist in determining the validity of the prescription.

- (1) Through (5) NO CHANGE
- (6) Mandatory Continuing Education:
- (a) All pharmacists shall complete a Board-approved 2-hour continuing education course on the **Validation of Prescriptions** for Controlled Substances. All licensed pharmacists shall complete the required course during the biennium ending on September 30, 2017. A 2-hour course shall be taken every biennium thereafter. All newly licensed pharmacists must complete the required course before the end of the first biennial renewal period. After the biennium ending on September 30, 2017, the continuing education course must be taken through an in-person seminar or a live interactive video teleconference. The course content shall include the following:
  - 1. Ensuring access to controlled substances for all patients with a valid prescription;
  - 2. Use of the Prescription Drug Monitoring Program's Database;
  - 3. Assessment of prescriptions for appropriate therapeutic value;
  - 4. Detection of prescriptions not based on a legitimate medical purpose; and,
  - 5. The laws and rules related to the prescribing and dispensing of controlled.
- (b) All pharmacists shall complete a Board-approved 1-hour continuing education course on **Opioid Addiction Prevention**. All licensed pharmacists shall complete the required course during the biennium ending on September 30, 2019. A 1-hour course shall be taken every biennium thereafter. All newly licensed pharmacists must complete the required course before the end of the first biennial renewal period. The continuing education course must be taken through an in-person seminar or a live interactive video teleconference. The course content shall include the following:

<u> 1.</u>	Counseling of patients who have opioid prescriptions;	
2.	;	
3		;
4		; and
5.		

- (c) An applicant for licensure as a pharmacist shall be awarded credit for the continuing education mandated by paragraphs (a) and (b) if the applicant took the course(s) as a student at an accredited pharmacy school. To receive credit, the course(s) must have been taken during the applicant's final year of pharmacy school and the application for licensure must be received no later than 1-year following graduation.
- (d) The continuing education required by paragraphs (a) and (b) shall count towards the required 30 hours of CE necessary for licensure renewal, and the 10 hours of "live" CE mandated by rule 64B16-26.103(1)(m).
- (7) Summary Record: Every pharmacy permit holder shall maintain a computerized record of controlled substance prescriptions dispensed. A hard copy printout summary of such record, covering the previous 60-day period, shall be made available within 72 hours following a request for it by any law enforcement personnel entitled to request such summary under authority of Section 893.07(4), F.S. Such summary shall include information from which it is possible to determine the volume and identity of controlled substances being dispensed under the prescription of a specific prescriber, and the volume and identity of controlled substances being dispensed to a specific patient.

Rulemaking Authority 456.013, 465.005, 465.0155, 465.009, 465.022(12) FS. Law Implemented 456.013, 456.42, 456.43, 465.0155, 465.003, 465.009, 465.016(1)(i), (s), 465.017, 465.022(12), 893.04 FS. History–New 8-29-02, Amended 2-24-03, 11-18-07, 12-24-15.



# **TAB #3**

#### 64B16-27.410 Registered Pharmacy Technician to Pharmacist Ratio.

- (1) General Conditions. When the pharmacist delegates tasks to a registered pharmacy technician, such delegation must enhance the ability of the pharmacist to practice pharmacy to serve the patient population. A pharmacist shall not supervise more than one (1) registered pharmacy technician nor shall a pharmacy allow a supervision ratio of more than one (1) registered pharmacy technician to one (1) pharmacist (1:1), unless specifically authorized to do so pursuant to the provisions of this rule.
- (2) Required Documentation. Regardless of the technician ratio, every pharmacy, pharmacist, Prescription Department Manager (PDM) and Consultant Pharmacist (CP) that employs or utilizes registered pharmacy technicians must comply with the following conditions:
- (a) Establish and maintain a written Policy and Procedures Manual regarding the number of registered pharmacy technician positions and their utilization that includes the specific scope of delegable tasks of the technicians, job descriptions, and task protocols. The Policy and Procedures Manual or Manuals must include policies and the procedures for implementing the policies for each category enumerated below:
  - 1. Supervision by a pharmacist;
  - 2. Minimum qualifications of the registered pharmacy technician as established by statute and rule;
  - 3. In-service education or on-going training and demonstration of competency specific to the practice site and job function;
  - 4. General duties and responsibilities of the registered pharmacy technicians;
  - 5. All functions related to prescription processing;
- 6. All functions related to prescription legend drug and controlled substance ordering and inventory control, including procedures for documentation and recordkeeping;
- 7. All functions related to retrieval of prescription files, patient files, patient profile information and other records pertaining to the practice of pharmacy;
  - 8. All delegable tasks and non-delegable tasks as enumerated in Rule 64B16-27.420, F.A.C.;
  - 9. Confidentially and privacy laws and rules;
  - 10. Prescription refill and renewal authorization;
  - 11. Registered pharmacy technician functions related to automated pharmacy systems; and
  - 12. Continuous Quality Improvement Program.
- (b) Establish and maintain documentation that is signed by the registered pharmacy technician acknowledging the technician has reviewed the Policy and Procedures Manual(s). Compliance with this paragraph must be achieved by April 7, 2015, or within ninety (90) days from the date the registered pharmacy technician is hired.
- (c) Establish and maintain documentation that demonstrates the registered pharmacy technician has received training in the established job description, delegable tasks, task protocols, and policy and procedures in the specific pharmacy setting where the delegable tasks will be performed. Documentation shall consist of one of the following items:
  - 1. Certification by the supervising licensee;
  - 2. Certification by an instructor, trainer, or other similar person;
  - 3. Training attendance logs or completion certificates, accompanied by an outline of the materials addressed; or
  - 4. Exam or written questionnaires.
- (3) The Policy and Procedures Manual(s) required by paragraph (2)(a) must be maintained on-site where the pharmacy technician will perform the delegable tasks and must be available during a Department inspection or at the request of the Board of Pharmacy. However, any and all documentation required by paragraphs (2)(b) and (c) must be maintained and must be provided to the Board of Pharmacy or a Department inspector within 72 hours of a request.
- (4) Three to One (3:1) Ratio: Any pharmacy or any pharmacist engaged in sterile compounding, or any tasks relating to sterile compounding, including prescription data entry, shall not exceed a ratio of up to three (3) registered pharmacy technicians to one (1) pharmacist (3:1).
- (5) Four to One (4:1) Ratio: Any pharmacy or any pharmacist may allow a supervision ratio of up to four (4) registered pharmacy technicians to one (1) pharmacist (4:1), as long as the pharmacist or pharmacy is not engaged in sterile compounding, or any tasks relating to sterile compounding, including prescription data entry.
  - (6) Six to One (6:1) Ratio:
- (a) Non-dispensing pharmacies. Any pharmacy which does not dispense medicinal drugs, and the pharmacist(s) employed by such pharmacy, may allow a supervision ratio of up to six (6) registered pharmacy technicians to one (1) pharmacist (6:1), as long as

the pharmacy or pharmacist is not involved in sterile compounding, or any tasks relating to sterile compounding, including prescription data entry.

- (b) Dispensing pharmacies. A pharmacy which dispenses medicinal drugs may utilize a six to one (6:1) ratio in any physically separate area of the pharmacy from which medicinal drugs are not dispensed, provided no pharmacy technician is engaged in any task related to sterile compounding. A "physically separate area" is a part of the pharmacy which is separated by a permanent wall or other barrier which restricts access between the two areas.
- (7) Ten to One (10:1) Ratio: Any pharmacy that operates a limited duties call center in a physically separate area of the pharmacy at which medicinal drugs are neither stored nor dispensed, and the pharmacist(s) employed by such pharmacy call center, may allow a supervision ratio of up to ten (10) registered pharmacy technicians to one (1) pharmacist (10:1), as long as the duties of the registered pharmacy technicians at the call center are limited to:
  - 1. Entry of Patient demographics;
  - 2. Intake and documentation of information regarding patient allergies;
  - 3. Entry of prescription information, excluding prescriptions related to sterile compounding;
  - 4. Verification of physician National Provider Identifier (NPI) and/or state licensure;
  - 5. Claims adjudication;
  - 6. Claims resolution;
  - 7. Communication of payment information; and
  - 8. Collection of patient co-payments.

Rulemaking Authority 465.005, 456.069(1), 465.014, 465.017, 465.022 FS. Law Implemented 465.014, 465.022 FS. History—New 2-14-77, Amended 3-31-81, Formerly 21S-4.02, Amended 8-31-87, Formerly 21S-4.002, Amended 9-9-92, Formerly 21S-27.410, 61F10-27.410, Amended 1-30-96, Formerly 59X-27.410, Amended 2-23-98, 10-15-01, 1-1-10, 1-7-15, 7-6-15.



# **TAB #4**

#### 64B16-27.1001 Practice of Pharmacy.

Those functions within the definition of the practice of the profession of pharmacy, as defined by Section 465.003(13), F.S., are specifically reserved to a pharmacist or a duly registered pharmacy intern in this state acting under the direct and immediate personal supervision of a pharmacist. The following subjects come solely within the purview of the pharmacist.

- (1) A pharmacist or registered pharmacy intern must:
- (a) Supervise and be responsible for the controlled substance inventory.
- (b) Receive verbal prescriptions from a practitioner.
- (c) Interpret and identify prescription contents.
- (d) Engage in consultation with a practitioner regarding interpretation of the prescription and date in patient profile.
- (e) Engage in professional communication with practitioners, nurses or other health professionals.
- (f) Advise or consult with a patient, both as to the prescription and the patient profile record.
- (2) When parenteral and bulk solutions of all sizes are prepared, regardless of the route of administration, the pharmacist must:
- (a) Interpret and identify all incoming orders.
- (b) Mix all extemporaneous compounding or be physically present and give direction to the registered pharmacy technician for reconstitution, for addition of additives, or for bulk compounding of the parenteral solution.
  - (c) Physically examine, certify to the accuracy of the final preparation, thereby assuming responsibility for the final preparation.
- (d) Systemize all records and documentation of processing in such a manner that professional responsibility can be easily traced to a pharmacist.
- (3) Only a pharmacist may make the final check of the completed prescription thereby assuming the complete responsibility for its preparation and accuracy.
- (4) The pharmacist, as an integral aspect of dispensing, shall be directly and immediately available to the patient or the patient's agent for consultation and shall not dispense to a third party. No prescription shall be deemed to be properly dispensed unless the pharmacist is personally available.
- (5) The pharmacist performing in this state any of the acts defined as "the practice of the profession of pharmacy" in Section 465.003(13), F.S., shall be actively licensed as a pharmacist in this state, regardless of whether the practice occurs in a permitted location (facility) or other location.
- (6) The pharmacist may take a meal break, not to exceed 30 minutes in length, during which the pharmacy department of a permittee shall not be considered closed, under the following conditions:
- (a) The pharmacist shall be considered present and on duty during any such meal break if a sign has been prominently posted in the pharmacy indicating the specific hours of the day during which meal breaks may be taken by the pharmacist and assuring patients that a pharmacist is available on the premises for consultation upon request during a meal break.
- (b) The pharmacist shall be considered directly and immediately available to patients during such meal breaks if patients to whom medications are delivered during meal breaks are verbally informed that they may request that a pharmacist contact them at the pharmacist's earliest convenience after the meal break, and if a pharmacist is available on the premises during the meal break for consultation regarding emergency matters. Only prescriptions with the final certification by the pharmacist may be delivered.
- (c) The activities of registered pharmacy technicians during such a meal break shall be considered to be under the direct and immediate personal supervision of a pharmacist if the pharmacist is available on the premises during the meal break to respond to questions by the technicians, and if at the end of the meal break the pharmacist certifies all prescriptions prepared by the registered pharmacy technicians during the meal break.
- (7) The delegation of any duties, tasks or functions to registered pharmacy interns and registered pharmacy technicians must be performed subject to a continuing review and ultimate supervision of the pharmacist who instigated the specific task, so that a continuity of supervised activity is present between one pharmacist and one registered pharmacy technician. In every pharmacy, the pharmacist shall retain the professional and personal responsibility for any delegated act performed by registered pharmacy interns and registered pharmacy technicians in the licensee's employ or under the licensee's supervision.

Rulemaking Authority 465.005, 465.0155 FS. Law Implemented 465.003(11)(b), (13), 465.014, 465.026 FS. History–New 11-18-07, Amended 1-1-10.



## OFFICE OF THE ATTORNEY GENERAL Administrative Law

David D. Flynn
Assistant Attorney General
PL-01 The Capitol
Tallahassee, FL 32399-1050
Phone (850) 414-3300 Fax (850) 922-6425
http://www.myfloridalegal.com

September 19, 2017

Marjorie Holladay, Chief Attorney Joint Administrative Procedures Committee Room 680, Pepper Building Tallahassee, FL 32399-1400

Re: Board of Pharmacy Rule 64B16-27.1001, Fla. Admin. Code. Practice of Pharmacy

Dear Ms. Holladay:

I want to thank you for your patience and the additional opportunity to provide a more substantive response to your previous inquiries. I have the following response to your most recent correspondence dated September 14, 2017.

Your inquiry is aimed at the provision of the rule that mandates when parenteral and bulk solutions are prepared, the pharmacist must "be physically present and give direction to the registered pharmacy technician for reconstitution, for addition of additives, or for bulk compounding of the parental solution." Fla. Admin. Code R. 64B16.27.1001(2)(Jan. 2010). Please be assured that the rule does not allow the pharmacist to delegate the act of compounding to a pharmacy technician, which would be prohibited by section 465.014(1), *Florida Statutes*. The rule only allows a pharmacy technician to assist in the preparation of the final product. The pharmacist not only has to be physically present to give direction, but also must "[i]nterpret and identify all incoming orders" when any parenteral or bulk solutions are prepared. <u>Id</u> at § (2). Most importantly, the pharmacist shall assume full responsibility for the final product by physically examining and certifying to the products accuracy. <u>Id</u>. at § (2)(c). Finally, a pharmacist must maintain records and documentation of processing so that the responsibility of preparing the drug product can be traced to the responsible pharmacist. Id. at § (2)(d).

Further, rule 64B16-27.420, *Florida Administrative Code* (Jul. 2015), specifically states, "[a] pharmacy technician may only assist a pharmacist in executing or carrying out the practice of the profession of pharmacy, but shall never themselves engage in the practice of the profession of pharmacy as defined in Chapter 465, F.S." Moreover, a pharmacist may only delegate those tasks that are performed pursuant to the pharmacist's direction that does not require the pharmacy technician to exercise their own judgement and discretion and that does not require the technician to "exercise the independent professional judgment that is the foundation of the practice of the profession of pharmacy." Id. at § (1). The Board has made clear that a pharmacy technician may only assist in preparing the drug product. Moreover, when the technician assists in preparing the drug product, the technician may not engage in any of the task listed section (2) of the rule. <u>Id.</u> at §2. I hope you will find that the board has taken great care in drafting and promulgating rules to make certain a pharmacy technician is not practicing in contravention of section 465.014, *Florida Statues*.

As you are aware, the Board has also has been diligently updating all the rules related to sterile compounding and the standards of practice for compounding sterile drugs products. The language utilized in this rule needs to be reviewed and updated to avoid ambiguity. Therefore, this rule, along with your correspondence, will be placed on the Board's agenda for consideration in December. Immediately following the December Board meeting, I will provide you with an update.

Please do not hesitate to contact me directly if you have any further questions or concerns. Again, your review is greatly appreciated.

Sincerely,

David D. Flynn Assistant Attorney General Attorney for the Board

cc: C. Erica White, J.D, Executive Director Ed Tellechea, Bureau Chief Angela Southwell, Paralegal Specialist



# **TAB #6**

#### 64B16-28.100 Pharmacy Permits – Applications and Permitting.

This section addresses the application and permitting requirements of business establishments regulated under Chapter 465, F.S. Any establishment that is required to have a permit shall apply to the board for the appropriate permit on forms indicated in this rule. Applications and forms referenced in this section may be accessed or downloaded from the web at http://www.doh.state.fl.us/mqa/pharmacy or may be obtained by contacting the Board the Board of Pharmacy, at 4052 Bald Cypress Way, Bin #C04, Tallahassee, Florida 32399-3254, or (850)488-0595. Inquiries regarding the status of the application or license verification may be obtained at http://www.FLHealthsource.com. The application must be accompanied with a \$250 initial permit fee, payable to the Board.

- (1) All Permits: A permit is valid only for the name and address to which it is issued. The name in which the permit is issued must be the name in which the company is doing business, i.e., the name that appears on purchase and sales invoices.
- (a) A permit shall be issued only to a single entity at a single location. The service provided by the permit shall be consistent with the issued permit. A single location shall be defined as:
- 1. A contiguous area under the control of the permit holder. For purposes of this rule, a public thoroughfare will be considered to have not broken the area of contiguity; and,
  - 2. An area not more than one half (1/2) mile from the central location of the permit.
- (b) The name in which a permit is issued may be changed upon notification to the board. To change the name in which a permit is issued the person or establishment must file with the board an original Form DH-MQA 1227 "Pharmacy Permit Name Change Form" effective December 2010, which is incorporated by reference herein, and is available at <a href="http://www.flrules.org/Gateway/reference.asp?No=Ref-02297">http://www.flrules.org/Gateway/reference.asp?No=Ref-02297</a> or on the web at <a href="http://www.doh.state.fl.us/mqa/pharmacy">http://www.doh.state.fl.us/mqa/pharmacy</a>.
- (c) Each applicant must file with the board a legible set of fingerprint cards and a \$48 fee for each person who submits an application meeting the requirements in Section 465.022(3), F.S. An applicant may register demographic information and purchase fingerprint cards (FD-258) at http://http://www.fldoh.sofn.net/. If an applicant chooses not to purchase a fingerprint card, the applicant must make sure the police or agency that rolls the fingerprints uses a FD-258 fingerprint card. A Non-Resident Pharmacy Registration applicant is not required to submit a legible set of fingerprints upon application.
- (d) Passing an on-site inspection is a prerequisite to issuance of a new permit, whether based on an initial application, change of ownership, or change of address. At the time of the on-site inspection, the board inspector will document the applicant's compliance with all applicable rules and statutes.
- (e) 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.
- (2) Community Pharmacy Permit as authorized by Section 465.018, F.S., is required for every location where medicinal drugs are compounded, dispensed, stored, or sold or where prescriptions are filled or dispensed on an outpatient basis. Applicants for a community pharmacy permit must complete an application for a permit using an original Form DH-MQA 1214, "Community Pharmacy Permit Application and Information," effective August 2012 which is incorporated by reference herein and is available at <a href="http://www.flrules.org/Gateway/reference.asp?No=Ref-02298">http://www.flrules.org/Gateway/reference.asp?No=Ref-02298</a>.
  - (a) Applicants for a Community Pharmacy Permit must:
  - 1. Comply with all permitting requirement found in subsection (1) of this rule; and,
  - 2. Designate a prescription department manager as required by Section 465.018, F.S.;
- (b) The permittee and the newly designated prescription department manager shall notify the board within 10 days of any change in the prescription department manager using an original Form DH-MQA PH10, "Prescription Department Manager Change," effective December 2010, which is incorporated by reference herein and is available at <a href="http://www.flrules.org/Gateway/reference.asp?No=Ref-02299">http://www.flrules.org/Gateway/reference.asp?No=Ref-02299</a>.
- (c) The policy and procedure manual for Community Pharmacies shall contain the procedures implemented to minimize the dispensing of controlled substances based on fraudulent representations. The policy and procedural manual shall provide 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.

- (3) Institutional Pharmacy Permits as authorized by Section 465.019, F.S., is required for any location in any health care institution where medicinal drugs are compounded, dispensed, stored or sold. Applicants for a Institutional Pharmacy permit must complete an application for a permit using an original Form DH-MQA 1215, "Institutional Pharmacy Permit Application and Information," effective August 2012, which is incorporated by reference herein and is available at <a href="http://www.flrules.org/Gateway/reference.asp?No=Ref-02300">http://www.flrules.org/Gateway/reference.asp?No=Ref-02300</a>.
  - (a) Applicants for an Institutional Pharmacy Permit must:
  - 1. Comply with all permitting requirement found in subsection (1) of this rule; and,
  - 2. Designate a consultant pharmacist of record as required by Section 465.019, F.S.
- (b) The Board shall be notified in writing within 10 days of any change in the consultant pharmacist of record using an original Form DH-MQA 1184, "Change of Consultant Pharmacist of Record," effective December 2010, which is incorporated by reference herein and is available at <a href="http://www.flrules.org/Gateway/reference.asp?No=Ref-02301">http://www.flrules.org/Gateway/reference.asp?No=Ref-02301</a>.
- (4) Nuclear Pharmacy Permit as authorized by Section 465.0193, F.S., is required for every location where radioactive drugs and chemicals within the classification of medicinal drugs are compounded, dispensed, stored, or sold. Applicants for a Nuclear Pharmacy permit must complete an application for a permit using an original Form DH-MQA 1218, "Nuclear Pharmacy Permit Application and Information," effective August 2012, which is incorporated by reference herein and is available at <a href="http://www.flrules.org/Gateway/reference.asp?No=Ref-02302">http://www.flrules.org/Gateway/reference.asp?No=Ref-02302</a>.
  - (a) Applicants for a Nuclear Pharmacy Permit must:
  - 1. Comply with all permitting requirement found in subsection (1) of this rule; and,
  - 2. Designate a nuclear pharmacist of record as required by Section 465.0193, F.S.
- (b) The permittee and the newly designated prescription department manager shall notify the board within 10 days of any change in the prescription department manager using an original Form DH-MQA PH10, "Prescription Department Manager Change," effective December 2010.
- (5) Special Pharmacy Permits as authorized in Section 465.0196, F.S., is required for any location where medicinal drugs are compounded, dispensed, stored, or sold and which are not a community pharmacy, institutional pharmacy, nuclear pharmacy or internet pharmacy. Applicants for a Special-Limited Community, Special Parenteral and Enteral, Special Closed System Pharmacy, Special End Stage Renal Disease (ESRD), Special Parenteral/Enteral Extended Scope, and Special Assisted Living Facility (ALF) permits must complete an application for a permit using an original Form DH-MQA 1220, "Special Pharmacy Permit Application and Information," effective August 2012, which is incorporated by reference herein and is available at <a href="http://www.flrules.org/Gateway/reference.asp?No=Ref-02303">http://www.flrules.org/Gateway/reference.asp?No=Ref-02303</a>.
  - (a) Applicants for a Special Pharmacy Permit must:
  - 1. Comply with all permitting requirement found in subsection (1) of this rule; and,
  - 2. Designate a prescription department manager or consultant pharmacist of record as required by Section 465.0196, F.S.
- (b) The permittee and the newly designated prescription department manager shall notify the board within 10 days of any change in the prescription department manager using an original Form DH-MQA PH10, "Prescription Department Manager Change," effective December 2010.
- (c) The Board shall be notified in writing within 10 days of any change in the consultant pharmacist of record using an original Form DH-MQA 1184, "Change of Consultant Pharmacist of Record," effective December 2010.
  - (d) The Board recognized the following types of Special Pharmacy permits:
- 1. Special Limited Community Permit may be obtained by an Institutional Class II Pharmacy that dispenses medicinal drugs to employees, medical staff, emergency room patients, and other patients on continuation of a course of therapy.
- 2. Special Parenteral and Enteral Permit is required to provide parenteral (IV), enteral, and cytotoxic pharmacy services to outpatients. The applicant must be compliant with the Standard for Compounding Sterile Preparations found in Rule 64B16-27.797, F.A.C. Special Parenteral and Enteral Pharmacy Permits may stand-alone or be used in conjunction with a Community Pharmacy or Special Closed System Pharmacy Permit. The permittee must provide 24-hour telephone accessibility.
- 3. Special Closed System Pharmacy Permit is not open to the public and prescriptions are individually prepared for dispensing utilizing closed delivery systems, for ultimate consumers in health care institutions including nursing homes, jails, ALF's, Intermediate Care Facility/Mentally Retarded (ICF-MR's) or other custodial care facilities when defined by AHCA rules which the Board may approve. This permit may not provide medications to in-patients in a hospital.

- 4. Special Pharmacy End Stage Renal Disease (ESRD) Permit is a type of special pharmacy which is limited in scope of pharmacy practice to the provision of dialysis products and supplies to persons with chronic kidney failure for self-administration at the person's home or specified address.
- 5. Special Pharmacy Parenteral/Enteral Extended Scope Permit is required for pharmacies to compound patient specific parenteral/enteral preparations in conjunction with institutional pharmacy permits, provided requirements set forth herein are satisfied.
- 6. Special Assisted Living Facility (ALF) Permit is an optional facility license for those Assisted Living Facilities providing a drug delivery system utilizing medicinal drugs provided in unit dose packaging.
- (6) Internet Pharmacy Permit as authorized by Section 465.0197, F.S., is required for any location not otherwise licensed or issued a permit under this chapter, within or outside this state that uses the Internet to communicate with or obtain information from consumers and uses the information to fill or refill prescriptions or to dispense, distribute, or otherwise engage in the practice of pharmacy in this state. Applicants for an Internet Pharmacy permit must complete an application for a permit using an original Form DH-MQA 1220, "Special Pharmacy Permit Application and Information," effective August 2012.
  - (a) Applicants for an Internet Pharmacy Permit must:
  - 1. Comply with all permitting requirement found in subsection (1) of this rule; and,
  - 2. Designate a prescription department manager or consultant pharmacist of record as required by Section 465.0197, F.S.
- (b) As set forth in Section 465.0197, F.S., the permittee shall notify the board within 30 days of any change of location, corporate officers, and the pharmacist serving as the prescription department manager using an original Form DH-MQA PH10, "Prescription Department Manager Change," effective December 2010.
- (7) Special Sterile Compounding Permit: Except those pharmacies which already hold an active stand alone Special Parenteral/Enteral or Special Parenteral/Enteral Extended Scope Compounding permit, any pharmacy engaged in sterile compounding must obtain a special sterile compounding permit by filing an application on form DH-MQA 1270, "Special Sterile Compounding Permit Application and Information," effective May 2013, which is incorporated by reference herein and is available at <a href="http://www.flrules.org/Gateway/reference.asp?No=Ref-03142">http://www.flrules.org/Gateway/reference.asp?No=Ref-03142</a>.
- (a) All applicants that hold an active pharmacy permit that are currently engaged in sterile compounding have 180 days from the effective date of this amendment (eff. 9/23/13) to obtain a Special Sterile Compounding Permit. All pharmacies, which obtain the permit within the 180 days, on or before March 21, 2014, are exempt from paying an additional application or license fee.
  - (b) Applicants for a Special Sterile Compounding Permit must:
  - 1. Comply with all permitting requirements in subsection (1) of this rule,
  - 2. Designate a prescription department manager or consultant pharmacist of record.
- (c) The permittee and the newly designated prescription department manager of record or consultant pharmacist of record shall notify the board within 10 days of any change in the prescription department manager or consultant pharmacists of record on FORM DH-MQA PH10, "Prescription Department Manager Change," effective December 2010 or FORM DH-MQA 1184, "Change of Consultant Pharmacist of Record."

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 456.013, 456.025(3), 456.0635, 465.018, 465.019, 465.0193, 465.0196, 465.0197, 465.022 FS. History–New 2-21-13, Amended 9-23-13, 5-31-17.

## 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

October 2017



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 processing delays caused by large volumes 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 your 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 7-14 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

#### 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 1270, "Special Sterile Compounding Permit" and pay the additional permitting fee.

A community pharmacy provides outpatient pharmacy services, and is open for a minimum of 20 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 (cashier's 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. 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 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 PDM or Consultant Pharmacist of Record to submit fingerprints.

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/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 for you to sign this affirmation is included as an addendum to the application as Item #1.

#### 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 7-10 days. You will receive the actual copy of your license within 7 days. Please wait 7-14 days from your satisfactory inspection before checking on the status of your permit with the Board office.
- You may look up your license number on our website at <a href="http://www.flhealthsource.com/">http://www.flhealthsource.com/</a> under "Verify a License."

#### **Drug Enforcement Administration (DEA)**

The DEA will not issue a registration until the Florida Board of Pharmacy has issued a pharmacy permit.

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 <a href="http://www.DEAdiversion.usdoj.gov">http://www.DEAdiversion.usdoj.gov</a>.

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

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 contenedre 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. <u>465.003(14)</u> or s. <u>893.02</u> 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.

### 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.

COMMUNITY 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?
Attestation from Certified Public Accountant for previous tax year or Florida Corporate Income /Franchise and Emergency Excise Tax Return (if applicable)?
PDM Designation and Privacy Statement Acknowledgement provided (Application Item #1)?
Affiliate/Owner Privacy Statement Acknowledgement provided for each affiliate/owner (Application Item #2)?
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?
Controlled Substances dispensing questions answered?



#### FLORIDA BOARD OF PHARMACY

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



### **APPLICATION**

Application Type - Please choose	one of the follow	<u>ing:</u>	
New Establishment (\$255.00 fee)		Change of Location (\$100.00 fee)	
Change of Ownership (\$255.00 fee)			insfer (no fee)
SECTION A. Please comple	te for all App	lication Types	
Please list your Federal Employer	Identification Nu	ımber:	
1. Corporate Name		•	Telephone Number
2. Doing Business As (d/b/a)			E-Mail Address
3. Mailing Address			
City	State		Zip
4. Physical Address			
City	State		Zip
5. Prescription Department Manag	ger (PDM) Inform	nation	
Name			License Number
Email		Telephone Numb	er
6. Contact Person		Title	
Email		Telephone Numb	er

7. Operating Hours			
Prescription Department Hours Monday - Friday: Open:			
Saturday: Open:	_ Close:	Sunday: Open: 0	Close:
8. Ownership Information			
a. Type of Ownership:Indiv	/idual _	CorporationPartnership	
NOTE: If the applicant is a corpor Articles of Incorporation on file wi		ed partnership you must include with your applicate a Secretary of State's office.	on a copy of the
b. Are the applicants, officers,	directors, s	shareholders, members and partners over the a	ge of 18?
Yes No			
•	blic Accounta	<b>100 million of business taxable assets in this s</b> ant for previous tax year or Florida Corporate Income /F	•
Yes No			
interest of 5 percent or greater the operation of the applicant i of fingerprints and fees unless submit fingerprints for the Pre- yes and the prints are on file w	and any pe including of you answe scription De vith DOH or	corporation. Each person listed below having the corporation of the property, manages, over the corporation of the board of directors not	sees, or controls nust submit a set is below and only of Record. If 8c is
Owner/Officer-Title	Date of Birth	Mailing Address, City, State, Zip Code	% of Ownership
	1 1		%
	1 1		%
	1 1		%
	1 1		%
	1 1		%
business permit which was di	sciplined, s	rship interest of 5% or more in a pharmacy or a uspended, revoked, or closed involuntarily with disclosing the reason the entity was closed.	
Yes No			
	oluntarily re	ership interest of 5% or more in a pharmacy or a linquished or closed voluntarily within the past g the reason the entity was closed.	
Yes No			
convicted of, or entered a plea	of guilty o	d a pharmacy permit by misrepresentation or fr r nolo contendere to, regardless of adjudication raud? If yes, please provide documents concerning the	n, a crime in any
Yes No	_		

Pursuant to Section 456.0635(2) and 465.022(5), Florida Statutes, questions 11 through 19 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.
11. 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 #15.)
Yes No
12a. If "yes" to 11, 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
12b. If "yes" to 11, 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 12c. If "yes" to 11, for the felonies of the third degree under Section 893.13(6)(a), Florida Statutes, has it
12c. If "yes" to 11, 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
12d. If "yes" to 11, 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
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 since July 1, 2009? (If yes, explain on a separate sheet providing accurate details.)
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, do not answer question #15. If yes, explain on a separate sheet providing accurate details.)
Yes No
15. 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? (If yes, explain on a separate sheet providing accurate details.)
Yes No

applicant ever been terminated for c or federal government, from any oth	al, officer, agent, managing employed ause, pursuant to the appeals proced er state Medicaid program or the federal of the state of the second	ures established by the state eral Medicare program?
Yes No		
	al, officer, agent, managing employee in a state Medicaid program for the most providing accurate details.)	•
Yes No		
18. Did the termination occur at least (If yes, explain on a separate sheet provide	st 20 years prior to the date of this apling accurate details.)	plication?
Yes No		
	officer, agent, managing employee, of Department of Health Human Service ities? (If yes, please submit proof.)	
Yes No		
20. Are you currently registered or pand permit number for each permit.	permitted in any other states? If yes, (Attach a separate sheet if necessary.)	provide the state, permit type
Yes No		
State	Permit Type	Permit Number
	son, partner, officer, director ever ow te where the pharmacy is located and the st s, if necessary.)	
Pharmacy Name	State	Status
	been taken against any license, pern officer, director, or prescription depaing accurate details.)	
Yes No		

23. Has the applicant, or any officer misdemeanor, excluding minor traffi even if adjudication was withheld by (If yes, explain on a separate sheet provided)	ic convictions? \ the court, so that	ou must include a	II misdemeanors and felonies,
Yes No			
24. Does the applicant, affiliated persoverpayments assessed by a final of explain on a separate sheet providing accurate.	rder of the depart		
Yes No			
24a. Does the applicant, affiliated pe the department? (If yes, explain on a se			a repayment plan approved by
Yes No			
25. Is the policy and procedure man fraudulent representation or invalid	-		•
Yes No			
26. Will the Pharmacy Dispense Sch	nedule II and/or II	I Controlled Substa	ances?
Yes No			
27. Will the Pharmacy act as a Cent	ral Fill Pharmacy	?	
Yes No			
SECTION B. Please complete	e for Change	of Location <u>on</u>	<u>y</u> .
1. Current Practice Location Addres	ss		
City	State		Zip
Email		Telephone Numb	er
2. New Practice Location Address			
City	State		Zip
Email	•	Telephone Numb	er

Please provide your existing Pharmacy Permit Number:
Please provide your existing federal DEA Number:
SECTION C. Please complete for Change of Ownership only.
1. Are you changing physical locations with this change of ownership?
Yes No NOTE: If yes, please complete <b>Section B</b> above.
2. Please provide date when business transaction for the change of ownership will be completed?
Date:
3. Do you have a signed letter from both the buyer and seller which indicates dates that pharmacy permit license should be transferred? NOTE: A copy of the signed letter should be provided with your application.
Yes No
SECTION D. Please complete for Stock Transfer of Ownership only.
1. 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 <b>Section C</b> 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 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)

DH-MQA, 1214 10/17 Rule 64B16-28.100, F.A.C. Page -7-

#### 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

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.doh.state.fl.us/mqa/background.html;
- Failure to submit background screening will delay your application;
- Applicants may use any Livescan service provider approved by the Florida Department of Law Enforcement to submit their background screening to the department;
- If you do not provide the correct Originating Agency Identification (ORI) number to the livescan service provider the Board office <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)*;
- If you do not have a SSN you will need to contact the Board office for a fingerprint card then return the card to the Board office:
- The ORI number for the Board of Pharmacy is EDOH4680Z
- Typically background screening results submitted through a Livescan service provider are received by the Board within 24-72 hours of being processed.
- If you obtain your livescan from a service provider who does not capture your photo you may be required to be reprinted by another agency in the future.

Name:		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		

## Keep this form for your records.



# Item #1- PDM Designation and Privacy Statement Acknowledgement

Florida Board of Pharmacy
Post Office Box 6320
Tallahassee, FL 32314-6320
(850) 245-4292- phone
(850) 413-6982 - fax
info@floridaspharmacy.gov

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

Section A. Prescription	Department Manager (PDM)	Designation
Applicant/Pharmacy Name:		
Applicant/Pharmacy Mailing	Address:	
City	State	Zip
Incoming PDM Name:		License#:
		PS
Date Beginning as PDM:	Incoming PDM Signature	
PDM Transaction Control Nu	│ µmber (TCN) – related to Livescan Fin	dernrints:
		ge. p
***Only provide following inf	ormation is there is an Outgoing PDM at	current pharmacy location ***
Outgoing PDM Name:		License#:
		PS
Date Ending as PDM:	Outgoing PDM Signature	
Section B. Incoming F	PDM Privacy Statement Ackno	wledgement
	be completed by same person listed in <u>Sec</u>	
regarding the sharing, retention	d the statement from the Florida Depart on, privacy and right to challenge incor document from the Federal Bureau of Ir	rect criminal history records
Date:	Incoming PDM 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
MQA.Pharmacy@flhealth.gov

Affiliate / Owner Name:		File # (required		
Applicant Name:				
Affiliate/Owner Mailing Address:				
City	State	Zip		
Affiliate/Owner Email	Affiliate/Owne	r Telephone Number		
Affiliate/Owner Transaction Control Number (TCN) – related to Livescan Fingerprint				
have been provided and read the statement from the Florida Department of Lav				
Enforcement regarding the sharing, retention, privacy and right to challenge				
ncorrect criminal history records and the "Privacy Statement" document from the Federal Bureau of Investigation."				
-euclai bulcau oi ilivestigation.				
Affiliate/Owner Signature (Required) Date (of signature)				

## 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

October 2017 August 2012

DH-MQA 1214, 10/17 Ruls 64B16-281100s714.C. Rule 64B16-28.100, F.A.C.





Dear Florida Pharmacy Permit Applicant,

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

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

When your application arrives, your fees will be deposited and verified before the staff review can begin. You will receive a letter acknowledging receipt of your application. The staff will notify you

DH-MQA 1214, 10/17

Role 64846-284108/15A.C.

Rule 64816-28.100, F.A.C.

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 <a href="mag\_pharmacy@doh.state.fl.us">mag\_pharmacy@doh.state.fl.us</a>, <a href="mag\_info@floridaspharmacy.gov">info@floridaspharmacy.gov</a> 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, 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
1		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

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.

## 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. 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:

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

www.doh.state.fl.us/mqa/pharmacy, select Apply for a License, select Pharmacy Permit-Information, select Livescan vendor list.

DH-MQA 1214, 10/17 Rule 64B16-28.100, F.A.C.

DH-MQA 1214, 08/12 Rule-64B16-28.100, F.A.C.

## 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.
- You must provide the correct ORI number.

b) You must provide the correct ORI number.

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

The ORI number for the pharmacy profession is **EDOH4680Z**. **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).

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 for you to sign this affirmation is included as an addendum to the application as Item #1.

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

## **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 <a href="http://www.DEAdiversion.usdoj.gov">http://www.DEAdiversion.usdoj.gov</a>. 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 <u>Delegand</u> 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 contenedre 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. <u>465.003(14)</u> or s. <u>893.02</u> 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.

## PHARMACY PERMIT APPLICATION CHECKLIST

## Keep a copy of the completed application for your records.

**COMMUNITY PHARMACY PERMIT** 

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.

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?
Attestation from Certified Public Accountant for previous tax year or Florida  Corporate Income /Franchise and Emergency Excise Tax Return (if applicable)?
PDM Designation and Privacy Statement Acknowledgement provided (Application Item #1)?
Affiliate/Owner Privacy Statement Acknowledgement provided for each affiliate/owner (Application Item #2)?
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?
Controlled Substances dispensing questions answered?

## 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.
<ul> <li>"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.</li> </ul>
• 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/mga/enforcement/359_Comm_Pharm.pdf



## **FLORIDA BOARD OF PHARMACY**

P.O. Box 6320 Tallahassee, FL 32314-6320 850-245-4292



http://www.floridaspharmacy.gov

## **FLORIDA BOARD OF PHARMACY**

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

### **COMMUNITY PHARMACY PERMIT APPLICATION**

Application Type - Please choose	one of the following:	
New Establishment (\$255.00	fee) C	hange of Location (\$100.00 fee)
Change of Ownership (\$255.0	00 fee) S	tock Transfer (no fee)
<b>SECTION A. Please comple</b>	ete for all Application	<u>Types</u>
Please list your Federal Employe	r Identification Number:	
Application Type - Please choose	one of the following:	
• • • • • • • • • • • • • • • • • • • •		e \$255 fee(existing permit number)
Change of Location \$100 fee		
		<u>(existing permit number)</u>
Will the Pharmacy Dispense Sche Will the Pharmacy act as a Centra Please list your Federal Employer	Fill Pharmacy?Yes	No
1. Corporate Name		Telephone Number
2. Doing Business As (d/b/a)		E-Mail Address
3. Mailing Address		
, and a second		
City	State	Zip
		·
4. Physical Address		
T I II I I I I I I I I I I I I I I I I		
City	State	Zip
5. List the Prescription Departme	<u>-</u>	
Name	License No. Start	Date PDM Signature

6. Contact Person	Telephone Number		
7. DEA Registration Number	8. Date ready for inspe	ection (within 9	90 days)
		•	-
9. Please provide the name, address, telephone	number, and permit number	er of vour pres	scription drug
wholesale distributor. (write pending if not know		, , <sub>p</sub>	
Name	Telephone Number	Permit No	umber
	-		
Street Address	City	State	<del>Zip</del>
			•
10. Pharmacy Technician Ratio 2:1 or 3:1 (Option	nal)		
Rule 64B16-27.410, Florida Administrative Code, pro		epartment man	nager or
consultant pharmacist of record is required to submit			
Pharmacy prior to the pharmacy allowing a pharmac			
technician. If you would like to apply for the Registe			
by checking the appropriate selection below. Select			
board office for approval to practice with a 2:1 or 3:1		- <b>,</b>	- 4
Name	Lice	nse Number	
Email	Telephone Number		
6. Contact Person	Title		
Email	Telephone Number		

	of the work	3:1 Ratio flow needs that include the operating hours of the pharn I registered pharmacy technicians employed to justify the		
744. Operating Hours				
Store/Facility Hours				
Monday-Friday: Open:	Close:			
Saturday: Open:	Close:	<u></u>		
812. Ownership Information	looo:			
a. Type of Ownership:Ind	ividual	CorporationPartnership		
Oth	ner:	<u>.</u>		
NOTE: If the applicant is a cornor	ration or limi	ited nartnershin you must include with your annication a	CODV	
	•	shareholders, members and partners over the age of	1 10 ?	
	-	-		
c. Does the corporation have more than \$100 million of business taxable assets in this state? <u>If yes, provide attestation from Certified Public Accountant for previous tax year or Florida Corporate Income /Franchise and Emergency Excise Tax Return (F-1120).</u>				
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)				
controls the operation of the		y person who, directly or indirectly, manages, over so of the board of directors must submit a set of fi		
unless you answered yes to	1 <mark>82</mark> c. If §	8 <mark>42c is yes, please list the owners below and or nent Manager or Consultant Pharmacist of Record.</mark>	nly submit	
unless you answered yes to	on Departm Date of	nent Manager or Consultant Pharmacist of Record.	nly submit If <u>812</u> c is	
unless you answered yes to fingerprints for the Prescription	Date of Birth	Mailing Address, City, State, Zip Code	nly submit If <u>8</u> 12c is % of Ownership	
unless you answered yes to fingerprints for the Prescription	on Departm Date of	nent Manager or Consultant Pharmacist of Record.	nly submit If <u>812</u> c is % of Ownership	
unless you answered yes to fingerprints for the Prescription	Date of Birth	nent Manager or Consultant Pharmacist of Record.	nly submit If <u>8</u> 12c is % of Ownership	
unless you answered yes to fingerprints for the Prescription	Date of Birth	nent Manager or Consultant Pharmacist of Record.	nly submit If <u>8</u> 12c is % of Ownership %	
unless you answered yes to fingerprints for the Prescription	Date of Birth	nent Manager or Consultant Pharmacist of Record.	% of Ownership %	
unless you answered yes to fingerprints for the Prescription	Date of Birth  / / / / / /	nent Manager or Consultant Pharmacist of Record.	% of Ownership % %	
unless you answered yes to fingerprints for the Prescription Owner/Officer-Title  913. Has anyone listed in 8.12 business permit which was dis	Date of Birth  / /  / /  / /  / /  / /  / /  / /  d had an osciplined, so	nent Manager or Consultant Pharmacist of Record.	% of Ownership % % % % % % % % %	
unless you answered yes to fingerprints for the Prescription Owner/Officer-Title  913. Has anyone listed in 8.12 business permit which was disyears? If yes, please provide a second of the prescription of th	Date of Birth  / / / / / / / / / / / / / / / / cd had an occiplined, signed affidavi	Mailing Address, City, State, Zip Code  Was a state of the control	% of Ownership % % % % % % % % % ny other	
unless you answered yes to fingerprints for the Prescription Owner/Officer-Title  913. Has anyone listed in 8.12 business permit which was disyears? If yes, please provide a series of the purchase of the pu	Date of Birth  / /  / /  / /  / /  / /  / /  / /  /	Mailing Address, City, State, Zip Code  where the Address is the Consultant Pharmacist of Record.  Mailing Address, City, State, Zip Code  where the Address is the Consultant Pharmacy or an appended, revoked, or closed involuntarily within the	nly submit If 812c is % of Ownership % % % % ny other e past 5	

been convicted of	f, or entered a plea of g	stained a pharmacy permit by misrepresentation or fraud or uilty or nolo contendere to, regardless of adjudication, a crime care fraud? ? If yes, please provide documents concerning this
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.
115. 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 #156.)
Yes No Yes No
125a. If "yes" to 115, 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 Yes No No
125b. If "yes" to 115, 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).
<u>Yes No <b>Yes No </b></u>
125c. If "yes" to 115, 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?
<u>Yes No <b>Yes</b> No </u>
125d. If "yes" to 115, 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).
<u>Yes No Yes No No No</u>
136. 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? (If yes, explain on a separate sheet providing accurate details.)
Yes No (If yes, explain on a separate sheet providing
147. 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 question 15-18. If yes, explain on a separate sheet providing accurate details.))
Yes No Yes — (If yes, explain on a separate sheet providing accurate details)
158. 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
(If you explain on a congrete cheet providing accurate details)

No

applicant ever been terminated for c	pal, officer, agent, managing employed ause, pursuant to the appeals proced by other state Medicaid program or the	lures established by the	
Yes No Yes	No If yes, please provi	de documents concerning this	
1720. Has the applicant or any princ	cipal, officer, agent, managing employ has state Medicaid program for the most providing accurate details.)		
Yes No	(If yes, explain on a separate sheet	et providing accurate details)	
1821. Did the termination occur at le	east 20 years prior to the date of this	application?	
(If yes, explain on a separate sheet provid	<del>-</del>		
	Yes No	(If yes, explain on a separate sheet	
applicant listed on the United States	oal, officer, agent, managing employed s Department of Health Human Service als and Entities? <u>(If yes, please submit p</u>	es Office of Inspector	
Yes No	(If yes please submit proof)		
203. Are you currently registered or permitted in any other states? (Hf yes, provide the state, permit type and permit number for each permit. Attach a separate sheet if necessary.)			
Yes No			
<u>State</u> <del>St</del>	Permit Type	Permit Number	
<b>2<u>1</u>4. Has the applicant, affiliated pe</b> yes, provide the name of the pharmacy, the Attach a separate sheet if necessary.	erson, partner, officer, director ever one state where the pharmacy is located and	wned a pharmacy? (⊮f the status of the pharmacy.	
Yes No	(If yes, explain on a separate sheet pro	oviding accurate details)	
Pharmacy Name	<u>State</u>	<u>Stat</u>	
	er been taken against any license, per ner, officer, director, or prescription of ling details.)		

Yes No Yes (If yes, explain on a separate sheet providing accurate
23. Has the applicant, or any officer, member or partner 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.
(If yes, explain on a separate sheet providing details.)
24. 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 #24a, and explain on a separate sheet providing accurate details.)
Yes No
24a. Does the applicant, affiliated person, partner, officer, director have a repayment plan approved by the department? (If yes, explain on a separate sheet providing accurate details.)
Yes No
25. 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?
Yes No
26. Will the Pharmacy Dispense Schedule II and/or III Controlled Substances?
Vac Na
Yes No
27. Will the Pharmacy act as a Central Fill Pharmacy?
27. Will the Pharmacy act as a Central Fill Pharmacy?  Yes No
27. Will the Pharmacy act as a Central Fill Pharmacy?
27. Will the Pharmacy act as a Central Fill Pharmacy?  Yes No  28. Does the applicant, affiliated person, partner, officer, director have any outstanding fines, liens
27. Will the Pharmacy act as a Central Fill Pharmacy?  Yes No  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) (You must include all misdemeanors and felonies, even if adjudication was
27. Will the Pharmacy act as a Central Fill Pharmacy?  Yes No  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) (You must include all misdemeanors and felonies, even if adjudication was You No 128d. Does the applicant, affiliated person, partner, officer, director have a repayment plan approved
27. Will the Pharmacy act as a Central Fill Pharmacy?  Yes No  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

#### 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 filling of the application and the final grant or denial of the license, which might affect the decision of the department.

Lecrtify that the statements contained in this application are true, complete, and correct and Lagree that said statements shall formthe basis of my application and Ldo authorize the Florida Board of Pharmacy to make any investigations that they deem appropriate
and to secure any additional information concerning me, and Lfurther authorize them to furnish any information they may have orhave in the future concerning me to any person, corporation, institution, association, board, or any municipal, county, state, orfederal governmental agencies or units, and Lunderstand according to the Florida Board of Pharmacy Statutes that a PharmacyPermit may be revoked or suspended for presenting any false, fraudulent, or forged statement, certificate, diploma, or other item, inconnection 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 establish
SECTION B. Please comple	ete for Change	of Location or	nly.
1. Current Practice Location Add	<u>ress</u>		
<u>City</u>	<u>State</u>		Zip
<u>Email</u>		Telephone Numb	<u>er</u>
2. New Practice Location Addres	<u>s</u>		
<u>City</u>	<u>State</u>		Zip
		Talambana Numb	
<u>Email</u>		Telephone Numb	<u>er</u>
Please provide your existing Pha	macy Permit Num	<u>ber:</u>	
Please provide your existing fede	ral DEA Number:		
SECTION C. Please comple	ete for Change	of Ownership	only.
1. Are you changing physical loc	ations with this ch	ange of ownership	?
Yes No			
NOTE: If yes, please complete <b>Section</b>	n B above.		
2. Please provide date when bus	ness transaction t	or the change of o	wnership will be completed?
Date:			

DH-MQA 1214, 10/17 Rule 64B16-28.100, F.A.C.

3. Do you have a signed letter from both the buyer and seller which indicates dates that pharmacy permit license should be transferred? NOTE: A copy of the signed letter should be provided with your application.
V N-
Yes No
SECTION D. Please complete for Stock Transfer of Ownership only.
1. 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 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.

DATE

SIGNATURE

(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.

COMMON	HYPHARWAGY PERWIII
	Application Completed (all questions answered)
	Application signed
	Pharmacy Manager Signature
<del>fee)</del>	\$255.00 Fee Attached (Permit fee includes \$250 application fee and \$5.00 unlicensed activity
State	Articles of Incorporation from the Secretary of
departmen	Fingerprints have been submitted via livescan for all officers and owners and the prescription nt 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

#### 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.

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

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**

<u>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.</u>

- Background screening results are obtained from the Florida Department of Law Enforcement and the Federal Bureau of Investigation by submitting to a fingerprint scan using the Livescan method;
- You can find a Livescan service provider at: http://www.doh.state.fl.us/mga/background.html;
- Failure to submit background screening will delay your application;
- Applicants may use any Livescan service provider approved by the Florida Department of Law
   Enforcement to submit their background screening to the department;
- If you do not provide the correct Originating Agency Identification (ORI) number to the livescan service
  provider the Board office will not receive your background screening results;
- You must provide accurate demographic information to the livescan service provider at the time your fingerprints are taken, including your Social Security number (SSN);
- If you do not have a SSN you will need to contact the Board office for a fingerprint card then return the card to the Board office;
- The ORI number for the Board of Pharmacy is EDOH4680Z

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

- 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: (MM	/ / //DD/YYYY)	Place of Birth:		
Weight:	Height:	Eye Color:	Hair Color:	
Race: (W-White/Latino(a); NA-Native American		Sex: (M=Male; F=Female)		
Citizenship:	<u>., o o</u>	_		
Transaction Contr	ol Number (TCN#	):		

Keep this form for your records.



Florida Board of Pharmacy

## Item #1- PDM Designation and Privacy Statement Acknowledgement

File #: (if known):

Post Office Box 6320	<del></del>	
Tallahassee, FL 32314		
(850) 245-4292- phone		License #: (if applicable):
(850) 413-6982 - fax info@floridaspharmacy	dov	
<u>IIIIO@IIOIIdaspilaiTilacy.</u>	<u>.gov</u>	
Section A. Prescriptio	n Department Manager (PDM)	Designation
Applicant/Pharmacy Name:		
Applicant/Pharmacy Mailin	a Addrose:	
Applicative flatflacy Mailli	<u>y Audress.</u>	
City	<u>State</u>	<u>Zip</u>
Incoming PDM Name:		<u>License#:</u>
		<u>PS</u>
Date Beginning as PDM:	Incoming PDM Signature	
PDM Transaction Control N	│ lumber (TCN) – related to Livescan Fi	ngernrints:
1 Bin Transaction Control	remoer (1914) Terated to Erreseari I	ngerprintes.
	nformation is there is an Outgoing PDM at	
Outgoing PDM Name:		<u>License#:</u>
		PS
Date Ending as PDM:	Outgoing PDM Signature	
Section B. Incoming	<b>PDM Privacy Statement Ackn</b>	owledgement
	l be completed by same person listed in Se	

Date:

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."

**Incoming PDM Signature** 



## <u>Item #2- Affiliate/Owner Privacy Statement Acknowledgement</u>

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

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

From:	Affiliate / Owner Name:		File # (required):		
	Applicant Name:				
	Affiliate/Owner Mailing Address:				
	City	<u>State</u>	Zip		
	Affiliate/Owner Email	Affiliate/Owner	Affiliate/Owner Telephone Number		
	Affiliate/Owner Transaction Control Number (TCN) – related to Livescan Fingerprints:				
		a statement frame that Dis	vide Dependence to file		

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)
--	--------------------------------------	---------------------

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



# INSTITUTIONAL PHARMACY PERMIT APPLICATION AND INFORMATION

October 2017



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 processing delays caused by large volumes 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 your 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 7-14 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

#### INSTITUTIONAL PHARMACY PERMIT APPLICATION INFORMATION

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

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

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

- 1. <u>Institutional Class I Pharmacy</u> An Institutional Class I pharmacy is an institutional pharmacy in which all medicinal drugs are administered from individual prescription containers to the individual patient and in which medicinal drugs are not dispensed on the premises. <u>No medicinal drugs may be dispensed in a Class I Institutional pharmacy</u>. A Special- Closed System Pharmacy Permit, Special Parenteral and Enteral Pharmacy Permit, or Community Pharmacy Permit provide the individual patient prescriptions.
- **2.** <u>Institutional Class II Pharmacy Permit</u> An Institutional Class II pharmacy is an institutional pharmacy that employs the services of a registered pharmacist or pharmacists who, in practicing institutional pharmacy, provide dispensing and consulting services on the premises to patients of that institution, for use on the premises of that institution. An Institutional Class II pharmacy is required be open sufficient hours to meet the needs of the hospital facility.

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

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

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

## <u>Application Processing:</u> 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 setup 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 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 PDM or Consultant Pharmacist of Record to submit fingerprints.

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 for you to sign this affirmation is included as an addendum to the application as Item #1.

### **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 7-10 days. You will receive the actual copy of your license within 7 days. Please wait 7-14 days from your satisfactory inspection before checking on the status of your permit with the Board office.
- You may look up your license number on our website at <a href="http://www.flhealthsource.com/">http://www.flhealthsource.com/</a> under "Verify a License."

#### **Drug Enforcement Administration (DEA)**

## The DEA will not issue a registration until the Florida Board of Pharmacy has issued a pharmacy permit.

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 <a href="http://www.DEAdiversion.usdoj.gov">http://www.DEAdiversion.usdoj.gov</a>.

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

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 contenedre 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. <u>465.003(14)</u> or s. <u>893.02</u> 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.

## PHARMACY PERMIT APPLICATION CHECKLIST

Keep a copy of the completed application for your records.

**COMMUNITY PHARMACY PERMIT** 

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.

 _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?
_Attestation from Certified Public Accountant for previous tax year or Florida Corporate Income /Franchise and Emergency Excise Tax Return (if applicable)?
 _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 <b>Institutional Pharmacy</b> applicants (Application Item #3)?
 _Answers to Policy and Procedure Questions provided for <b>Modified Class II</b> Institutional Pharmacy applicants (Application Item #4)?
 _Applicant/Affiliate/Owner supplemental documents provided for explaining any previous ownership, disciplinary actions, voluntary relinquishments and/or crimina activity?
_Applicant/Affiliate/Owner pharmacy permit questions answered and supplemental documents provided?
_Controlled Substances dispensing questions answered?



## FLORIDA BOARD OF PHARMACY

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



## **APPLICATION**

Application Type – Please choose one of the following:				
New Establishment (\$25		Change of Location (\$100.00 fee)		
Change of Ownership (\$	255.00 fee)	Stock T	ransfer (no fee)	
Pharmacy Permit Type - Plea	ase choose one of the	<u>following:</u>		
Institutional Class IInstitutional Class II	Modified Institutional C	Class II A(	Class II B	Class II C
<b>SECTION A. Please cor</b>	nplete for all App	lication Types	6	
Please list your Federal Emp	oloyer Identification Nu	ımber:		
1. Corporate Name		Telephone Number		
2. Doing Business As (d/b/a)			E-Mail Addres	SS
3. Mailing Address				
City	State		Zip	
4. Physical Address				
City State			Zip	
5. Consultant Pharmacist of Record (COR) Information				
Name			License Nu	ımber
Email		Telephone Number		
6. Contact Person		Title		
Email		Telephone Num	ber	

7. Operating Hours			
Prescription Department Hours Monday - Friday: Open:			
Saturday: Open:	_ Close:	Saturday: Open:	_ Close:
8. Ownership Information			
a. Type of Ownership:Indiv	/idual _	CorporationPartnership	
NOTE: If the applicant is a corpor Articles of Incorporation on file wi		ed partnership you must include with your applic a Secretary of State's office.	ation a copy of the
b. Are the applicants, officers,	directors, s	shareholders, members and partners over the	age of 18?
Yes No			
	blic Accounta	100 million of business taxable assets in this ant for previous tax year or Florida Corporate Income	-
Yes No			
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 8c. If 8c is yes, please list the owners below and only submit fingerprints for the Prescription Department Manager or 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. Attach a separate sheet if necessary.			
Owner/Officer-Title	Date of Birth	Mailing Address, City, State, Zip Code	% of Ownership
	1 1		%
	1 1		%
	1 1		%
	1 1		%
	1 1		%
9. Has anyone listed in 8.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? If yes, please provide a signed affidavit disclosing the reason the entity was closed.			
Yes No			
9a. Has anyone listed in 8.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?  If yes, please provide a signed affidavit disclosing the reason the entity was closed.			
Yes No			
10. Has anyone listed in 8.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? If yes, please provide documents concerning this conviction.			
Yes No	_		

Pursuant to Section 456.0635(2) and 465.022(5), Florida Statutes, questions 11 through 19 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.
11. 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 #15.)
Yes No
12a. If "yes" to 11, 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
12b. If "yes" to 11, 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
12c. If "yes" to 11, 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
12d. If "yes" to 11, 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
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, a felony under 21 U.S.C. ss. 801-970 (relating to controlled substances) or 42 U.S.C. ss. 1395-1396 (relating to public health, welfare, Medicare and Medicaid issues)? (If yes, explain on a separate sheet providing accurate details.)
Yes No
13a. If "yes" to 13, has it been more than 15 years before the date of application since the sentence and any subsequent period of probation for such conviction or plea ended?
Yes No
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, do not answer question #15. If yes, explain on a separate sheet providing accurate details.)
Yes No

15. 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? (If yes, explain on a separate sheet providing accurate details.)				
Yes No				
applicant ever been terminated for c or federal government, from any oth	al, officer, agent, managing employe ause, pursuant to the appeals proceer state Medicaid program or the fed 3. If yes, please provide documents concerns.	dures established by the state eral Medicare program?		
Yes No				
	al, officer, agent, managing employe h a state Medicaid program for the m t providing accurate details.)	- ·		
Yes No				
<b>18. Did the termination occur at leas</b> (If yes, explain on a separate sheet provide	st 20 years prior to the date of this ap ing accurate details.)	oplication?		
Yes No				
	officer, agent, managing employee, Department of Health Human Service ities? (If yes, please submit proof.)			
Yes No				
20. Are you currently registered or pand permit number for each permit.	permitted in any other states? If yes (Attach a separate sheet if necessary.)	, provide the state, permit type		
Yes No				
State	Permit Type	Permit Number		
	son, partner, officer, director ever ov te where the pharmacy is located and the s s, if necessary.)			
Yes No				
Pharmacy Name	State	Status		

22. Has any disciplinary action ever applicant, affiliated person, partner, any other? (If yes, explain on a separate	officer, director,	or consultant phar	
Yes No			
23. Has the applicant, or any officer misdemeanor, excluding minor traffi even if adjudication was withheld by (If yes, explain on a separate sheet provided)	c convictions? Y	You must include a	II misdemeanors and felonies,
Yes No			
24. Does the applicant, affiliated persoverpayments assessed by a final or explain on a separate sheet providing accurate.	rder of the depar		
Yes No			
24a. Does the applicant, affiliated pe the department? (If yes, explain on a se			a repayment plan approved by
Yes No			
25. Is the policy and procedure man fraudulent representation or invalid p	ual for preventin	g controlled substa	
Yes No			
26. If compounding sterile preparati	ions, is your esta	ıblishment Rule 64	B16-27.797, F.A.C. compliant?
Yes No			
27. Is there any other permit issued on this application? (If yes, explain on			• •
Yes No	<u>, , , , , , , , , , , , , , , , , , , </u>	<u> </u>	,
SECTION B. Please complete		of Location <u>onl</u>	у.
1. Current Practice Location Addres	S		
City	State		7in
City	State		Zip
Email		Telephone Numb	er
2. New Practice Location Address			
City	State		Zip
Email		Telephone Numb	er

Please provide your existing Pharmacy Permit Number:	
Please provide your existing federal DEA Number:	
SECTION C. Please complete for Change of Owner	ership <u>only</u> .
1. Are you changing physical locations with this change of ow	vnership?
Yes No NOTE: If yes, please complete <b>Section B</b> above.	
2. Please provide date when business transaction for the chan	nge of ownership will be completed?
Date:	
3. Do you have a signed letter from both the buyer and seller we license should be transferred? NOTE: A copy of the signed letter s	• • • •
Yes No	
SECTION D. Please complete for Stock Transfer of	of Ownership <u>only</u> .
1. Please provide the date when the transfer of ownership inte	rest took place?
Date:	
2. Did your company's FEIN change as a result of the transfer of D, Question 1 above? <u>NOTE: If yes, please complete Section C above</u>	•
Yes No	
ALL QUESTIONS MUST BE ANSWERED OR YOUR APPLI	
Section 456.013(1), F.S., requires that applicants supplement their applic in any circumstances or conditions stated in the application, which takes and the final grant or denial of the license, which might affect the decision	place between the initial filing of the application
I certify that the statements contained in this application are true, completed shall form the basis of my application and I do authorize the Florida Board of deem appropriate and to secure any additional information concerning reinformation they may have or have in the future concerning me to any per or any municipal, county, state, or federal governmental agencies or units, of Pharmacy Statutes that a Pharmacy Permit may be revoked or suspend statement, certificate, diploma, or other item, in connection with an applicate 465.015(2)(a), F.S.	of Pharmacy to make any investigations that they me, and I further authorize them to furnish any rson, corporation, institution, association, Board, and I understand according to the Florida Board led for presenting any false, fraudulent, or forged
Under penalty of perjury I have read the foregoing document and that the fa false information may result in disciplinary action against my license or crir	
SIGNATURE	DATE

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

Name:		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		

## Keep this form for your records.



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

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

File #:	(if known <b>):</b>
Licens	e #: (if applicable):

Section A. Consultant	Pharmacist of Record (COR) I	Designation
Applicant/Pharmacy Name:		
Applicant/Pharmacy Mailing	Address:	
City	State	Zip
Incoming COR Name:		License#:
		PU
Date Beginning as COR:	Incoming COR Signature	
COR Transaction Control Nu	⊥ umber (TCN) – related to Livescan Fin	gerprints:
	ormation is there is an Outgoing COR at	<u> </u>
Outgoing COR Name:		License#:
		PU
Date Ending as COR:	Outgoing COR Signature	
Section B. Incoming (	COR Privacy Statement Ackno	wledgement
Note: Acknowledgment should	be completed by same person listed in <u>Sec</u>	tion A above as <u>Incoming COR</u> .
regarding the sharing, retention	d the statement from the Florida Depart on, privacy and right to challenge incor document from the Federal Bureau of Ir	rect criminal history records
Date:	Incoming COR Signature	



## <u>Item #2- Affiliate/Owner Privacy Statement Acknowledgement</u>

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

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

State	
stato	
itato	
itato	
tato.	
tato	
naic	Zip
Affiliate/Owner Teleph	one Number
(TCN) - related to Liv	escan Finger
	<u> </u>
n, privacy and right t	o challenge
)	ent from the Florida D on, privacy and right t Privacy Statement" do



## **Item #3 - Policy and Procedure Questions**

## To be completed by Institutional Class II Pharmacy Permit Applicants

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

1) List the following:

Firm Name:

Doing business as (d/b/a):

Telephone number: Address:

Permit number (if already licensed as an institutional pharmacy):

- 2) Explain the practice setting of the proposed facility.
- 3) What are the objectives and purpose of the permittee? Give detailed explanation of the services of the facility scope and practice.
- 4) What are the experience, qualifications, special education, and/or training of the compounding pharmacist? Please provide a resume.
- 5) Address the ratio of supportive personnel to each pharmacist. How will the supportive personnel be utilized? Include a job description for any such supportive personnel.
- 6) Describe the drug delivery system. Begin with the ordering of medications and track your procedures up to delivery to the patient. If utilizing remote medication order processing and the pharmacist is not an employee of the institution, describe the pharmacist and institution's responsibility.
- 7) What categories of parenteral/enteral products will be prepared (i.e. IV, enteral, irrigating, and oncology products)? Include sample labels.
- 8) What is the policy regarding the delivery of parenteral/enteral products to the patient? Describe methods used and trace the path the product takes from the time it leaves the permittee until it reaches the patient. Describe how products are protected from extreme temperature conditions.
- 9) Address the policy and procedure, special equipment and special techniques to dispense sterile preparations for parenteral therapy/nutrition. If this type of dispensing will not be performed, please state so accordingly.

- 10) Address the policy and procedure, special equipment and special techniques to dispense sterile jejunostomy feeding/sterile irrigation solutions. If this type of dispensing will not be performed, please state so accordingly.
- Address the policy and procedure, special equipment and special techniques to dispense cytotoxic or anti-neoplastic agents. If this type of dispensing will not be performed, please state so accordingly.
- 12) What is the procedure for the annual review and updating of the policy and procedure manual?
- 13) Include the layout/floor plan of the pharmacy. The drawing must include the dimensions of the clean room and the pharmacy, location of the hood, sink and other equipment. The drawing must also show the location of the clean room relative to other pharmacy and storage areas.
- 14) Include a sample copy of a patient profile.
- 15) Address the use of aseptic techniques.
- 16) Describe the Quality Assurance Program.
- 17) Describe with detail the policy and procedure for patient education, including the personnel involved.
- 18) Address the policy and procedure for handling waste and returns.
- 19) Describe the type of certified laminar flow hood(s) used and the frequency of certification.
- 20) Describe the refrigerator/freezer to be used.
- 21) Describe appropriate waste containers for:
  - a. Used needles and syringes.
  - b. Cytotoxic waste including disposable apparel used in preparation.
- Address the following supplies to be used: gloves, mask, gowns, needles, syringes, disinfectant cleaning agents, clean towels, hand-washing materials with bactericidal properties, vacuum containers/transfer sets, and spill kits for cytotoxic agent spills.
- 23) Address the following references to be used:
  - a. Chapters 465 and 893, F.S., and Rule Title 64B16, F.A.C.
  - b. Authoritative Therapeutic Reference.
  - c. Handbook of injectable drugs by American Society of Health-System Pharmacists.
- 24) Occupational Safety and Health Administration guidelines for safe handling of cytotoxic drugs.



## <u>Item #4 - Policy and Procedure Questions</u>

## To be completed by Modified Institutional Class II Pharmacy Permit Applicants

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

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

- 1) List the following:
  - Firm Name:
  - Doing business as (d/b/a):
  - Telephone number:
  - Address:
  - Consultant pharmacist of record:
- 2) Describe the purpose of the establishment. What sector of the community are you serving?
- 3) Is this is an inpatient facility? If so, how many beds are housed in the facility? What is the average length of stay?
- 4) List the drug formulary to be used.
- 5) Include a diagram of pharmacy storage space and a description of drug security measures.
- 6) Describe the consultant pharmacist of record's responsibilities.
- 7) Under whose DEA registration will controlled substances be ordered?
- 8) Describe the drug delivery system. Begin with the ordering of medications and track your procedures up to delivery to the patient.
- 9) Include a statement that perpetual inventory records will be maintained for controlled substances and injectable inventory.
- 10) Include a statement to the effect that no drugs will be dispensed from the facility.

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

- 11) If compounding sterile preparations, describe compliance with Rule 64B16-27.797, F.A.C.
- 12) What categories of parenteral/enteral products will be prepared (i.e. IV, enteral, irrigating, and oncology products)? Include sample labels.
- 13) What is the policy regarding the delivery of parenteral/enteral products to the patient? Describe methods used and trace the path the product takes from the time it leaves the permittee until it reaches the patient. Describe how this product is protected from extreme temperature conditions.
- Address the policy and procedure, special equipment and special techniques to dispense sterile preparations for parenteral therapy/nutrition. If this type of dispensing will not be performed, please state so accordingly.
- Address the policy and procedure, special equipment and special techniques to dispense sterile jejunostomy feeding/sterile irrigation solutions. If this type of dispensing will not be performed, please state so accordingly.
- Address the policy and procedure, special equipment and special techniques to dispense cytotoxic or anti-neoplastic agents. If this type of dispensing will not be performed, please state so accordingly.
- 17) What is the procedure for the annual review and updating of the policy and procedure manual?
- 18) Include the layout/floor plan of the pharmacy. The drawing must include the dimensions of the clean room and the pharmacy, location of the hood, sink and other equipment. The drawing must also show the location of the clean room relative to other pharmacy and storage areas.
- 19) Include a sample copy of a patient profile.
- 20) Address the use of aseptic techniques.
- 21) Describe the Quality Assurance Program.
- 22) Describe with detail the policy and procedure for patient education, including the personnel involved.
- 23) Address the policy and procedure for handling waste and returns.
- 24) Describe the type of certified laminar flow hood(s) to be used and the frequency of certification.
- 25) Describe the refrigerator/freezer to be used.
- 26) Describe appropriate waste containers for:
  - a. Used needles and syringes.
  - b. Cytotoxic waste including disposable apparel used in preparation.
- 27) Address the following supplies to be used: gloves, mask, gowns, needles, syringes, disinfectant cleaning agents, clean towels, hand-washing materials with bactericidal properties, vacuum containers/transfer sets, and spill kits for cytotoxic agent spills.
- 28) Address the following references to be used:
  - a. Chapters 465 and 893, F.S., and Title 64B16, F.A.C.
  - b. Authoritative Therapeutic Reference.
  - c. Handbook of Injectable Drugs by American Society of Health-System Pharmacists.
  - d. Occupational Safety and Health Administration guidelines for safe handling of cytotoxic drugs.

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





INSTITUTIONAL PHARMACY PERMIT APPLICATION AND INFORMATION





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 30-7 - 14 days if any materials are incomplete.

If you need to communicate with the board staff, you are encouraged to email the board staff at <a href="mailto:info@floridaspharmacy.govmqa\_pharmacy@doh.state.fl.us">info@floridaspharmacy.govmqa\_pharmacy@doh.state.fl.us</a>, 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

Sincerely,

The Florida Board of Pharmacy

DH-MQA 1215, 12/10 Rule 64B16-28.100 F.A.C.

#### Institutional Pharmacy Permit Application Information

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

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

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

- 1. <u>Institutional Class I Pharmacy</u> An Institutional Class I pharmacy is an institutional pharmacy in which all medicinal drugs are administered from individual prescription containers to the individual patient and in which medicinal drugs are not dispensed on the premises. No medicinal drugs may be dispensed in a Class I Institutional pharmacy. A Special- Closed System Pharmacy Permit, Special Parenteral and Enteral Pharmacy Permit, or Community Pharmacy Permit provide the individual patient prescriptions
- **2.** <u>Institutional Class II Pharmacy Permit</u> An Institutional Class II pharmacy is an institutional pharmacy that employs the services of a registered pharmacist or pharmacists who, in practicing institutional pharmacy, provide dispensing and consulting services on the premises to patients of that institution, for use on the premises of that institution. An Institutional Class II pharmacy is required be open sufficient hours to meet the needs of the hospital facility.

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

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

#### 3. Modified Institutional Class II Pharmacy Permits -

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

#### Application Processing -

Please read all application instructions before completing your application.

#### 1) Mail Application.

<u>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:</u>

#### **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 setup an inspection appointment. If your application is incomplete, you will be notified in writing of what is required to make your application complete.

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

Florida Department of Health
Board of Pharmacy
P.O. Box 6320
Tallahassee, Florida 32314-6320
OR, use the following address if you are using express mail: Florida Department of Health
Board of Pharmacy
4052 Bald Cypress Way, Bin C-04
Tallahassee, FL 32399-3254

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

#### 2) Submit fingerprint results.

Failure to submit fingerprints will delay your application. All officers, officers and prescription department managers are required to submit a set of fingerprints unless the corporation is exempt under the Section 465.022, Florida Statutes for corporations having more than \$100 million of business taxable assets in this state. These corporations are only required to have the prescription

<u>DH-MQA 1215, 10/17</u> <u>Rule 64B16-28.100 F.A.C.</u> 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:

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

<u>www.doh.state.fl.us/mqa/pharmacy</u>, 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. You must provide the <u>correct ORI number.</u> -

- 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 <u>EDOH4680Z. FL924190Z</u>

#### 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).

#### 3) Privacy Statement and Attestation

DH-MQA 1215, 10/17 Rule 64B16-28.100 F.A.C. 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 for you to sign this affirmation is included as an addendum to the application as Item #1.

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

#### Institutional Class II Pharmacy Permit Applicants Complete the Following Questions.

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

List the following: Firm Name:

Doing business as (d/b/a): Telephone number: Address:

Permit number (if already licensed as an institutional pharmacy):

- 2) Explain the practice setting of the proposed facility.
- What are the objectives and purpose of the permittee? Give detailed explanation of the services of the facility scope and practice.
  - What are the experience, qualifications, special education, and/or training of the compounding pharmacist? Please provide a resume.
- 5) Address the ratio of supportive personnel to each pharmacist. How will the supportive personnel be utilized? Include a job description for any such supportive personnel.
  - Describe the drug delivery system. Begin with the ordering of medications and track your procedures up to delivery to the patient. If utilizing remote medication order processing and the pharmacist is not an employee of the institution, describe the pharmacist and institution's responsibility.
    - What categories of parenteral/enteral products will be prepared (i.e. IV, enteral, irrigating, and oncology products)? Include sample labels.
- What is the policy regarding the delivery of parenteral/enteral products to the patient?

  Describe methods used and trace the path the product takes from the time it leaves the permittee until it reaches the patient. Describe how products are protected from extreme temperature conditions.
- Address the policy and procedure, special equipment and special techniques to dispense sterile preparations for parenteral therapy/nutrition. If this type of dispensing will not be performed, please state so accordingly.
- 10) Address the policy and procedure, special equipment and special techniques to dispense sterile

<u>DH-MQA 1215, 10/17</u> Rule 64B16-28.100 F.A.C.

	jejunostomy feeding/sterile irrigation solutions. If this type of dispensing will not be performed please state so accordingly.
11)	Address the policy and procedure, special equipment and special techniques to dispense cytotoxic or anti-neoplastic agents. If this type of dispensing will not be performed, please state so accordingly.
12)	What is the procedure for the annual review and updating of the policy and procedure manual?
13)	Include the layout/floor plan of the pharmacy. The drawing must include the dimensions of the clean room and the pharmacy, location of the hood, sink and other equipment. The drawing must also show the location of the clean room relative to other pharmacy and storage areas.
	14) Include a sample copy of a patient profile.
	15) Address the use of aseptic techniques.
	16) Describe the Quality Assurance Program.
17)	Describe with detail the policy and procedure for patient education, including the personne involved.
	18) Address the policy and procedure for handling waste and returns.
19)	Describe the type of certified laminar flow hood(s) used and the frequency of certification.
	20) Describe the refrigerator/freezer to be used.
	21) Describe appropriate waste containers for:
	a. Used needles and syringes.
	b. Cytotoxic waste including disposable apparel used in preparation.
<del>22)</del>	Address the following supplies to be used: gloves, mask, gowns, needles, syringes disinfectant cleaning agents, clean towels, hand-washing materials with bactericidal properties vacuum containers/transfer sets, and spill kits for cytotoxic agent spills.
	23) Address the following references to be used:
	<ul> <li>a. Chapters 465 and 893, F.S., and Rule Title 64B16,F.A.C.</li> <li>b. Authoritative Therapeutic Reference.</li> <li>c. Handbook of injectable drugs by American Society of Health-System Pharmacists.</li> </ul>
24)	Occupational Safety and Health Administration quidelines for safe handling of cytotoxic drugs

Modified Institutional Class II Pharmacy Permit Applicants Complete the Following Questions

Modified Institutional Class II pharmacies are those institutional pharmacies in short-term, primary care treatment centers that meet all the requirements for a Class II permit, except space and equipment requirements. Modified Class II Institutional pharmacies are designated as Type

"A", Type "B" and Type "C" according to the type of specialized pharmaceutical delivery system utilized. Please review Rule 64B16-28.702, Florida Administrative Code for specific requirements.

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

•	1)	List the following: Firm Name:
	,	· · · · · · · · · · · · · · · · · · ·
		Doing business as (d/b/a): Telephone number: Address:
		Doing business as (arbra). Telephone number. Mariess.
		Consultant pharmacist of record:
		Consultant priarriacist of record.

- Describe the purpose of the establishment. What sector of the community are you serving?
  - 3) Is this is an inpatient facility? If so, how many beds are housed in the facility? What is the average length of stay?
  - 4) List the drug formulary to be used.
  - Include a diagram of pharmacy storage space and a description of drug security measures.
  - Describe the consultant pharmacist of record's responsibilities.
  - 7) Under whose DEA registration will controlled substances be ordered?
  - Describe the drug delivery system. Begin with the ordering of medications and track your procedures up to delivery to the patient.
  - Include a statement that perpetual inventory records will be maintained for controlled substances and injectable inventory.
  - 10) Include a statement to the effect that no drugs will be dispensed from the facility. If compounding sterile preparations, please answer the additional questions below.
  - 11) If compounding sterile preparations, describe compliance with Rule 64B16-27.797, F.A.C.
- 12) What categories of parenteral/enteral products will be prepared (i.e. IV, enteral, irrigating, and encology products)? Include sample labels.
- What is the policy regarding the delivery of parenteral/enteral products to the patient? Describe methods used and trace the path the product takes from the time it leaves the permittee until it reaches the patient. Describe how this product is protected from extreme temperature conditions.
- Address the policy and procedure, special equipment and special techniques to dispense sterile preparations for parenteral therapy/nutrition. If this type of dispensing will not be performed, please state so accordingly.
- 15) Address the policy and procedure, special equipment and special techniques to dispense sterile jejunostomy feeding/sterile irrigation solutions. If this type of dispensing will not be performed, please state so accordingly.

<u>DH-MQA 1215, 10/17</u> <u>Rule 64B16-28.100 F.A.C.</u>

- Address the policy and procedure, special equipment and special techniques to dispense cytotoxic or anti-neoplastic agents. If this type of dispensing will not be performed, please state so accordingly. What is the procedure for the annual review and updating of the policy and procedure manual? Include the layout/floor plan of the pharmacy. The drawing must include the dimensions of the clean room and the pharmacy, location of the hood, sink and other equipment. The drawing must also show the location of the clean room relative to other pharmacy and storage areas. Include a sample copy of a patient profile. 20) Address the use of aseptic techniques. Describe the Quality Assurance Program. Describe with detail the policy and procedure for patient education, including the personnel involved. Address the policy and procedure for handling waste and returns. Describe the type of certified laminar flow hood(s) to be used and the frequency of certification. Describe the refrigerator/freezer to be used. <del>26)</del>— Describe appropriate waste containers for: a. Used needles and syringes. b. Cytotoxic waste including disposable apparel used in preparation. Address the following supplies to be used: gloves, mask, gowns, needles, syringes,
- disinfectant cleaning agents, clean towels, hand-washing materials with bactericidal properties, vacuum containers/transfer sets, and spill kits for cytotoxic agent spills.
  - Address the following references to be used: <del>28)</del>
  - a. Chapters 465 and 893, F.S., and Title 64B16, F.A.C. b. Authoritative Therapeutic Reference.
  - c. Handbook of Injectable Drugs by American Society of Health-System Pharmacists.
  - d. Occupational Safety and Health Administration guidelines for safe handling of cytotoxic drugs.

#### **Licensure Process**

- Once the application is deemed complete, the board staff authorizes an inspection. Upon completion of the inspection, the inspector notifies the board office as to whether the inspection was satisfactory or unsatisfactory. If the inspection is satisfactory, a permit number is issued within 10 days. Please wait 10 days from your satisfactory inspection before checking on the status of your permit.
- You may look up your license number on our website at http://www.flhealthsource.com/ under "Verify a License."

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 <a href="http://www.DEAdiversion.usdoj.gov">http://www.DEAdiversion.usdoj.gov</a>. DEA Form 224 may be obtained in paper form by writing to:

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

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

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

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. <u>465.003</u>(14) or s. <u>893.02</u> 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.

### 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.

#### **COMMUNITY 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?

Attestation from Certified Public Accountant for previous tax year or Florida Corporate Income /Franchise and Emergency Excise Tax Return (if applicable)?

\_COR Designation and Privacy Statement Acknowledgement provided (Application Item #1)?

\_Affiliate/Owner Privacy Statement Acknowledgement provided for each affiliate/owner (Application <a href="Item#2">Item #2</a>)?

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

Answers to Policy and Procedure Questions provided for **Modified Class II Institutional Pharmacy** applicants (Application Item #4)?

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

<u>Applicant/Affiliate/Owner pharmacy permit questions answered and supplemental documents</u> provided?

Controlled Substances dispensing questions answered?

#### 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.?

DH-MQA 1215, 10/17 Rule 64B16-28.100 F.A.C. DH-MQA 1215, 08/12 Rule 64B16-28.100,-F.A.C.

	partment equipped an area suitable for private patient counseling it applying for acy permit pursuant to Rule 64B16-
_Are all required sign	<del>s displayed?</del>
0	Daily operating hours pursuant to Rule 64B16-28.1081, F.A.C.
egenerically equivaler	"Consult your pharmacist regarding the availability of a less expensive at drug and the requirements of Florida law" pursuant to Section 465.025(7),
0	Prescription Department Closed pursuant to Rule 64B16-28.109, F.A.C.
0	Pharmacist meal breaks pursuant to Rule 64B16-27.1001(6), F.A.C.
0	Patient Consultation Area pursuant to Rule 64B16-28.1035, F.A.C.
	rile preparations, is your pharmacy compliant with Standards for Compounding- pursuant to Rule 64B16-27.797, F.A.C?
	Cancer Drug Donation Program, check question #25 on the application and



#### FLORIDA BOARD OF PHARMACY

P.O. Box 6320 Tallahassee, FL 32314-6320 850-245-4292

**Application Type – Please choose one of the following:** 

New Establishment (\$255.00 fee)

http://www.floridaspharmacy.gov

## FLORIDA BOARD OF PHARMACY

P.O. Box 6320

Tallahassee, FL 32314-6320 Telephone (850) 488-0595

http://www.doh.state.fl.us/mqa/pharmacy

**INSTITUTIONAL** 

**PHARMACY** 

**PERMIT** 

Change of Location (\$100.00 fee)

# INSTITUTIONAL PHARMACY PERMIT APPLICATION APPLICATION

Change of Ownership (	\$255.00 fee)	Stock Fransfer (no fee	<u>e)</u>
Pharmacy Permit Type - Ple	ase choose one of the following:		
Institutional Class I Institutional Class II	Modified Institutional Class II A	Class II B	Class II C
<b>SECTION A. Please co</b>	mplete for all Application	<u>Types</u>	
Please list your Federal Em	ployer Identification Number:		
Type of Institutional Pharma Institutional Class I	· ·	the following: ed Institutional Class II	,
1. Corporate Name		Telephone N	umber
•			
2. Doing Business As (d/b/a	)	E-Mail Addre	ess
3. Mailing Address			
City	State	Zip	

4. Physical Address						
City	State		Zip			
Oity	Otate		Lip			
5. List Consultant Pharmacist	of Record and subr	nit a set of fingerprin	nts with	\$48 fee.		
Name	License No.	Start Date		Signatu	ıre	
				o ignati		
C. Contact Dovern		Tolonkona Numba				
6. Contact Person		Telephone Numbe	F			
7. DEA Registration Number		8. Date ready for i			within 90 days	
		of the date of the application)				
9. Please provide the name, ac	<del>ldress, telephone n</del>	umber, and permit n	<del>umber c</del>	of your presc	ription drug	
wholesale distributor.						
Name		Telephone Numb	Telephone Number		Permit Number	
Street Address		City State Zip		Zin		
0.100171441000		- City		Otato	p	
E O I ( t D) i - t - t E	) I (OOD) I (					
5. Consultant Pharmacist of R	<u>(ecora (COR) intorn</u>	<u>nation</u>				
<u>Name</u>			Licen	se Number		
		T =				
<u>Email</u>		Telephone Number	<u>er</u>			
0.0.1.15		T141				
6. Contact Person		<u>Title</u>				
<u>Email</u>		Telephone Number	<u>er</u>			

10. Pharmacy Technician Ratio	2:1 or 3:1	<del>(Optional)</del>	
Rule 64B16-27.410, Florida Adm	inistrative C	ode, provides that the consultant pharmacist of record t	e required
		n the Board of Pharmacy prior to practicing with either a	
ratio of supervision.		3	
•	harmacy Te	echnician 2:1 or 3:1 ratio, you may do so by checking the	appropriate
		erves as your official notification to the board office that	
		3:1 ratio. The board will provide notice of application app	
denial.	1111 4 2.1 01 0	Tallo. The board will provide holide of application app	70 (41 01
deriidi.	2:1 Rati	o 3:1 Ratio	
	<del>2.1 Nati</del>	<del> 5.1 Natio</del>	
<b>711.</b> Operating Hours			
Prescription Department Hours	•		
Monday - Friday: Open:	Close:		
Saturday: Open:	Close:	Sunday: Open: Close:	
Prescription Department Hours 812. Ownership Information	•		
<u>o+2</u> . Ownership information			
a Type of Ownership: Indiv	vidual	Corporation Partnership	
NOTE: If the applicant is a corpora	ation or limit	ed partnership you must include with your application a c	ony of the
		a Secretary of State's office. Type of Ownership: _Indivi	
		shareholders, members and partners over the age of	
		marenoiders, members and partners over the age or	10:
Yes No			
c. Does the corporation have n	nore than \$	100 million of business taxable assets in this state?_	? If yes,
provide attestation from Certified Pul	blic Accounta	nt for previous tax year or Florida Corporate Income /Franchis	se and
Emergency Excise Tax Return (F-11	<u>20).</u>		
Yes No		If yes, provide attestation from Certified Public Accountant for year or Florida Corporate Income/Franchise and Emergency E	
d List all the owners and office	re of the co	prporation. Each person listed below having an own	
		rson who, directly or indirectly, manages, oversees,	
controls the operation of the	and any pe	rison who, unechy or munechy, manages, oversees,	Oi
	ad mambar	s of the board of directors must submit a set of finar	ornrinto
	ia member	s of the board of directors must submit a set of finge	rprints
and fees_	0- 16 0- 1-	place list the suman below and only submit fi	
_		yes, please list the owners below and only submit fi	
tor the Prescription Departmen	<u>t Wanager (</u>	or Consultant Pharmacist of Record. If 8c is yes and	tne prints
Own and Office or Title	Date of	Mallian Address City Ctate 7in Cade	% of
Owner/Officer-Title	Birth	Mailing Address, City, State, Zip Code	Ownership
	1 1		%
	' '		/0
	/ /		%
	/ /		%
	/ /		%
1	1		1

DH-MQA 1215, 10/17

Rule 64B16-28.100 F.A.C. DH-MQA, 1215, 08/12 Rule 64B16-28.100, F.A.C.

9. Has any	one listed in 8.d has	s an owners	hip interest of 5% or more in a pharmacy or any other	
			spended, revoked, or closed involuntarily within the p	<u> </u>
			lisclosing the reason the entity was closed.	
<u> </u>	, jo. 0 d. 0 0   p. 0 1 d. 0 d. 0 . g.		<u></u>	
Yes	No	_		
40 11				
	•		a pharmacy permit by misrepresentation or fraud or be	
			nolo contendere to, regardless of adjudication, a crime	
jurisdiction	n which relates to he	ealth care fra	aud? If yes, please provide documents concerning this convicti	<u>on.</u>
Yes	No			
				0/
		<i>I</i>		<del>%</del>
		<i> </i>		<del>%</del>
		<i>I</i> — <i>I</i>		<del>%</del>
		ı		

Pursuant to Section 456.0635(2) and 465.022(5), Florida Statutes, questions 11 through 19 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.
11. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under Chapter 409, F.S. (relating to social and economic assistance), Chapter 817, F.S. (relating to fraudulent practices), Chapter 893, F.S. (relating to drug abuse prevention and control) or a similar felony offense(s) in another state or jurisdiction? (If you responded "no", skip to #12.)
YesNo
13. Has anyone listed in 12.d has an ownership interest of 5% or more in a pharmacy or any other- business permit which was disciplined, suspended, revoked, or closed involuntarily within the past 5- years?
14. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under Chapter 409, F.S. (relating to social and economic assistance), Chapter 817, F.S. (relating to fraudulent practices), Chapter 893, F.S. (relating to drug abuse prevention and control) or a similar felony offense(s) in another state or jurisdiction? (If you responded "no", skip to #15.)
Yes No
114a. If "yes" to 114, 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
114 b. If "yes" to 114, 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
114c. If "yes" to 1114, 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
1144d. If "yes" to 1144, 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
125. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under 21 U.S.C. ss. 801-970 (relating to controlled substances) or 42 U.S.C. ss. 1395-1396 (relating to public health, welfare, Medicare and Medicaid issues)? (If yes, explain on a separate sheet providing accurate details.)

Yes No	_				
	ore than 15 years before the date of a				
Yes No					
applicant ever been terminated for	cipal, officer, agent, managing emplor cause from the Florida Medicaid Production not answer next question 17. ) If yes, or	gram pursuant to Section			
Yes No					
applicant has been terminated, ha	1417. 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? (If yes, explain on a separate sheet providing accurate details.)				
Yes No	-				
Voc.		sheet providing accurate details)			
applicant ever been terminated for or federal government, from any o	cipal, officer, agent, managing emplor cause, pursuant to the appeals proc ther state Medicaid program or the fe . If yes, please provide documents concern	edures established by the state deral Medicare program?			
Yes No	- (If was explain on a congrete	sheet providing accurate details)			
160 Has the applicant or any prin	cipal, officer, agent, managing emplo				
	een in good standing with a state Me				
Yes No					
103	- <del>(If yes, explain on a separate</del>	sheet providing accurate details)			
270. Did the termination occur at least 20 years prior to the date of this application? (If yes, explain on a separate sheet providing accurate details.)					
Yes No					
	al, officer, agent, managing employee nited States Department of Health and				
	cipal, officer, agent, managing emplo				
Yes No	_				
19. 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			

23. Has the applicant, affiliated pe	rsons, partners, officer, directors, or	consultant pharmacist of record
ever owned a pharmacy? If yes, pro	vide the name of the pharmacy, the state w	here the pharmacy is located and the
status of the pharmacy. Attach a separa	te sheet if necessary.	
Yes No	_	
	1	Ī
Pharmacy Name	<u>State</u>	<u>Status</u>

applicant, affiliated p	ersons, partners,	een taken against any license, per officers, directors or consultant p	
		e sheet providing accurate details.)	
Yes	No	the Department of Health leasted a	at the physical leasting
		the Department of Health located a plain on a separate sheet providing accur	
Yes	No		
	sterile preparation	s, is your establishment Rule 64B1	6-27.797, F.A.C. compliant?
Yes No			
		al for preventing controlled substar actitioner-patient relationship avail	
Yes	No		
overpayments asses accurate details.)		on, partner, officer, director have ar er of the department? (If yes, explain	
Yes	<u>No</u>		
record ever owned pharmacy is located	a pharmacy? If you and the status o	ons, partners, officer, directors, or c es, provide the name of the pharma f the pharmacy. <i>Attach a separate</i>	cy, the state where the sheet if necessary.
<del>Yes</del>	<u>No</u>	(If yes, explain on a separate sheet p	,
Pharmacy	Name	State	<del>Sta</del>
		been taken against any license, p ners, officers, directors or consulta	
<u>Yes</u>	No	(If yes, explain on a separate s	sheet providing accurate details)
25. Is there any oth address on this app	•	by the Department of Health located	l at the physical location
<u>Yes</u>	No	(If yes, explain on a separate s	sheet providing accurate details)
Yes No		ons, is your establishment Rule 64E	
		ual for preventing controlled substa practitioner-patient relationship ava	
Yes	No		
Yes	ant, affiliated per	son, partner, officer, director have der of the department?	any outstanding fines, liens or

ALL QUESTIONS MUST BE ANSWERED OR YOUR APPLICATION WILL BE RETURNED

L certify that the statements contained in this application are true, complete, and correct and Lagree that said statements shall form the basis of my application and Ldo authorize the Florida Board of Pharmacy to make any investigations that they deem appropriate and to secure any additional information concerning me, and Lfurther 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 Lunderstand according to the Florida Board of Pharmacy Statutes that a Pharmacy Permit may be revoked or suspended for presenting any false, fraudulent, or forged statement, certificate, diploma, or other thing, in connection with an application for a license or permit, as set forth in Section 465.015(2)(a), F.S.

denial of the license, which might affect the decision of the department.

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 may result in disciplinary action against my license or criminal penalties		-I recognize that providing false informa	ı <del>tion</del>
SIGNATURE	TITLE	DATE	=

### PHARMACY PERMIT APPLICATION CHECKLIST

**INSTITUTIONAL PHARMACY PERMITS** 

### 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 anincomplete application. Final approval for inspection can not be granted until the application is complete.

Faxed applications will not be accepted.

	Application Completed (a	II questions answered)
	Application signed	
	Pharmacy Manager or Co	nsultant Listed with Signature
		it fee includes \$250 application fee and
\$5.00 unlicensed activ		ne Corporation from the Secretary of
State	Gertinodic of Otatus for th	ic corporation from the occircumy of
		mitted via livescan for all officers and owners
and the consultant or	<del>record.</del>	
	Attach Proof from AHCA tha	at the fingerprints are on file if
<del>applicable</del>		
applicable	Attestation for Business Tax	xable Assets of \$100 million if
	Bill of Sale is required for	Change of Ownership
	se complete for Change of L	
1. Current Practice Lo	ocation Address	
City	<u>State</u>	Zip
<u>Email</u>	<u>Te</u>	lephone Number
2. New Practice Loca	tion Address	
City	<u>State</u>	<u>Zip</u>

Please provide your existing Pharmacy Permit Number:
Please provide your existing federal DEA Number:
SECTION C. Please complete for Change of Ownership only.
1. Are you changing physical locations with this change of ownership?
Yes No NOTE: If yes, please complete Section B above.
2. Please provide date when business transaction for the change of ownership will be completed?
Date:
3. Do you have a signed letter from both the buyer and seller which indicates dates that pharmacy permi
license should be transferred? NOTE: A copy of the signed letter should be provided with your application.
<u>Yes</u> No
SECTION D. Please complete for Stock Transfer of Ownership only.
1. 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? NOTE: If yes, please complete Section C above and include necessary fee.
<u>Yes</u> 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 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.
<u>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.</u>

SIGNATURE (Owner or officer of establishment)

DATE

### 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

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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.

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

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

### <u>US Department of Justice, Federal Bureau of Investigation,</u> 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**

<u>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.</u>

- Background screening results are obtained from the Florida Department of Law Enforcement and the Federal Bureau of Investigation by submitting to a fingerprint scan using the Livescan method;
- You can find a Livescan service provider at: http://www.doh.state.fl.us/mga/background.html;
- Failure to submit background screening will delay your application;
- Applicants may use any Livescan service provider approved by the Florida Department of Law
   Enforcement to submit their background screening to the department;
- If you do not provide the correct Originating Agency Identification (ORI) number to the livescan service
  provider the Board office will not receive your background screening results;
- You must provide accurate demographic information to the livescan service provider at the time your fingerprints are taken, including your Social Security number (SSN);
- If you do not have a SSN you will need to contact the Board office for a fingerprint card then return the card to the Board office;
- The ORI number for the Board of Pharmacy is EDOH4680Z

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

- 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:	/ / <u> M/DD/YYYY)</u>	Place of Birth:		
Weight:	Height:	Eye Color:	Hair Color:	
Race: (W-White/Latino(a	a); B-Black; A-Asian; can; U-Unknown)	Sex: (M=Male; F=Female)		
Citizenship:		-		
<b>Transaction Cor</b>	ntrol Number (TCN#)	<u>:</u>		

Keep this form for your records.



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

_		File #: (if known):
<u>To:</u>	Florida Board of Pharmacy	<u> </u>
	Post Office Box 6320	
	Tallahassee, FL 32314-6320	
	(850) 245-4292- phone	License #: (if applicable)
	(850) 413-6982 - fax	
	info@floridaspharmacy.gov	
-		

Section A. Consultant	Pharmacist of Record (COR) I	<u>Designation</u>	
Applicant/Pharmacy Name:			
<b>Applicant/Pharmacy Mailing</b>	Address:		
City	<u>State</u>	Zip	
Incoming COR Name:		<u>License#:</u>	
		<u>PU</u>	
Date Beginning as COR:	Incoming COR Signature		
<b>COR Transaction Control Nu</b>	umber (TCN) - related to Livescan Fin	gerprints:	
	formation is there is an Outgoing COR at		
Outgoing COR Name:		<u>License#:</u>	
		<u>PU</u>	
Date Ending as COR:	Outgoing COR Signature		
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."			
		<u>ivestigation."</u>	
Date:	Incoming COR Signature		



# Item #2- Affiliate/Owner Privacy Statement Acknowledgement

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

Florida Board of Pharmacy

Post Office Box 6320

To:

	Tallahassee, FL 32314-6320 (850) 245-4292- phone (850) 413-6982 - fax MQA.Pharmacy@flhealth.gov		
From:	Affiliate / Owner Name:		File # (required):
	Applicant Name:		
	Affiliate/Owner Mailing Address:		
	City	<u>State</u>	<u>Zip</u>
	Affiliate/Owner Email	Affiliate/Owner Teleph	one Number
	Affiliate/Owner Transaction Control Num	ber (TCN) – related to Liv	rescan Fingerprints:
	I have been provided and read the state		-
	Enforcement regarding the sharing, reter incorrect criminal history records and the		
	Federal Bureau of Investigation."	•	

Affiliate/Owner Signature (Required)

Date (of signature)



# <u>Item #3 - Policy and Procedure Questions</u>

## To be completed by Institutional Class II Pharmacy Permit Applicants

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

1) List the following:

Firm Name:

Doing business as (d/b/a):

Telephone number: Address:

Permit number (if already licensed as an institutional pharmacy):

- 2) Explain the practice setting of the proposed facility.
- 3) What are the objectives and purpose of the permittee? Give detailed explanation of the services of the facility scope and practice.
- 4) What are the experience, qualifications, special education, and/or training of the compounding pharmacist? Please provide a resume.
- 5) Address the ratio of supportive personnel to each pharmacist. How will the supportive personnel be utilized? Include a job description for any such supportive personnel.
- 6) Describe the drug delivery system. Begin with the ordering of medications and track your procedures up to delivery to the patient. If utilizing remote medication order processing and the pharmacist is not an employee of the institution, describe the pharmacist and institution's responsibility.
- 7) What categories of parenteral/enteral products will be prepared (i.e. IV, enteral, irrigating, and oncology products)? Include sample labels.
- 8) What is the policy regarding the delivery of parenteral/enteral products to the patient? Describe methods used and trace the path the product takes from the time it leaves the permittee until it reaches the patient. Describe how products are protected from extreme temperature conditions.
- 9) Address the policy and procedure, special equipment and special techniques to dispense sterile preparations for parenteral therapy/nutrition. If this type of dispensing will not be performed, please state so accordingly.
- 10) Address the policy and procedure, special equipment and special techniques to dispense sterile

- jejunostomy feeding/sterile irrigation solutions. If this type of dispensing will not be performed, please state so accordingly.
- 11) Address the policy and procedure, special equipment and special techniques to dispense cytotoxic or anti-neoplastic agents. If this type of dispensing will not be performed, please state so accordingly.
- 12) What is the procedure for the annual review and updating of the policy and procedure manual?
- 13) Include the layout/floor plan of the pharmacy. The drawing must include the dimensions of the clean room and the pharmacy, location of the hood, sink and other equipment. The drawing must also show the location of the clean room relative to other pharmacy and storage areas.
- 14) Include a sample copy of a patient profile.
- 15) Address the use of aseptic techniques.
- 16) Describe the Quality Assurance Program.
- 17) Describe with detail the policy and procedure for patient education, including the personnel involved.
- 18) Address the policy and procedure for handling waste and returns.
- 19) Describe the type of certified laminar flow hood(s) used and the frequency of certification.
- 20) Describe the refrigerator/freezer to be used.
- 21) Describe appropriate waste containers for:
  - a. Used needles and syringes.
  - b. Cytotoxic waste including disposable apparel used in preparation.
- 22) Address the following supplies to be used: gloves, mask, gowns, needles, syringes, disinfectant cleaning agents, clean towels, hand-washing materials with bactericidal properties, vacuum containers/transfer sets, and spill kits for cytotoxic agent spills.
- 23) Address the following references to be used:
  - a. Chapters 465 and 893, F.S., and Rule Title 64B16, F.A.C.
  - b. Authoritative Therapeutic Reference.
  - c. Handbook of injectable drugs by American Society of Health-System Pharmacists.
- 24) Occupational Safety and Health Administration guidelines for safe handling of cytotoxic drugs.



## <u>Item #4 - Policy and Procedure Questions</u>

### To be completed by Modified Institutional Class II Pharmacy Permit Applicants

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

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

1) List the following:

Firm Name:

Doing business as (d/b/a):

Telephone number:

Address:

Consultant pharmacist of record:

- 2) Describe the purpose of the establishment. What sector of the community are you serving?
- 3) Is this is an inpatient facility? If so, how many beds are housed in the facility? What is the average length of stay?
- 4) List the drug formulary to be used.
- 5) Include a diagram of pharmacy storage space and a description of drug security measures.
- 6) Describe the consultant pharmacist of record's responsibilities.
- 7) Under whose DEA registration will controlled substances be ordered?
- 8) Describe the drug delivery system. Begin with the ordering of medications and track your procedures up to delivery to the patient.
- 9) Include a statement that perpetual inventory records will be maintained for controlled substances and injectable inventory.
- 10) Include a statement to the effect that no drugs will be dispensed from the facility.

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

- 11) If compounding sterile preparations, describe compliance with Rule 64B16-27.797, F.A.C.
- What categories of parenteral/enteral products will be prepared (i.e. IV, enteral, irrigating, and oncology products)? Include sample labels.
- 13) What is the policy regarding the delivery of parenteral/enteral products to the patient? Describe methods used and trace the path the product takes from the time it leaves the permittee until it reaches the patient. Describe how this product is protected from extreme temperature conditions.
- 14) Address the policy and procedure, special equipment and special techniques to dispense sterile preparations for parenteral therapy/nutrition. If this type of dispensing will not be performed, please state so accordingly.
- Address the policy and procedure, special equipment and special techniques to dispense sterile jejunostomy feeding/sterile irrigation solutions. If this type of dispensing will not be performed, please state so accordingly.
- Address the policy and procedure, special equipment and special techniques to dispense cytotoxic or anti-neoplastic agents. If this type of dispensing will not be performed, please state so accordingly.
- 17) What is the procedure for the annual review and updating of the policy and procedure manual?
- 18) Include the layout/floor plan of the pharmacy. The drawing must include the dimensions of the clean room and the pharmacy, location of the hood, sink and other equipment. The drawing must also show the location of the clean room relative to other pharmacy and storage areas.
- 19) Include a sample copy of a patient profile.
- Address the use of aseptic techniques.
- 21) Describe the Quality Assurance Program.
- 22) Describe with detail the policy and procedure for patient education, including the personnel involved.
- 23) Address the policy and procedure for handling waste and returns.
- 24) Describe the type of certified laminar flow hood(s) to be used and the frequency of certification.
- 25) Describe the refrigerator/freezer to be used.
- 26) Describe appropriate waste containers for:
  - a. Used needles and syringes.
  - b. Cytotoxic waste including disposable apparel used in preparation.
- 27) Address the following supplies to be used: gloves, mask, gowns, needles, syringes, disinfectant cleaning agents, clean towels, hand-washing materials with bactericidal properties, vacuum containers/transfer sets, and spill kits for cytotoxic agent spills.
- 28) Address the following references to be used:
  - a. Chapters 465 and 893, F.S., and Title 64B16, F.A.C.
  - b. Authoritative Therapeutic Reference.
  - c. Handbook of Injectable Drugs by American Society of Health-System Pharmacists.
  - d. Occupational Safety and Health Administration guidelines for safe handling of cytotoxic drugs.

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



# NUCLEAR PHARMACY PERMIT APPLICATION AND INFORMATION

October 2017

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

### **NUCLEAR 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 Nuclear Pharmacist.

Chapter 465, F.S., requires Nuclear Pharmacies to be under the professional supervision of the Nuclear Pharmacist licensed in the State of Florida as the Prescription Department Manager (PDM). A Florida licensed pharmacist shall perform compounding and dispensing of medicinal drugs.

A Nuclear Pharmacy provides radiological pharmaceutical products for administration..

# <u>Application Processing - Please read all application instructions before completing your application.</u>

### 1) Mail Application.

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:

**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 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 pharmacist 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 within one year of the receipt date of the application and are available to the Department. 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.

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 for you to sign this affirmation is included as an addendum to the application as Item #1.

### **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 7-10 days. You will receive the actual copy of your license within 7 days. Please wait 7-14 days from your satisfactory inspection before checking on the status of your permit with the Board office.

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

### **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 <a href="http://www.DEAdiversion.usdoj.gov">http://www.DEAdiversion.usdoj.gov</a>.

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

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. <u>465.003(14)</u> or s. <u>893.02</u> 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

To prepare for your inspection, please review the inspection form. You may download a copy of the inspection form from the website at

http://www.floridahealth.gov/licensing-and-regulation/enforcement/inspection-program/inspection-forms.html

# **NUCLEAR 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 can not be granted until the application is complete.</u> Faxed applications will not be accepted.

### **NUCLEAR PHARMACY PERMIT:**

 Application completed (all questions answered)
 Application signed
 Nuclear Pharmacist Manager Signature
 \$255.00 Fee Attached (Permit fee includes \$250 application fee and \$5.00 unlicensed activity fee)
 Certificate of Status for the Corporation from the Secretary of State
 Fingerprints have been submitted via livescan for all officers and owners and the prescription department manager
 Attestation for Business Taxable Assets of \$100 million if applicable
 PDM Designation and Privacy Statement Acknowledgement Provided
 Affiliate/Owner Privacy Statement Acknowledgement provided for each affiliate/owner (Application Item #2)
 Applicant/affiliate/owner supplemental documents provided explaining any previous ownership, disciplinary actions, voluntary relinquishments and/or criminal activity.
 Applicant/Affiliate/Owner pharmacy permit questions answered and supplemental documents provided.



### FLORIDA BOARD OF PHARMACY

P.O. Box 6320 Tallahassee, FL 32314-6320 Telephone (850) 488-0595 http://www.floridaspharmacy.gov



### **APPLICATION**

Application Type – Please choose one of the following:				
New Establishment \$255 fee		Change of Location \$100 fee		
Change of Ownership \$255 fe	e	Stock Transfe	er (no fee)	
SECTION A. Please compl	ete for all Ap	plication Type	S	
Please list your Federal Employer	Identification Nu	ımber:		
1. Corporate Name			Telephone Number	
2. Doing Business As (d/b/a)			E-Mail Address	
3. Mailing Address				
City	State		Zip	
4. Physical Address				
City	State		Zip	
5. List the Nuclear Pharmacist De	partment Manage	er Information:		
Name			License Number (PS and NP)	
Email			Telephone Number	
6. Contact Person Telephone Num		Telephone Numb	er	
Email		Phone Number		
		1		

7. Operating Hours				
Prescription Department I	Hours			
Monday-Friday: Open				
	Close:			
Sunday: Open:		<del></del>		
8. Ownership Information				
		CorporationPartnership		
NOTE: IF CORPORATION OR LIMIT INCORPORATION ON FILE WITH THE		IU MUST INCLUDE WITH YOUR APPLICATION A COPY OF THE ARTICLI ARY OF STATE'S OFFICE.	<u>ES OF</u>	
b. Are the applicants, offi	cers, directors,	shareholders, members and partners over the age o	18?	
Yes	No			
c. Does the corporation h	ave more than \$	5100 million of business taxable assets in this state?		
Yes	No	If yes, provide attestation from Certified Public Accountant for previou Florida Corporate Income/Franchise and Emergency Excise Tax Retu		
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 8c. If 8c is yes please list the owners below and only submit fingerprints for the Prescription Department Manager or 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.				
Attach a separate sheet if necessity  Owner/Officer-Title	Date of Birth	Mailing Address, City, State, Zip Code	% of Ownership	
	1 1		%	
	1 1		%	
	1 1		%	
	1 1		%	
	1 1		%	
	1 1		%	
9. Has anyone listed in 8.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 e	ntity was closed.	
		ership interest of 5% or more in a pharmacy or any o inquished or closed voluntarily within the past 5 yea		
Yes	No	If yes, please provide a signed affidavit disclosing the reason the e	ntity was closed.	
	plea of guilty or	d a pharmacy permit by misrepresentation or fraud or nolo contendere to, regardless of adjudication, a cread?		
Yes	No	If yes, please provide documents concerning this conviction.		

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
11. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under Chapter 409, F.S. (relating to social and economic assistance), Chapter 817, F.S. (relating to fraudulent practices), Chapter 893, F.S. (relating to drug abuse prevention and control) or
a similar felony offense(s) in another state or jurisdiction?(If yes, provide court documents concerning this conviction, If No skip to question #16)
Yes No
11a. If "yes" to 11, 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
11b. If "yes" to 11, 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
11c. If "yes" to 11, 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
11d. If "yes" to 11, 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
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 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)
13. 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)
14. 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)

Pursuant to Section 456.0635(2) and 465.022 (5), Florida Statutes, questions 11 through 17 are being

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 federal government, from any other state Medicaid program or the federal Medicare program? (If no, do not answer 20 and 21)				
Yes No				
16. Has the applicant been in good program for the most recent five ye	I standing with a state Medicaid progears?	gram or the federal Medicare		
Yes No	(If yes, explain on a separate sh	neet providing accurate details)		
17. Did the termination occur at lea	ast 20 years prior to the date of this	application?		
Yes No	 (If yes, explain on a separate sh	neet providing accurate details)		
	al, officer, agent, managing employers es Department of Health Human Serv	e, or affiliated person of the		
Yes No	(If yes please submit proof)			
19. Are you currently registered or permitted in any other states? If yes, provide the state, permit type and permit number for each permit. <i>Attach a separate sheet if necessary.</i>				
Yes No				
State	Permit Type	Permit Number		
20. 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		
	er been taken against any license, po r, officer, director, or prescription de			
No Yes documentation from the licensing agency who		oviding accurate details and submit		

22. Has the applicant, or any officer, member or partner ever been convicted of a felony or misdemeanor, excluding minor traffic convictions?				
Yes No	withheld by the court, so that yo	ou would i driving whi	le impaired is NOT a minor traffic	
23. Is there any other permit issue address on this application?	d by the Department of Health locat	ed at th	e physical location	
Yes No	(If yes, explain on a separate sheet pr	oviding a	ccurate details)	
• •	erson, partner, officer, director have order of the department? If yes plea	_	•	
Yes No	(If yes, explain on a separate sheet pr	oviding a	ccurate details)	
24d. Does the applicant, affiliated pthe department?	person, partner, officer, director hav	е а гера	ayment plan approved by	
Yes No	(If yes, explain on a separate sheet pr	oviding a	ccurate details)	
25. 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?				
Yes No				
SECTION B. Please complete for a Change of Location only				
1. Current Practice Location A	ddress			
City	State	Zip		
Email			Telephone Number	
2. New Practice Location Addr	2000			
2. New Fractice Location Addr	ess			
	<b>.</b>			
City	State	Zip		
Email			Telephone Number	
Linuii			reiephone Hamber	
3. Please provide your existing Pharmacy Permit Number(s):				
Please provide your existing Federal DEA Number:				

SECTION C. Please complete for Change of Ownership only			
1.	Are you changing physical locations with this change of ownership?		
Yes _	No Note: If yes, please complete Section B above		
2.	Please provide date when business transaction for the change of ownership will be completed?		
Date:			
3.	Do you have a signed letter from both the buyer and seller which indicates dates the pharmacy permit license should be transferred?		
Yes _	No Note: A copy of the signed letter should be provided with your application		
SEC	TION D. Please complete for Stock Transfer of Ownership only		
1.	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?		
	No  If yes, please complete Section C above and include the necessary fee		
	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 or Pharmacy Statutes that a Pharmacy Permit may be revoked or suspended for presenting any false, fraudulent, or forget 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.			
	penalty of perjury I have read the foregoing document and that the facts stated in it are true. I recognize that ng false information may result in disciplinary action against my license or criminal penalties.		
SIGN	ATURE DATE or officer of establishment)		
(Owner			

"

### 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 The fingerprints submitted will be retained by FDLE and the are elderly or disabled. 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.doh.state.fl.us/mga/background.html;
- Failure to submit background screening will delay your application;
- Applicants may use any Livescan service provider approved by the Florida Department of Law Enforcement to submit their background screening to the department;
- If you do not provide the correct Originating Agency Identification (ORI) number to the livescan service provider the Board office <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);
- If you do not have a SSN you will need to contact the Board office for a fingerprint card then return the card to the Board office;
- The ORI number for the Board of Pharmacy is EDOH4680Z
- Typically background screening results submitted through a Livescan service provider are received by the Board within 24-72 hours of being processed.
- If you obtain your livescan from a service provider who does not capture your photo you may be required to be reprinted by another agency in the future.

Name:		SSN#:	
Aliases:			
Address:		Apt. Number:	
City:	State:	Zip Code:	
Date of Birth:// (MM/DD/YYYY)	Place 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 Sca			

# Keep this form for your records.



# <u>Item #1- Nuclear Pharmacist Designation and Privacy Statement</u> <u>Acknowledgement</u>

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

File #:	(if known):
Licens	Se #: (if applicable):

Section A. Nuclear Pha						
Applicant/Pharmacy Name:						
Applicant/Pharmacy Mailing Address:						
City	State	Zip				
<b>Incoming Nuclear Pharma</b>	cist Name:	License#:				
		PS				
Date Beginning:	Incoming Nuclear Pharmacist Sig	nature				
PDM Transaction Control	│ Number (TCN) – related to Livesca	n Fingerprints:				
***Only provide following inf	ormation is there is an Outgoing PDM at	current pharmacy location.***				
Outgoing Nuclear Pharma		License#:				
		PS				
Date Ending as PDM:						
Section B. Incoming F	PDM Privacy Statement Ackno	wledgement				
	be completed by same person listed in Sect					
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:	te: Incoming Nuclear Pharmacist 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
	MOA Pharmacy@flhealth.gov

Affiliate / Owner Name:

Applicant Name:

Affiliate/Owner Mailing Address:

City

State

Zip

Affiliate/Owner Email

Affiliate/Owner Telephone Number

Affiliate/Owner Transaction Control Number (TCN) – related to Livescan

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)



## Item #3 - Policy and Procedure Questions

# To be completed by Nuclear Pharmacy Applicants

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

1) List the following:

Firm Name:

Doing business as (d/b/a):

Telephone number:

Address:

Permit number (if already licensed as an institutional pharmacy):

- 2) Explain the practice setting of the proposed facility.
- 3) What are the objectives and purpose of the permittee? Give detailed explanation of the services of the facility scope and practice.
- 4) What are the experience, qualifications, special education, and/or training of the compounding pharmacist? Please provide a resume.
- 5) Address the ratio of supportive personnel to each pharmacist. How will the supportive personnel be utilized? Include a job description for any such supportive personnel.
- 6) What categories of parenteral/enteral products will be prepared (i.e. IV, enteral, irrigating, and oncology products)? Include sample labels.
- 7) What is the policy regarding the delivery of parenteral/enteral products to the patient? Describe methods used and trace the path the product takes from the time it leaves the permittee until it reaches the patient. Describe how products are protected from extreme temperature conditions.
- 8) Address the policy and procedure, special equipment and special techniques to dispense sterile preparations for parenteral therapy/nutrition. If this type of dispensing will not be performed, please state so accordingly.
- 9) Address the policy and procedure, special equipment and special techniques to dispense sterile jejunostomy feeding/sterile irrigation solutions. If this type of dispensing will not be performed, please state so accordingly.
- 10) Address the policy and procedure, special equipment and special techniques to dispense cytotoxic or anti-neoplastic agents. If this type of dispensing will not be performed, please state so accordingly.
- 11) What is the procedure for the annual review and updating of the policy and procedure manual?

- 12) Include the layout/floor plan of the pharmacy. The drawing must include the dimensions of the clean room and the pharmacy, location of the hood, sink, and other equipment. The drawing must also show the location of the clean room relative to other pharmacy and storage areas.
- 13) Include a sample copy of a patient profile.
- 14) Address the use of aseptic techniques.
- 15) Describe the Quality Assurance Program.
- 16) Describe with detail the policy and procedure for patient education, including the personnel involved.
- 17) Address the policy and procedure for handling waste and returns.
- 18) Describe the type of certified laminar flow hood(s) to be used and the frequency of certification.
- 19) Describe the refrigerator/freezer to be used.
- 20) Describe appropriate waste containers for:
  - Used needles and syringes.
  - b. Cytotoxic waste including disposable apparel used in preparation.
- 21) Address the following supplies to be used: gloves, mask, gowns, needles, syringes, disinfectant cleaning agents, clean towels, hand-washing materials with bactericidal properties, vacuum containers/transfer sets, and spill kits for cytotoxic agent spills.
- 22) Address the following references to be used:
  - a. Chapters 465 and 893, F.S., and Rule 64B16, F.A.C.
  - b. Authoritative Therapeutic Reference.
  - c. Handbook of injectable drugs by American Society of Health-System Pharmacists.
- 23) Occupational Safety and Health Administration guidelines for safe handling of cytotoxic drugs.

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





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DH-MQA <u>121</u>8XXXX, <u>10/17</u>08/12 Rule 64B16-28.100, F.A.C.

# NUCLEAR PHARMACY PERMIT APPLICATION AND INFORMATION

August 2012 October 2017

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 <a href="mag\_pharmacy@doh.state.fl.usinfo@floridaspharmacy.gov">mag\_pharmacy@doh.state.fl.usinfo@floridaspharmacy.gov</a>, 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

### **NUCLEAR 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 Nuclear Pharmacist.

Chapter 465, F.S., requires Nuclear Pharmacies to be under the professional supervision of the Nuclear Pharmacist licensed in the State of Florida as the Prescription Department Manager (PDM). A Florida licensed pharmacist shall perform compounding and dispensing of medicinal drugs.

A Nuclear Pharmacy provides radiological pharmaceutical products for administration..

#### **Application Processing -**

Please read all application instructions before completing your application.

#### Mail Application.

<del>1)</del> 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:

Express Mail ONLY

Department of Health

4052 Bald Cypress Way, Bin C-04

Tallahassee, FL 32399-3254

**Board of Pharmacy** 

**Application & Fees:** Department of Health Board of Pharmacy P.O. Box 6320

Tallahassee, Florida 32314-6320

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 Pharmacv 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.

Page 1-of 14

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DH-MQA 1218, 10/17 Rule 64B16-28.100, F.A.C. DH-MQA,XXXX1218 08/12 Rule 64B16-28.100, F.A.C.

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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 pharmacist 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 within one year of the receipt date of the application and are available to the Department. 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.

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 LLivescan 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

1. , select Apply for a License, select Pharmacy Permit Information, select Livescan vendor ◆ list.

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 FL924190ZEDOH4680Z

## 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).

### 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

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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 for you to sign this affirmation is included as an addendum to the application as Item #1.

 Nuclear Pharmacy Applicants must complete and submit answers to questions below with the application.

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

- 1) List the following:
  - Firm Name:
  - Doing business as (d/b/a):
  - Telephone number:
  - Addross:
  - Permit number (if already licensed as an institutional pharmacy):
- Explain the practice setting of the proposed facility.
- 3) What are the objectives and purpose of the permittee? Give detailed explanation of the services of the facility scope and practice.
- 4) What are the experience, qualifications, special education, and/or training of the compounding pharmacist? Please provide a resume.
- 5) Address the ratio of supportive personnel to each pharmacist. How will the supportive personnel be utilized? Include a job description for any such supportive personnel.
- 6) What categories of parenteral/enteral products will be prepared (i.e. IV, enteral, irrigating, and encology products)? Include sample labels.
- 7) What is the policy regarding the delivery of parenteral/enteral products to the patient? Describe methods used and trace the path the product takes from the time it leaves the permittee until it reaches the patient. Describe how products are protected from extreme temperature conditions.
- 8) Address the policy and procedure, special equipment and special techniques to dispense sterile preparations for parenteral therapy/nutrition. If this type of dispensing will not be performed, please state so accordingly.
- Address the policy and procedure, special equipment and special techniques to dispense sterile jejunostomy feeding/sterile irrigation solutions. If this type of dispensing will not be performed, please state so accordingly.
- 40) Address the policy and procedure, special equipment and special techniques to dispense cytotoxic or anti-neoplastic agents. If this type of dispensing will not be performed, please state so accordingly.

- 41) What is the procedure for the annual review and updating of the policy and procedure manual?
- 12) Include the layout/floor plan of the pharmacy. The drawing must include the dimensions of the clean room and the pharmacy, location of the hood, sink, and other equipment. The drawing must also show the location of the clean room relative to other pharmacy and storage areas.
- 13) Include a sample copy of a patient profile.
- 14) Address the use of aseptic techniques.
- 15) Describe the Quality Assurance Program.
- 46) Describe with detail the policy and procedure for patient education, including the personnel involved.
- 17) Address the policy and procedure for handling waste and returns.
- 48) Describe the type of certified laminar flow hood(s) to be used and the frequency of certification.
- 19) Describe the refrigerator/freezer to be used.
- 20) Describe appropriate waste containers for:
  - a. Used needles and syringes.
  - b. Cytotoxic waste including disposable apparel used in preparation.
- 21) Address the following supplies to be used: gloves, mask, gowns, needles, syringes, disinfectant cleaning agents, clean towels, hand washing materials with bactericidal properties, vacuum containers/transfer sets, and spill kits for cytotoxic agent spills.
- 22) Address the following references to be used:
  - a. Chapters 465 and 893, F.S., and Rule 64B16, F.A.C.
  - b. Authoritative Therapeutic Reference.
  - Handbook of injectable drugs by American Society of Health-System Pharmacists.
- 23) Occupational Safety and Health Administration guidelines for safe handling of cytotoxic drugs.

### **Licensure Process**

Once the application is deemed complete, the Board staff authorizes an inspection. Upon completion of the inspection, the inspector notifies the Board office as to whether the inspection was satisfactory or unsatisfactory. If the inspection is satisfactory, a permit number is issued within 7-10 days. You will receive the actual copy of your license within 7 days. Please wait 7-14 days from your satisfactory inspection before checking on the status of your permit with the Board office.

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

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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/mga.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 <a href="http://www.DEAdiversion.usdoj.gov">http://www.DEAdiversion.usdoj.gov</a>. 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.

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

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.

DH-MQA 1218, 10/17 Rule 64B16-28.100, F.A.C. DH-MQA,XXXX1218.08/12 Rule 64B16-28.100, F.A.C. Page 5-of 14

IMPORTANT NOTICE: The Department or Beoard 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. <u>465.003(14)</u> or s. <u>893.02</u>, 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,

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# **PRE-INSPECTION CHECKLIST**

To prepare for your inspection, please review the inspection form.

You may download a copy of the inspection form from the website at

http://www.floridahealth.gov/licensing-and-regulation/enforcement/inspection-program/inspection-forms.html

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### **NUCLEAR PHARMACY PERMIT APPLICATION CHECKLIST**

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#### 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.

### **NUCLEAR PHARMACY PERMIT:**

Application completed (all questions answered)
Application signed
Nuclear Pharmacist Manager Signature
\$255.00 Fee Attached (Permit fee includes \$250 application fee and \$5.00 unlicensed activity fee)
Certificate of Status for the Corporation from the Secretary of State
Fingerprints have been submitted via livescan for all officers and owners and the prescription department manager
Attestation for Business Taxable Assets of \$100 million if applicable
PDM Designation and Privacy Statement Acknowledgement Provided
Affiliate/Owner Privacy Statement Acknowledgement provided for each affiliate/owner (Application Item #2)
Applicant/affiliate/owner supplemental documents provided explaining any previous ownership, disciplinary actions, voluntary relinquishments and/or criminal activity.
Applicant/Affiliate/Owner pharmacy permit questions answered and supplemental documents provided.

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,



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<del>F.A.C.?</del>		
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Is the pharmacy department equipped with an area suitable for private patient	4	Formatted: Left, Indent: Left: 0", First line: 0"
counseling if applying for a community pharmacy permit pursuant to Rule 64B16-28.1035, F.A.C.?		Formatted: Left, Indent: Left: 0"
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Are all required signs displayed?		
Daily operating hours pursuant to Rule 64B16-28.1081, F.A.C.		
<ul> <li>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.</li> </ul>	<del>,</del>	
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• Prescription Department Closed pursuant to Rule 64B16-28.109, F.A.C.	-	Formatted: Left, Indent: Left: 0", First line: 0"
Pharmacist meal breaks pursuant to Rule 64B16-27.1001 (6), F.A.C.		
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• Patient Consultation Area pursuant to Rule 64B16-28.1035, F.A.C.	1	Formatted: Left, Indent: Left: 0", First line: 0"
	•	Formatted: Indent: Left: 0", First line: 0"
If compounding sterile preparations, is your pharmacy compliant with Standards for Compounding Sterile Preparations pursuant to Rule 64B16-27.797, F.A.C?		
Does the pharmacy meet the minimum Nuclear Pharmacy requirements in Rule 64B16-28.902, F.A.C?		
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Application Type - Please choose one of the following:

5. List the Nuclear Pharmacist Department Manager Information:

Application Type - Please choose one of the following:

\_ New Establishment \$255 fee

\_Additional Permit Type \$255 fee

### FLORIDA BOARD OF PHARMACY

**NUCLEAR PHARMACY PERMIT APPLICATION** 

issued) \$255

P.O. Box 6320 Tallahassee, FL 32314-6320 Telephone (850) 488-0595 http://www.floridaspharmacy.gov

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# \_\_\_(existing permit number) Change of Ownership Location \$255100 fee (existing permit number) **SECTION A. Please complete for all Application Types** Formatted: Font: 14 pt Please list your <u>Federal Employer Identification Number:</u> Formatted: Font: Bold **Corporate Name Telephone Number** 2. Doing Business As (d/b/a) E-Mail Address 3. Mailing Address City State Zip 4. Physical Address City State Zip

and NP)

**Telephone Number** 

Change of Location \$100 feeOwnership
Stock Transfer (no fee)(a new permit number will be

(existing permit number)

Signature License Number (PS

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Name

**Email** 

**Start Date** 

6. Contact Person	Telephone Number			
- Contact i croon	Telephone Humber			
<u>Email</u>	Phone Number			
7. DEA Registration Number	8. Date ready for inspecti	ion (within 90	<del>days)</del>	
9. Please provide the name, address, telephone no wholesale distributor.	umber, and permit number	of your presc	ription dr	<del>ug</del>
Name	Telephone Number	Permit Num	ber	
Street Address	City	State	<del>Zip</del>	
	<u> </u>		1	
10. Pharmacy Technician Ratio 2:1 or 3:1 (Optional	<del>1</del> 1			
Rule 64B16-27.410, Florida Administrative Code, prov		partment mana	<del>ger or</del>	
consultant pharmacist of record is required to of recor	d issubmit a written request a	and receive ap	proval fro	<del>m the</del>
Beard of Pharmacy prior to the pharmacy allowing a p	harmacist to supervise more	than one regis	tered	
pharmacy technician. If you would like to apply for the may do so by checking the appropriate selection below	s <del>Registered Pharmacy Lech</del>	SORVES 25 VOL	<del>: i ratio, yo</del> r written	<del>ou</del>
request to the board office for approval to practice with		ocives as you	Witter	
2:1 Ratio 3:1 Ratio				
(please attach a brief description of the workflow need number of pharmacist, registered interns and registered	s that include the operating l	hours of the ph	armacy,	
request)	<del>о рнаннасу сеснивань етгр</del>	<del>лоува то justiny</del>	<del>- ine railo</del>	
, ,				
Rule 64B16-27.410, Florida Administrative Code, prov	ides that the prescription dep	oartment mana	<del>ger of rec</del>	<del>ord</del>
isbe required to submit a request and receive approva	I from the Board of Pharmacy	<del>y prior to practi</del>	cing with	either
a 2:1 or 3:1 ratio of supervision.				
T			a.	
If you would like to apply for the Pharmacy Technician appropriate selection below. Selecting an option below	2:1 or 3:1 ratio, you may do	so by checking	<del>) the</del> oard office	n that
you are requesting approval to practice with a 2:1 or 3	·1 ratio. The board will provide	de notice of an	<del>oara omoc</del> <del>plication</del>	<del>J triat</del>
approval or denial				
2:1 Ratio	3:1 Ratio			
744. Operating Hours				
Store/Facility Hours				
Monday-Friday: OpenClose:				
Saturday: Open: Close:				

<del>Sunday: (</del>				
1 1	<del>Open:</del>			
	partment Hours	_		
Monday-Friday: (				
	Open:			
	Open:	Close:		
812. Ownership	Information			
a. Type of Owne	rship:Indi	vidual _	CorporationPartnership	
	Otl	her:		
Federal Employe	or Identification N	umber:		
INCORPORATION ON	I FILE WITH THE FLO	RIDA SECRETA	U MUST INCLUDE WITH YOUR APPLICATION A COPY OF THE ART IRY OF STATE'S OFFICE.	
b. Are the appli	icants, officers,	directors, s	shareholders, members and partners over the ago	e of 18?
Yes	No			
c. Does the cor	poration have n	nore than \$	100 million of business taxable assets in this sta	te?
Yes	No		If yes, provide attestation from Certified Public Accountant for pre Florida Corporate Income/Franchise and Emergency Excise Tax	
Prescription Department	artment Manager d available to the	or Consulta Board of Ph	es please list the owners below and only submit fingerent Pharmacist of Record. If 842c is yes and the prints narmacy the requirement to submit the prints for this prints for	are on file with person is met.
Owner/Off	ficer-Title	Date of Birth	Mailing Address, City, State, Zip Code	% of Ownership
		1 1		
		1 1		%
				%
		1 1		
		<i>I I I I</i>		%
				% %
				% % % %
business permi	ne listed in <u>842</u> .c t which was dis	/ / / / / / / had an ov	wnership interest of 5% or more in a pharmacy or uspended, revoked, or closed involuntarily within	% % % % %
business permi years?	t which was dis	/ / / / / / d had an ov ciplined, su	uspended, revoked, or closed involuntarily within	% % % % % any other the past 5
business permi years? Yes	t which was dis	/ / / / / / d had an ov ciplined, su	uspended, revoked, or closed involuntarily within  If yes, please provide a signed affidavit disclosing the reason the	% % % % % rany other the past 5
years? Yes	No one listed in 842	/ / / / / / / had an overiplined, su	uspended, revoked, or closed involuntarily within	% % % % % any other the past 5 he entity was closed.
years? Yes	No one listed in 842 t which was vol	/ / / / / / / had an overiplined, su	If yes, please provide a signed affidavit disclosing the reason the support of th	% % % % % r any other the past 5 he entity was closed. or any other years?

`	Yes No If yes, please provide documents concerning this conviction.		
		For	matted: Font: Not Italic
ä	Pursuant to Section 456.0635(2) and 465.022 (5), Florida Statutes, questions 1 <u>1</u> 5 through <u>1724</u> are bei 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 <del>.</del>		natted. Fort. Not Italic
a F	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 contendere to, regardless of adjudication, a felony under Chapter 409, F.S. (relating to social and economic assistance), Chapter 87. (relating to fraudulent practices), Chapter 893, F.S. (relating to drug abuse prevention and control a similar felony offense(s) in another state or jurisdiction? (If yes, provide court documents concerning the conviction, If No skip to question #16)	I) or	
١	Yes No		
	15a. If "yes" to 151, 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?	m	
١	Yes No		
t	15b. If "yes" to 115, for the felonies of the third degree, has it been more than 10 years from the date 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).	e of	
`	res No		
İ	15c. If "yes" to 115, for the felonies of the third degree under Section 893.13(6)(a), Florida Statutes, It been more than 5 years from the date of the plea, sentence and completion of any subsequent probation?	has	
	Yes No		
ľ f	15d. If "yes" to 115, has the applicant or any principal, officer, agent, managing employee, or affiliate 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).	ed	
١	Yes No		
ä	2.6. 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 adjudicat to a felony under 21 U.S.C. ss.801-970 or 42 U.S.C. ss. 1395-1396 since July 1, 2009?	e tion	
)	es No (If yes, explain on a separate sheet providing accurate detai	ils)	
ä	37. 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	9	

Yes No (If yes, explain on a separate sheet providing accurate details)							
48. 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 sl	heet providing accurate details)					
159. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant ever been terminated for cause, pursuant to the appeals procedures established by the state or federal government, from any other state Medicaid program or the federal Medicare program? (If no, do not answer 20 and 21)							
Yes No	(If yes, explain on a separate si	heet providing accurate details)					
1620. Has the applicant been in g program for the most recent five y	ood standing with a state Medicaid p rears?	rogram or the federal Medica	ire				
Yes No	(If yes, explain on a separate sl	heet providing accurate details)					
1724. Did the termination occur a	t least 20 years prior to the date of th	is application?					
Yes No	 (If yes, explain on a separate sl	heet providing accurate details)					
	cipal, officer, agent, managing emplo es Department of Health Human Serv	yee, or affiliated person of th					
Yes No	(If yes please submit proof)						
	d or permitted in any other states? If permit. Attach a separate sheet if ne		it				
Yes No							
State	Permit Type	Permit Number					
	person, partner, officer, director eve r, the state where the pharmacy is loc et if necessary.		,				
<u> </u>	(If yes, explain on a separate sheet	providing accurate details)					
Pharmacy Name	State	Status					

		n taken against any licens			the
		· •		_	
Nodocumentation from the	Yese licensing agency who took the	(If yes, explain on a separate shee disciplinary action)	et providing a	accurate details and submit	
	licant, or any officer, me cluding minor traffic con	mber or partner ever been victions?	convicte	d of a felony or	
Yes	No	withheld by the court, so the	at you would or driving w	nd felonies, even if adjudication of the following that a record of conviction the following that the following that the following the following that the fellowing the fellowing that the fellowing that the fellowing the fellowing the fellowing that the fellowing the fellowi	
237. Is there any address on this ap		he Department of Health le	ocated at	the physical location	
YesNe	<u>No</u> Yes	(If yes, explain o	on a separat	e sheet providing accurate deta	ils)
		partner, officer, director h f the department? If yes p			or
YesNo	<u>No</u> Yes	(If yes, explain o	on a separat	e sheet providing accurate deta	iis)
248d. Does the ap the department?	plicant, affiliated persor	n, partner, officer, director	have a re	epayment plan approved	by
YesNo	<u>No</u> Yes	(If yes, explain o	on a separat	e sheet providing accurate deta	ils)
		or preventing controlled stioner-patient relationship			?
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YesNo	NoYes				Formatted Table
SECTION B	Please complete for	r a Change of Location	on only		Formatted: Font: Bold
	actice Location Address		on only	•/	Formatted: Indent: Left: -0.01", Hanging: 0.06", Numbered + Level: 1 + Numbering Style: 1, 2, 3, + Start at: 1 + Alignment: Left + Aligned at: 0.25" + Indent at:
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Email				Telephone Number	Formatted: Space Before: 0 pt
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2. New Practi	ce Location Address			4	Formatted: Indent: Left: 0", Hanging: 0.05", Space Before: 0 pt, Numbered + Level: 1 + Numbering Style: 1, 2, 3, + Start at: 1 + Alignment: Left + Aligned at: 0.25" + Indent
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City	<u>State</u>		Zip	<u> </u>	Formatted: Space After: 0 pt
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	mail		Tolor	phone Numbe	m.	Formatted Table	
^	<u> </u>		Tele	priorie Numbe	1.	Formatted: Space After: 0 pt	
	— Please provide the name, a	ddress, telephone number, an	d permit number of	your prescrip	otion	<b>Formatted:</b> Numbered + Level: 1 + Numbering St 3, + Start at: 1 + Alignment: Left + Aligned at: Indent at: 0.5"	
	drug wholesale distributor.					Formatted: Font: Bold	
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	<del>lame</del>	Permit Number	Telephone I	<del>Number</del>	7	Formatted: Font: Bold	
						Formatted: Space After: 0 pt	
	Street Address	City	State	Zip.	1	Formatted Table	
	treet Address	<del>Gity</del>	<del>Jidit</del>	± <del>110</del>		Formatted: Font: Bold	
						Formatted: Font: Bold	
4	. Please provide your existing Pl	harmacy Permit Number(s):			•	Formatted: Font: Bold	
-	. Trease provide your existing in	narmacy i erinit Number(s).			A	Formatted: Font: Bold	
	Please provide your existing Fe		vohin only			Formatted: Indent: Left: -0.01", Numbered + Lev Numbering Style: 1, 2, 3, + Start at: 1 + Alignme Aligned at: 0.25" + Indent at: 0.5"	
Å	SECTION C. Please comple	ete for Change of Owne	ership only		_/ / /	Formatted Table	
	1. Are you changing physical	locations with this change of	ownership?		4	Formatted: Font: Bold	
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-	Yes No Note: If ye	es, please complete Section B al	<u>bove</u>			Formatted Table	
	2. Please provide date when b	ousiness transaction for the ch	nange of ownership	will be comp	leted?	Formatted: Font: Bold	
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Ī	Date:					Formatted: Font: Bold	
	2. De you have a signed letter	from both the buyer and colle	v which indicates d	lotoo the phor		Formatted	(
	3. Do you have a signed letter permit license should be tra	from both the buyer and selle	er which indicates d	iates the phar	<u>IMACY</u>	Formatted Table	
	permit nocited should be tre	anoromou.				Formatted: Font: Bold	
2	Yes No Note: A c	opy of the signed letter should b	e provided with your	application		Formatted	(
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3	SECTION D. Please comple	<u>ete for Stock Transfer o</u>	<u>f Ownership or</u>	<u>ıly</u>		Formatted: Font: 14 pt, Bold	
						Formatted Table	
	1. Please provide the date who	en the transfer of ownership if	nterest took place?			Formatted: Font: Bold	
	Date:				4	Formatted	(
	20.10, 1				The '	Formatted Table	
	2. Did your company's FEIN c		fer of ownership int	erest referenc	ed in	Formatted: Font: 11 pt	
	Section D, question 1 above	<u>e?</u>			111/	Formatted: Indent: Left: 0.5", No bullets or num	bering
,	Yes No					Formatted Table	
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•	Note: If yes, please complete Section	n C above and include the nece	ssary tee		_\ \	Formatted: Font: 11 pt	
		<b>_</b>			_\\\ \	Formatted: Font: Bold	
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	ALL QUESTIONS MUST BE AN	SWERED OR YOUR APPLIC	ATION WILL BE F	RETURNED		Formatted Table	
,	2 oction 456 042(4)		iono oo noodad tati-		~*****	Formatted Table	
3	Section 456.013(1), F.S., requires that a ny circumstances or conditions stated i	ipplicants supplement their application the application, which takes place	ions as needed to refle se between the initial fi	ling of the applic	change cation a	Formatted: Font: Italic, Underline	
2	, , , station of the station is	and approximation takes place				Formatted: Font: (Default) Arial	

DH-MQA 1218, 10/17 Rule 64B16-28.100, F.A.C. DH-MQA,XXXX1218.08/12 Rule 64B16-28.100, F.A.C. the final grant or denial of the license, which might affect the decision of the department.

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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 ceem 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.

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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.

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\$IGNATURE DATE

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(Owner or officer of establishment)

4

### FLORIDA DEPARTMENT OF LAW ENFORCEMENT

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

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### 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

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DH-MQA 1218, 10/17 Rule 64B16-28.100, F.A.C. DH-MQA,XXXX1218 08/12 Rule 64B16-28.100, F.A.C. Page 17-of-14

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.

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

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

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### 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).

DH-MQA 1218, 10/17 Rule 64B16-28.100, F.A.C. DH-MQA,XXXX1218 08/12 Rule 64B16-28.100, F.A.C. Page 18-of 14

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**

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

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

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Name:	SSN#:	 -	
Aliases:			

DH-MQA 1218, 10/17 Rule 64B16-28.100, F.A.C. DH-MQA,XXXX1218.08/12 Rule 64B16-28.100, F.A.C. Page 19-of 14

Address:			Apt. N	umber:	<u></u>
City:		State:		Zip Code:	_
Date of Birth:	/ / (MM/DD/YYYY)	Place of Birth:			<u> </u>
Weight:	Height:	Eye Color:	Hair Co	olor:	_
NA-Native Amer	(a); B-Black; A-Asian; ican: U-Unknown)	Sex: (M=Male; F=Female)			
_	Control Number (TCN#)  vided to you by the Live Sc.  Keep		ecords.	-	
Florida HEALTH	Item #1- Nuclear	Pharmacist Designation Acknowledgement		cy Statement	Formatted: Font: (Default) Arial
To: Flo	ride Beerd of Bherma			File #: (if known).	Formatted: Line spacing: single
Pos	rida Board of Pharma at Office Box 6320	<del></del>		4	Formatted: Line spacing: single
(85)	lahassee, FL 32314-6 0) 245-4292- phone 0) 413-6982 - fax	<u>320</u>		License #: (if applica	Formatted: Line spacing: single
	@floridaspharmacy.go	<u>ov</u>			Formatted: Font: (Default) Arial
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			<u>PS</u>		
<u>Date Beginning:</u> <u>Incoming Nuclear Pharmacist Signature</u>					

PDM Transaction Control	Number (TCN) - relate	ed to Livescan F	ingerprints:		
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Outgoing Nuclear Pharma	icist Name:		cense#:	-	Formatted: Line spacing: single
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and the "Privacy Statement"					
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Florida Board of Pharm	nacy				
Post Office Box 6320	0000				
Tallahassee, FL 32314- (850) 245-4292- phone	<u>6320</u>				
(850) 413-6982 - fax					
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	inforcement regarding the sharing, riminal history records and the "Pri			rect	
	Bureau of Investigation."				
	.ffiliate/Owner Signature (Require	d) Date (of signal	ture)		
******	ALL QUESTIONS MUST BE ANSWE			ED ******	***
	on 456.013(1), F.S., requires that applicants sup ances or conditions stated in the application, whi	ich takes place between the initial t	filing of the application and th		Formatted: Centered
I certify th	denial of the license, which	ch might affect the decision of the care true, complete, and correct and	•	shall form th	e
basis of n	ny application and I do authorize the Florida Boa ny additional information concerning me, and I f	ard of Pharmacy to make any invest urther authorize them to furnish an	stigations that they deem app ny information they may have	opriate and to or have in the	<del>to</del> e
agencies	ncerning me to any person, corporation, institutions or units, and I understand according to the Floor suspended for presenting any false, fraudulen	rida Board of Pharmacy Statutes t	hat a Pharmacy Permitist's lic	ense may be	<b>}</b>
Under		permit, as set forth in Section 465.		u ddiaa falaa	
<del>Under  </del>	penalty of perjury I have read the foregoing docu information may result in discipl	inary action against my license or		viding laise	stops: 1.55", Left
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	Item #3 - Polic	y and Procedure Que	<u>estions</u>		

DH-MQA 1218, 10/17 Rule 64B16-28.100, F.A.C. DH-MQA,XXXX1218.08/12 Rule 64B16-28.100, F.A.C.

Page 22<del> of 14</del>

### Formatted: Font: 12 pt, Bold The Nuclear Pharmacist is responsible for developing and maintaining a current policy and procedure manual. The permittee must make available the policy and procedure manual to the appropriate state or federal agencies upon inspection. Do not send the policy and procedure manual to the board office. The board office will approve the policy and procedure manual based upon answers submitted for the following questions, where applicable, by using excerpts or summaries from the policy and procedure manual. List the following: Firm Name: Formatted: Indent: Hanging: 0.55", Tab stops: 0.49", Left Doing business as (d/b/a): Formatted: Indent: Left: 0" Telephone number: Address: Permit number (if already licensed as an institutional pharmacy): Formatted: Space After: 0 pt Explain the practice setting of the proposed facility. What are the objectives and purpose of the permittee? Give detailed explanation of the services of the facility scope and practice. What are the experience, qualifications, special education, and/or training of the compoundin Formatted: Space Before: 0 pt pharmacist? Please provide a resume. Address the ratio of supportive personnel to each pharmacist. How will the supportive personnel be utilized? Include a job description for any such supportive personnel. What categories of parenteral/enteral products will be prepared (i.e. IV, enteral, irrigating, and oncology products)? Include sample labels. What is the policy regarding the delivery of parenteral/enteral products to the patient? Describe methods used and trace the path the product takes from the time it leaves the permittee until it reaches the patient. Describe how products are protected from extreme temperature conditions. Address the policy and procedure, special equipment and special techniques to dispense sterile preparations for parenteral therapy/nutrition. If this type of dispensing will not be performed, please state so accordingly. Address the policy and procedure, special equipment and special techniques to dispense sterile jejunostomy feeding/sterile irrigation solutions. If this type of dispensing will not be performed, please state so accordingly. Formatted: Indent: Left: 0.55", Space Before: 0 pt, No Address the policy and procedure, special equipment and special techniques to dispense cytotoxic bullets or numbering anti-neoplastic agents. If this type of dispensing will not be performed, please state so accordingly, Formatted: Space Before: 0 pt Formatted: List Paragraph, Left, No bullets or numbering, What is the procedure for the annual review and updating of the policy and procedure manual? Tab stops: Not at 1" Formatted: Indent: Left: 1", Space Before: 0 pt, No bullets or numbering Formatted: Space Before: 0 pt Include the layout/floor plan of the pharmacy. The drawing must include the dimensions of the clear Formatted: Indent: Left: 0.55", Space Before: 0 pt, No room and the pharmacy, location of the hood, sink, and other equipment. The drawing must also sho bullets or numbering the location of the clean room relative to other pharmacy and storage areas. Formatted: Space Before: 0 pt Formatted: List Paragraph, Left, No bullets or numbering, Include a sample copy of a patient profile. Tab stops: Not at 1" Formatted: Space Before: 0 pt Address the use of aseptic techniques.

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DH-MQA 1218, 10/17 Rule 64B16-28.100, F.A.C. DH-MQA,XXXX1218.08/42 Rule 64B16-28.100, F.A.C.

Describe the Quality Assurance Program.

Page 23-of 14

Formatted: List Paragraph, Left, No bullets or numbering, Tab stops: Not at 1" Describe with detail the policy and procedure for patient education, including the personnel involved. Formatted: Space Before: 0 pt Address the policy and procedure for handling waste and returns. Formatted: List Paragraph, Left, No bullets or numbering, Tab stops: Not at 1" Describe the type of certified laminar flow hood(s) to be used and the frequency of certification. Formatted: Space Before: 0 pt Formatted: List Paragraph, Left, No bullets or numbering, Describe the refrigerator/freezer to be used. Tab stops: Not at 1" Formatted: Space Before: 0 pt 20) Describe appropriate waste containers for: Formatted: List Paragraph, Left, No bullets or numbering, <u>a.</u> Used needles and syringes. Tab stops: Not at 1" Cytotoxic waste including disposable apparel used in preparation. Formatted: Space Before: 0 pt Formatted: Indent: Left: 0.55", Space Before: 0 pt, No Address the following supplies to be used: gloves, mask, gowns, needles, syringes, disinfectant eleanir bullets or numbering agents, clean towels, hand-washing materials with bactericidal properties, vacuum containers/transf Formatted: Space Before: 0 pt sets, and spill kits for cytotoxic agent spills. Formatted: Indent: Left: 0.55", Space Before: 0 pt, No bullets or numbering Address the following references to be used: Formatted: Space Before: 0 pt Chapters 465 and 893, F.S., and Rule 64B16, F.A.C. Formatted: Indent: Left: 0.55", Space Before: 0 pt, No Authoritative Therapeutic Reference. bullets or numbering Handbook of injectable drugs by American Society of Health-System Pharmacists. Formatted: Space Before: 0 pt Occupational Safety and Health Administration guidelines for safe handling of cytotoxic drugs. Formatted: Indent: Left: 0.55", Space Before: 0 pt Formatted: Indent: Left: 0.55", Space Before: 0 pt, No Formatted: Space Before: 0 pt Formatted: Left

**PHARMACY PERMIT APPLICATION CHECKLIST** 

ФН-MQA 1218, 10/17 Rule 64B16-28.100, F.A.С. ФН-MQA,XXXX1218.08/12 Rule 64B16-28.100, F.A.С. Page 24 of 14

### 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.

NUCLEAR PHARMACY PERMITS	
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)	
Certificate of Status for the Corporation 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	
Nuclear Pharmacy Applicants must complete and submit answers to questions below	Formatted: No bullets or numbering
with the application.	
The Nuclear Pharmacist is responsible for developing and maintaining a current policy and procedure manual. The permittee must make available the policy and procedure manual to the appropriate state or federal agencies upon inspection. Do not send the policy and procedure manual to the board office. The board office will approve the policy and procedure manual based upon answers submitted for the following questions, where applicable, by using excerpts or summaries from the policy and procedure manual.	
List the following:	Formatted: No bullets or numbering
Firm Name:	Formatted: Indent: Left: 0", First line: 0"
Doing business as (d/b/a):  Telephone number:	Formatted: Indent: Left: 0"

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Address:

Permit number (if already licensed as an institutional pharmacy):

Explain the practice setting of the proposed facility.

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

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

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

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

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

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

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

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

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

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

Include a sample copy of a patient profile.

Address the use of aseptic techniques.

Describe the Quality Assurance Program.

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

Address the policy and procedure for handling waste and returns.

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

Describe the refrigerator/freezer to be used.

Describe appropriate waste containers for:

Used needles and syringes.

Cytotoxic waste including disposable apparel used in preparation.

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

Address the following references to be used:

Chapters 465 and 893, F.S., and Rule 64B16, F.A.C.

Authoritative Therapeutic Reference.

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

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

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



# SPECIAL PHARMACY PERMIT APPLICATION AND INFORMATION

October 2017



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

## **Special 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) or Consultant Pharmacist of Record.

Chapter 465, F.S., requires Special Pharmacies to be under the professional supervision of the PDM or Consultant Pharmacist of Record licensed in the State of Florida. A Florida licensed pharmacist shall perform compounding and dispensing of medicinal drugs.

There are six (6) types of Special Pharmacy Permit applicants. Please read the descriptions below. Check which permit type you are applying on the application.

- 1. Special- Limited Community Pharmacy Permit are only available to Institutional Class II permittees as an additional permit to allow the Institutional Class II permit to provide medications to employees, medical staff and up to a three-day supply of medication to patients being discharged under certain conditions.
- 2. Special- Parenteral and Enteral Pharmacy Permits provide parenteral (IV), enteral, and cytotoxic pharmacy services to outpatients. The applicant must be compliant with the Standard for Compounding Sterile Preparations found in Rule 64B16-27.797, F.A.C. Special-Parenteral and Enteral Pharmacy Permits may stand-alone or be used in conjunction with a Community Pharmacy or Special- Closed System Pharmacy Permit. The permittee must provide 24-hour telephone accessibility.
- 3. Special- Closed System Pharmacy Permits provide medicinal drugs, utilizing closed delivery systems, to facilities where prescriptions are individually prepared for the ultimate consumer, including nursing homes, jails, Assisted Living Facilities (ALF's), Intermediate Care Facility/Mentally Retarded (ICF-MR's) or other custodial care facilities when defined by Agency for Health Care Administration (AHCA) rules. A Special- Closed System Pharmacy may share locations with an establishment that holds a Community Pharmacy Permit; however, recordkeeping and inventory for each permittee must be maintained separately and distinct.
- **4. Special- End Stage Renal Dialysis (ESRD) Pharmacy** provides dialysis products and supplies to persons with chronic kidney failure and requires the services of a Consultant Pharmacist.
- **5. Special- Parenteral/Enteral Extended Scope** is required to compound patient specific enteral/parenteral preparations in conjunction with institutional pharmacy permits, provided requirements set forth herein are satisfied.
- **6. Special- Assisted Living Facility (ALF)** is an optional permit for those ALF's providing a drug delivery system utilizing medicinal drugs provided in unit dose packaging.

### **APPLICATION PROCESSING**

Please read all application instructions before completing your application.

1) Please mail the application and the \$255.00 application fee and fingerprint fees (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 poard office will notify you of the receipt of your application, any required documents, and your status. If the application is complete, you will be notified that an inspector will contact you to setup an inspection appointment. Please do not contact the board office concerning your inspection date, and allow 30 days for the inspector to contact you. If the inspector has not contacted you within 30 days, then notify the board. If your application is incomplete, you will be notified in writing of what is required to make your application complete.

## 2) Submit fingerprint results

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

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

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 <a href="http://www.flhealthsource.gov/background-screening">http://www.flhealthsource.gov/background-screening</a>.

### 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. 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 attesting 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 for you to sign this affirmation is included as an addendum to the application as Item #1.

### **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 15 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 <a href="http://www.DEAdiversion.usdoj.gov">http://www.DEAdiversion.usdoj.gov</a>. DEA Form 224 may be obtained in paper form by writing to:

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

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

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. <u>465.003(14)</u> or s. <u>893.02</u> 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

To prepare for your inspection, please review the inspection form.

You may download a copy of the inspection form from the website at <a href="http://www.floridahealth.gov/licensing-and-regulation/enforcement/inspection-program/inspection-forms.html">http://www.floridahealth.gov/licensing-and-regulation/enforcement/inspection-program/inspection-forms.html</a>

# SPECIAL 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> Faxed applications will not be accepted.

 Application completed (all questions answered and application signed)
 \$255.00 Fee Attached (Permit fee includes \$250 application fee and \$5.00 unlicensed activity fee)
 Copy of Articles of Incorporation from the Secretary of State's Office
 Fingerprints have been submitted via livescan for all officers and owners and the prescription department manager or consultant pharmacist of record.
 Attestation for Business Taxable Assets of \$100 million if applicable
 Consultant Pharmacist of Record/Prescription Department Manager Listed with Signature. (Section A, 5 of application)
 Consultant Pharmacist of Record/Prescription Department Manager 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 Special Parenteral and Enteral and Special Parenteral/Enteral Extended Scope applicants (Application Item #3)
 Applicant/Affiliate/Owner pharmacy permit questions answered and supplemental documents provided (Section 9 of application)
 Controlled Substances dispensing questions answered



# FLORIDA BOARD OF PHARMACY

P.O. Box 6320 Tallahassee, FL 32314-6320 Telephone (850) 488-0595 http://www.floridaspharmacy.gov



# **APPLICATION**

Application Type – Please choose one of the following:					
New Establishment \$255.00 fee		Change of Location \$100 fee			
Change of Ownership \$255.00 for		Stock Transfer – No fee			
Pharmacy Permit Type – Please cho	• • • •		rpe)		
Type of Special Pharmacy Permit - F	•	• •			
			_ Special- Closed System Pharmacy		
Special- ESRD Special- P	arenteral/Enteral E	xtended Scope	_ Special- ALF		
SECTION A. Please Comp	lete for all Ap	plication Typ	es		
Please list your Federal Employer Identification Number:					
1. Corporate Name			Telephone Number		
2. Doing Business As (d/b/a)			E-Mail Address		
3. Mailing Address					
City	State		Zip		
4. Physical Address					
City	State		Zip		
5. List Prescription Department Manager (PDM) or Consultant Pharmacist of Record					
Name		License Number			
Email Address		Telephone Number			
0.0.1.15		7141			
6. Contact Person		Title			
Email Address		Telephone Number			
	I.				

7. Please provide the name, address, telephone number, and permit number of your prescription drug wholesale distributor. If not available you may write in pending.					
Name	, ,	Telephone Number	Permit Num	ber	
Street Address		City	State	Zip	
8. Operating Hours		8a. Special- Parenteral & Provide Toll-Free T	•	nhor Rolow:	
Prescription Department Hours		Flovide Toll-Free T	elephone Nui	inci below.	
Monday-Friday: Open (		()		_	
Saturday: Open:		\			
Sunday: Open:(					
9. Ownership Information					
a. Type of Ownership:Indiv	ridualCo	orporationPartnershi	р		
Oth	ner:		· 		
NOTE: IF CORPORATION OR LIMITED PAR INCORPORATION ON FILE WITH THE FLOR	TNERSHIP YOU MUST IN	ICLUDE WITH YOUR APPLICATION A C	OPY OF THE ART	ICLES OF	
				of 402	
b. Are the applicants, officers,		olders, members and partners	s over the age	e of 18?	
c. Does the corporation have m	nore than \$100 mil	lion of business taxable asse	ets in this stat	te?	
Yes No If yes, provide attestation from Certified Public Accountant for previous tax year or Florida Corporate Income/Franchise and Emergency Excise Tax Return (F-1120). If no, continue to 12d.					
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 9c. If 9c. is yes please list the owners below and only submit fingerprints for the Prescription Department Manager or Consultant Pharmacist of Record. If 9c. 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	
	1 1			%	
	1 1			%	
	1 1			%	
	1 1			%	
	1 1			%	
10. Has anyone listed in 9.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 disc	closing the reason th	ne entity was closed.	

10a 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.		
convicted of, or ente		ed a pharmacy permit by misrepresentation or fraud or been or nolo contender to, regardless of adjudication, a crime in any fraud?		
Yes	No	If yes, please provide documents concerning this conviction.		
	he following questions	2(5), Florida Statutes, questions 12 through 18 are being asked. If you s, explain on a separate sheet providing accurate details and submit		
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 in another state or jurisdiction since July 1, 2009? (If yes, provide court documents concerning this conviction)				
Yes	No	_		
date of the plea, s	entence and comp	the third degree, has it been more than 10 years from the letion of any subsequent probation? (This question does ree under Section 893.13(6)(a), Florida Statutes).		
Yes	No			
12b. If "yes" to 12, 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			
12c. If "yes" to 12, 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			
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 since July 1, 2009?				
Yes		(If yes, explain on a separate sheet providing accurate details)		
13a. If "yes" to 13, has it been more than 15 years before the date of application since the sentence and any subsequent period of probation for such conviction or plea ended?				
Yes	No			

15. 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)  16. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant ever been terminated for cause, pursuant to the appeals procedures established by the state or federal government, from any other state Medicaid program or the federal Medicare program?  (If no, do not answer 20 and 21)  Yes No (If yes, explain on a separate sheet providing accurate details)  17. Has the applicant been in good standing with a state Medicaid program or the federal Medicare program for the most recent five years?  Yes No (If yes, explain on a separate sheet providing accurate details)  18. 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)  19. 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, submit proof)  20. 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  21. Has the applicant, affiliated persons, partners, officer, directors, or PDM 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.		ncipal, officer, agent, managing emplo	
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Medicaid Program for the most recent five years?  Yes	15. If the applicant or any princi	pal, officer, agent, managing employee	e, or affiliated person of the
No			n good standing with the Florida
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Yes No	(	(If was, explain on a separate s	neet providing accurate details)
Program for the most recent five years?   Yes	Yes No _	(ii yes, explain on a separate si	leet providing accurate details)
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23. Has the applicant, or any offi misdemeanor, excluding minor to	•	tner ever been convicted of a felony or	
Yes No		(You must include all misdemeanors and felonies, even if	
adjudication was withheld by the court, so t	hat you would not have a	record of conviction. Driving under the influence or driving while	
impaired is <u>NOT</u> a minor traffic offense for	the purposes of this quest	tion.)	
24. Is there any other permit issuaddress on this application?	ued by the Departmo	ent of Health located at the physical location	
Yes No	(If yes, explain	n on a separate sheet providing accurate details)	
		icer, director have any outstanding fines, liens or rtment? If yes, please answer 28a.	
Yes No	(If yes, explain	n on a separate sheet providing accurate details)	
25.a. Does the applicant, affiliat the department?	ed person, partner,	officer, director have a repayment plan approved b	У
Yes No			
		ng controlled substance dispensing based on ent relationship available for inspection by DOH?	
Yes No	_		
27. Will the Pharmacy Dispen	se Schedule II and	l/or III Controlled Substances?	
Yes No			
SECTION B. Please comp	lete for Change	e of Location ONLY	
1. Current Practice Location	Address		
City	State	Zip	
Email Address		Telephone Number	
2. New Practice Location Ad	dress		

City	State		Zip
Email Address		Telephone Numb	per
Please provide your existing Pharm Please provide your existing Feder	-	. ,	
<b>SECTION C. Please comple</b>	te for a Chang	e of Ownershi	p ONLY
1. Are you changing physical I	ocations with this	change of owners	ship?
Yes No			
If yes, please complete Section B abo	ove.		
2. Please provide date when be	usiness transactio	on for the change o	of ownership will be completed?
Date:			
			h indicates dates that pharmacy letter should be provided with your
Yes No			
Please provide your existing Pharm (Existing permits will be closed and new page 2)			shin)
Please provide your existing Feder	` ,		
<b>SECTION D. Please comple</b>	te for a Stock	Transfer of Ov	vnership ONLY
1. Please provide the date the	transfer of owners	ship interest took p	place?
Date:	_		
2. Did your company's FEIN ch Section D, question 1 above		of the transfer of o	wnership interest referenced in
Yes No			
If yes, please complete Section C above	ve and include the n	ecessary fee.	
Please provide your existing Pharm	nacy Permit Numb	er(s):	
Please provide your existing Feder	al DEA Number: _		

### 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 thing, in connection with an application for a license or permit, as set forth in Section 465.015(2)(a), F.S.

information may result in disciplinary action against my license or criminal penalties.

SIGNATURE \_\_\_\_\_\_DATE\_\_\_\_\_\_

Under penalty of perjury I have read the foregoing document and that the facts stated in it are true. I recognize that providing false

DH-MQA 1220, 10/17 Rule 64B16-28.100, F.A.C.

Owner/Officer

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

Name:	
Aliases:	
	Apt. Number:
City:	StateZip Code:
Date of Birth://(MM/DD/YYYY)	Place 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	



### <u>Item #1- Privacy Statement Acknowledgement</u>

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

File #:	(if known):
Licens	Se #: (if applicable):

		d (COR) or Prescription Department
Manager (PDM) Designatior	า	
Applicant/Pharmacy Name:		
Applicant/Pharmacy Mailing Ac	ldress:	
City	State	Zip
Incoming COR/PDM Name:		License#:
Date Beginning as COR/PDM:	Incoming COR/P	DM Signature
COR/PDM Transaction Control	Number (TCN) – re	elated to Livescan Fingerprints:
***Only provide following infor	mation is there is an (	Outgoing COR at current pharmacy location.***
Outgoing COR/PDM Name:		License#: please include PU# if applicable
Date Ending as COR/PDM:		
Section B. Incoming COR/	PDM Privacy St	atement Acknowledgement
Note: Acknowledgment should be com	pleted by same person	listed in <u>Section A</u> above as <u>Incoming COR</u> .
	right to challenge inc	orida Department of Law Enforcement regarding orrect criminal history records and the "Privacy igation."
Date:	Incoming COR/P	DM Signature



## <u>Item #2- Affiliate/Owner Privacy Statement</u> <u>Acknowledgement</u>

# 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

MQA.Pharmacy@flhealth.gov

Affiliate / Owner Name:		File # (required):
Applicant Name:		
Affiliate/Owner Mailing Address:		
City	State	Zip
Affiliate/Owner Email	Affiliate/Owner Telep	phone Number
Affiliate/Owner Transaction Control Nu	imber (TCN) - related	to Livescan Fingerprints:
From:		
I have been provided and read the Law Enforcement regarding the sha challenge incorrect criminal history document from the Federal Bureau	aring, retention, privacy records and the "Priva	∕ and right to
Affiliate/Owner Signature (Require	ed) Date (d	of signature)



#### <u>Item #3 - Policy and Procedure Questions</u>

Special- Parenteral and Enteral and Special- Parenteral/Enteral Extended Scope Applicants Complete the Following Questions.

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

1) List the following:

Firm Name:

Doing business as (d/b/a):

Telephone number:

Address:

Permit number (if already licensed as an institutional pharmacy):

- 2) Explain the practice setting of the proposed facility.
- 3) What are the objectives and purpose of the permittee? Give detailed explanation of the services of the facility scope and practice.
- 4) What are the experience, qualifications, special education, and/or training of the compounding pharmacist? Please provide a resume.
- 5) Address the ratio of supportive personnel to each pharmacist. How will the supportive personnel be utilized? Include a job description for any such supportive personnel.
- What categories of parenteral/enteral products will be prepared (i.e. IV, enteral, irrigating, and oncology products)? Include sample labels.
- 7) What is the policy regarding the delivery of parenteral/enteral products to the patient? Describe methods used and trace the path the product takes from the time it leaves the permittee until it reaches the patient. Describe how products are protected from extreme temperature conditions.
- 8) Address the policy and procedure, special equipment and special techniques to dispense sterile preparations for parenteral therapy/nutrition. If this type of dispensing will not be performed, please state so accordingly.
- 9) Address the policy and procedure, special equipment and special techniques to dispense sterile jejunostomy feeding/sterile irrigation solutions. If this type of dispensing will not be performed, please state so accordingly.
- 10) Address the policy and procedure, special equipment and special techniques to dispense cytotoxic or anti-neoplastic agents. If this type of dispensing will not be performed, please state so accordingly.

- 11) What is the procedure for the annual review and updating of the policy and procedure manual?
- 12) Include the layout/floor plan of the pharmacy. The drawing must include the dimensions of the clean room and the pharmacy, location of the hood, sink, and other equipment. The drawing must also show the location of the clean room relative to other pharmacy and storage areas.
- 13) Include a sample copy of a patient profile.
- 14) Address the use of aseptic techniques.
- 15) Describe the Quality Assurance Program.
- 16) Describe with detail the policy and procedure for patient education, including the personnel involved.
- 17) Address the policy and procedure for handling waste and returns.
- 18) Describe the type of certified laminar flow hood(s) to be used and the frequency of certification.
- 19) Describe the refrigerator/freezer to be used.
- 20) Describe appropriate waste containers for:
  - a. Used needles and syringes.
  - b. Cytotoxic waste including disposable apparel used in preparation.
- 21) Address the following supplies to be used: gloves, mask, gowns, needles, syringes, disinfectant cleaning agents, clean towels, hand-washing materials with bactericidal properties, vacuum containers/transfer sets, and spill kits for cytotoxic agent spills.
- 22) Address the following references to be used:
  - a. Chapters 465 and 893, F.S., and Rule Title 64B16, F.A.C.
  - b. Authoritative Therapeutic Reference.
  - c. Handbook of Injectable Drugs by American Society of Health-System Pharmacists.
- 23) Occupational Safety and Health Administration guidelines for safe handling of cytotoxic drugs.

### If applying for a Special- Parenteral/Enteral Extended Scope Permit, answer the additional questions below:

- 24) Describe the individual responsibilities of the Special- Parenteral/Enteral Extended Scope Permit and the supplied institutional pharmacy permits, if applicable.
- Address the maintenance of patient profiles and the offer to counsel if dispensing to outpatients.
- 26) Describe the system for the maintenance of compounding records.

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





### SPECIAL PHARMACY PERMIT APPLICATION AND INFORMATION

DH-MQA 1220, 08/12 Rule 64B16-28.100 F.A.C.

#### August 2012 October 2017



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 <a href="mag\_pharmacy@doh.state.fl.usinfo@floridaspharmacy.gov">mag\_pharmacy@doh.state.fl.usinfo@floridaspharmacy.gov</a>, 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

DH-MQA 1220, 08/12 Rule 64B16-28.100 F.A.C. 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

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#### **Special 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) or Consultant Pharmacist of Record.

Chapter 465, F.S., requires Special Pharmacies to be under the professional supervision of the PDM or Consultant Pharmacist of Record licensed in the State of Florida. A Florida licensed pharmacist shall perform compounding and dispensing of medicinal drugs.

There are esixight (68) types of Special Pharmacy Permit applicants. Please read the descriptions below. Check which permit type you are applying on the application.

- 1. Special- Limited Community Pharmacy Permit are only available to Institutional Class II permittees as an additional permit to allow the Institutional Class II permit to provide medications to employees, medical staff and up to a three-day supply of medication to patients being discharged under certain conditions.
- 2. Special- Parenteral and Enteral Pharmacy Permits provide parenteral (IV), enteral, and cytotoxic pharmacy services to outpatients. The applicant must be compliant with the Standard for Compounding Sterile Preparations found in Rule 64B16-27.797, F.A.C. Special-Parenteral and Enteral Pharmacy Permits may stand-alone or be used in conjunction with a Community Pharmacy or Special- Closed System Pharmacy Permit. The permittee must provide 24-hour telephone accessibility.
- 3. Special- Closed System Pharmacy Permits provide medicinal drugs, utilizing closed delivery systems, to facilities where prescriptions are individually prepared for the ultimate consumer, including nursing homes, jails, Assisted Living Facilities (ALF's), Intermediate Care Facility/Mentally Retarded (ICF-MR's) or other custodial care facilities when defined by Agency for Health Care Administration (AHCA) rules. A Special- Closed System Pharmacy may share locations with an establishment that holds a Community Pharmacy Permit; however, recordkeeping and inventory for each permittee must be maintained separately and distinct.
- 4. Special- Non-Resident Registration is required for those pharmacies located outside the state and ships, mails, or delivers a dispensed medicinal drug into this state.
- **45. Special- End Stage Renal Dialysis (ESRD) Pharmacy** provides dialysis products and supplies to persons with chronic kidney failure and requires the services of a Consultant Pharmacist.
- **56. Special- Parenteral/Enteral Extended Scope** is required to compound patient specific enteral/parenteral preparations in conjunction with institutional pharmacy permits, provided requirements set forth herein are satisfied.
- **67. Special- Assisted Living Facility (ALF)** is an optional permit for those ALF's providing a drug delivery system utilizing medicinal drugs provided in unit dose packaging.

8. Community/Special Parenteral/Enteral Pharmacy A community/special parenteral/enteral pharmacy provides outpatient parenteral, enteral and cytotoxic pharmacy

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services. The pharmacy must meet all requirements of both the community AND parenteral/enteral permits, but does not require two separate permits.

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Rule 64B16-28.100, F.A.C.

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#### APPLICATION PROCESSING

Please read all application instructions before completing your application.

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

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**Application & Fees:** 

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

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if you ar

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

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

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

—2) Submit fingerprint results

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

Applicants can use any Livescan vendor that has been approved by the Florida Department of Law Enforcement to submit their fingerprints to the department. Please ensure that the Originating Agency Identification (ORI) number is provided to the vendor when you submit your fingerprints. If you do not provide an ORI number or if you provide an incorrect ORI number to

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Rule 64B16-28.100, F.A.C.

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the vendor, the Board of Pharmacy <u>will not</u> receive your fingerprint results. The applicant is fully responsible for selecting the vendor and ensuring submission of the prints to the Department.

4. 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 <a href="http://www.flhealthsource.gov/background-screening-www.deh.state.fl.us/mga/pharmacy">http://www.flhealthsource.gov/background-screening-www.deh.state.fl.us/mga/pharmacy</a>, 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 EDOH4680ZFL924190Z

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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 attesting 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 for you to sign this affirmation is included as an addendum to the application as Item #1.

\_\_\_\_\_\_4) Special- Parenteral and Enteral, and Special- Parenteral/Enteral Extended Scope Pharmacy Applicants must complete and submit answers to questions below with the application.

Special- Parenteral and Enteral and Special- Parenteral/Enteral Extended Scope Applicants Complete the Following Questions.

The Consultant Pharmacist of Record is responsible for developing and maintaining a current of policy and procedure manual. The permittee must make available the policy and procedure

DH-MQA <u>1220</u>XXXX, 08/1210/17 Page 41

Rule 64B16-28.100, F.A.C.

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manual to the appropriate state or federal agencies upon inspection. Do not send the policy and procedure manual to the board office. The board office will approve the policy and procedure manual based upon answers submitted for the following questions, where applicable, by using excerpts or summaries from the policy and procedure manual.

1) List the following:

Firm Name:

Doing business as (d/b/a):

Telephone number:

Addross

Permit number (if already licensed as an institutional pharmacy):

- Explain the practice setting of the proposed facility.
- 3) What are the objectives and purpose of the permittee? Give detailed explanation of the services of the facility scope and practice.
- 4) What are the experience, qualifications, special education, and/or training of the compounding pharmacist? Please provide a resume.
- 5) Address the ratio of supportive personnel to each pharmacist. How will the supportive personnel be utilized? Include a job description for any such supportive personnel.
- 6) What categories of parenteral/enteral products will be prepared (i.e. IV, enteral, irrigating, and encology products)? Include sample labels.
- 7) What is the policy regarding the delivery of parenteral/enteral products to the patient? Describe methods used and trace the path the product takes from the time it leaves the permittee until it reaches the patient. Describe how products are protected from extreme temperature conditions.
- 8) Address the policy and procedure, special equipment and special techniques to dispense sterile preparations for parenteral therapy/nutrition. If this type of dispensing will not be performed, please state so accordingly.
- 9) Address the policy and procedure, special equipment and special techniques to dispense sterile jojunostomy feeding/sterile irrigation solutions. If this type of dispensing will not be performed, please state so accordingly.
- 10) Address the policy and procedure, special equipment and special techniques to dispense cytotoxic or anti-neoplastic agents. If this type of dispensing will not be performed, please state so accordingly.
- 11) What is the procedure for the annual review and updating of the policy and procedure manual?
- 12) Include the layout/floor plan of the pharmacy. The drawing must include the dimensions of the clean room and the pharmacy, location of the hood, sink, and other equipment. The drawing must also show the location of the clean room relative to other pharmacy and storage areas.
- 13) Include a sample copy of a patient profile.
- 14) Address the use of aseptic techniques.
- 15) Describe the Quality Assurance Program.
- 46) Describe with detail the policy and procedure for patient education, including the personnel involved.
- 17) Address the policy and procedure for handling waste and returns.
- 48) Describe the type of certified laminar flow hood(s) to be used and the frequency of certification.
- 19) Describe the refrigerator/freezer to be used.
- 20) Describe appropriate waste containers for:
- Used needles and syringes.
- Cytotoxic waste including disposable apparel used in preparation.

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

22) Address the following references to be used:

Chapters 465 and 893, F.S., and Rule Title 64B16, F.A.C.

b. Authoritative Therapeutic Reference.

Handbook of Injectable Drugs by American Society of Health System Pharmacists.

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

### If applying for a Special- Parenteral/Enteral Extended Scope Permit, answer the additional questions below:

24) Describe the individual responsibilities of the Special Parenteral/Enteral Extended Scope Permit and the supplied institutional pharmacy permits, if applicable.

25) Address the maintenance of patient profiles and the offer to counsel if dispensing to outpatients.

26) Describe the system for the maintenance of compounding records.

#### **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 15 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/mga 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 <a href="http://www.DEAdiversion.usdoj.gov">http://www.DEAdiversion.usdoj.gov</a>. DEA Form 224 may be obtained in paper form by writing to:

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

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

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.

Page 64

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#### PRE-INSPECTION CHECKLIST

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

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

Are all required signs displayed?

- 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.
- o 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?

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You may download a copy of the inspection form from the website at <a href="http://doh.state.fl.us/mga/enforcement/enforce-forms.html">http://doh.state.fl.us/mga/enforcement/enforce-forms.html</a>

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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,

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#### **PRE-INSPECTION CHECKLIST**

To prepare for your inspection, please review the inspection form.

You may download a copy of the inspection form from the website at <a href="http://www.floridahealth.gov/licensing-and-regulation/enforcement/inspection-program/inspection-forms.html">http://www.floridahealth.gov/licensing-and-regulation/enforcement/inspection-program/inspection-forms.html</a>

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08/12/10/17 Rule 64B16-28.100, F.A.C. Page 94

#### SPECIAL 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. Faxed applications will not be accepted.

Application completed (all questions answered and application signed)

\$255.00 Fee Attached (Permit fee includes \$250 application fee

and \$5.00 unlicensed activity fee)

Copy of Articles of Incorporation from the Secretary of State's Office

Fingerprints have been submitted via livescan for all officers and owners and the prescription department manager or consultant pharmacist of record.

Attestation for Business Taxable Assets of \$100 million if applicable

Consultant Pharmacist of Record/Prescription Department
Manager Listed with Signature. (Section A, 5 of application)

Consultant Pharmacist of Record/Prescription Department Manager 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 Special Parenteral and Enteral and Special Parenteral/Enteral Extended Scope

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Rule 64B16-28.100, F.A.C.

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#### applicants (Application Item #3)

Applicant/Affiliate/Owner pharmacy permit questions answered and supplemental documents provided (Section 9 of application).

Controlled Substances dispensing questions answered

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#### FLORIDA BOARD OF PHARMACY

P.O. Box 6320

P.O. Box 6320

Tallahassee, FL 32314-6320

Telephone (850) 488-0595

http://www.floridaspharmacy.gov.

# SPECIAL PHARMACY

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http://www.floridaspharmacy.gov Formatted: Font: 11 pt Formatted: Font: 11 pt SPECIAL PHARMACY PERMIT APPLICATION Formatted: Indent: Left: 0" application Type - Please choose one of the following: Formatted: Not Highlight New Establishment \$255.00 fee Change of Location \$100 fee Formatted: Centered, Indent: Left: 0", First line: 0" Change of Ownership \$255.00 fee Stock Transfer – No fee Formatted: Font: Bold Pharmacy Permit Type - Please choose permit type(s) (\$255 for each type) **Formatted Table** Type of Special Pharmacy Permit - Please choose permit type: Formatted: Font: Not Bold Special- Parenteral and Enteral Special- Closed System Pharmacy Special- Limited Community Special- ESRD Special-Parenteral/Enteral Extended Scope Special- ALF Formatted: Space Before: 0 pt, After: 0 pt Formatted: Font: 2 pt, Bold Please Complete for all Application Formatted: Font: Not Bold Application Type - Please choose one of the following: Formatted: Pattern: Clear (Custom Color(RGB(13,13,13))) New Establishment \$255 fee Formatted: Font: 14 pt Change of Location \$100 fee (existing permit number) Change of Ownership (a new permit number will be issued) \$255 (existing permit number) -Additional Permit Type \$255 fee \_\_\_\_\_\_(existing permit number) Type of Special Pharmacy Permit - Please choose permit typeone of the following: Special- Limited Community \_\_\_\_Special- Parenteral and Enteral \_\_\_\_Special- Closed System Pharmacy Special- ESRD Special- Parenteral/Enteral Extended Scope Special- ALF Special- Closed System Pharmacy/Parenteral and Enteral Community/Special Parenteral and Enteral Formatted: Font: 14 pt Formatted: Pattern: Clear (Custom Color(RGB(13,13,13))) Formatted: Pattern: Clear (Custom Color(RGB(13,13,13))) Please list your Federal Employer Identification Number:ex Formatted: Underline Formatted: Underline 1. Corporate Name Telephone Number **Formatted Table** Doing Business As (d/b/a) E-Mail Address 3. Mailing Address City State Zip Formatted: Font: (Default) Arial, 11 pt **Physical Address** rmatted: Font: (Default) Arial, 11 pt Formatted: Font: (Default) Arial, 11 pt Formatted: Strikethrough

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business pe	rmit which was vol	untarily relinquis	shed or closed voluntarily within the past	5 years?	
Yes	No	_	If yes, please provide a signed affidavit disclosing the reason	on the entity was	closed
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			a pharmacy permit by misrepresentation of contender to, regardless of adjudication,		
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Yes	No.		If yes, please provide documents concerning this convict	ion.	\ <u></u>
Durenent te S	Continu 456 0625(2) -	nd 465 022/5\ Fla	vida Statutos questions 425 through 4004	hoing ooks	_//⊱
Tursuant to S	ection 456.0635(2) at	nu 405.022(5), Floi	rida Statutes, questions 125 through 1821 are	being asked	.   f  //
				//	$/\!\!/$
DH-N	MQA 1220XXXX.		Page 34		/

08/12/10/17 Rule 64B16-28.100, F.A.C.

	es to any of the following que s of supporting documentation	stions, explain on a separate sheet providing. n.	g accurate details and	
applicant be a felony und another stat	en convicted of, or entered ler Chapter 409, Chapter 81 e or jurisdiction since July	officer, agent, managing employee, or a a plea of guilty or nolo contendere to, ro 7, or Chapter 893, Florida Statutes; or a 1, 2009? (If yes, provide court documents co	egardless of adjudicati similar felony offense i	in
Yes	No	_		
the date of	the plea, sentence and	s of the third degree, has it been mo completion of any subsequent prob d degree under Section 893.13(6)(a),	ation? (This questio	
Yes	No			
Statutes, ha	as it been more than 5 ye	of the third degree under Section 89 ars from the date of the plea, sentenc		
Yes	uent probation?			
affiliated pe	erson of the applicant suc	nt or any principal, officer, agent, man cessfully completed a drug court pro withdrawn or the charges dismissed	ogram that resulted in	
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applicant be	en convicted of, or entered	officer, agent, managing employee, or a a plea of guilty or nolo contendere to, roor 42 U.S.C. ss. 1395-1396 since July 1, 2	egardless of adjudicati	spacing: Multiple 1.02 li, Tab stops: Not at 1.55"
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	applicant listed on the United Stat ∟ist of Excluded Individuals and E	es Department of Health Human Sei	rvices Office of Inspector Ger	eral's	
	res No	(If yes, submit proof)			
2	023. Are you currently registered	d or permitted in any other states?		:	
t	ype, and permit number for each	permit. Attach a separate sheet if n	ecessary.		
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	State	Permit Type	Permit Number		
	State	remit Type	Fermit Number		
2	124. Has the applicant, affiliated	persons, partners, officer, directors	s or PDM or Consultant Pharr	acist	
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C	of Record ever owned a pharmacy	'? If yes, provide the name of the pi	harmacy, the state where the		
		of the pharmacy. Attach a separate			
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	427. Is there any other permit iss address on this application?	ued by the Departi	ment of Health located at the physic	al location	
,	YesNo NoYes		(If yes, explain on a separate sheet providing	ng accurate details)	
			officer, director have any outstanding treet? If yes, please answer 28a.	g fines, liens or	
,	<u>YesNo</u> <u>No</u> Yes		(If yes, explain on a separate sheet providing	ng accurate details)	
	25.8a. Does the applicant, affiliate by the department?	ed person, partner,	, officer, director have a repayment p	plan approved	
,	<u>Yes No</u> <u>Yes No</u>			4	Formatted: Space After: 0 pt
			ing controlled substance dispensing ent relationship available for inspect		
•	YesNe NoYes				
-	27. Will the Pharmacy Dispense	Schedule II and	/or III Controlled Substances?		
					-
	Yes No				
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	SECTION B. Blosse comple	oto for Change	of Location ONLY		Formatted: Font: Bold
4	SECTION B. Please comple 1. Current Practice Location A		OI LOCATION ONLY	•	
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	Please provide your existing Federal DEA Number:	
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1	SECTION C. Please complete for a Change of Ownership ONLY	Formatted: Space After: 0 pt
	1. Are you changing physical locations with this change of ownership?	Formatted: Line spacing: Multiple 1.15 li, Numbered + Level: 1 + Numbering Style: 1, 2, 3, + Start at: 1 + Alignment: Left + Aligned at: 0.25" + Indent at: 0.5"
	1. Are you changing physical locations with this change of ownership:	Formatted: Font: Not Bold
	Yes No	Formatted: Line spacing: 1.5 lines
	yes, please complete Section B above.	Formatted: Font: Not Bold
-	yes, please complete Section B above.	Formatted: Font: Not Bold
	2. Please provide date when business transaction for the change of ownership will be completed?  Date:	Formatted: Numbered + Level: 1 + Numbering Style: 1, 2, 3, + Start at: 1 + Alignment: Left + Aligned at: 0.25" + Indent at: 0.5"
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	3. Do you have a signed letter from both the buyer and seller which indicates dates that pharmacy permit license should be transferred? Note: A copy of the signed letter should be provided with your	Formatted: Numbered + Level: 1 + Numbering Style: 1, 2, 3, + Start at: 1 + Alignment: Left + Aligned at: 0.25" + Indent at: 0.5"
	<u>application</u>	Formatted: Space After: 12 pt, Line spacing: Multiple 1.15 li
	Yes No	Formatted: Font: Not Bold
	Please provide your existing Pharmacy Permit Number(s):	Formatted: Space Before: 0 pt
	(Existing permits will be closed and new permit number(s) issued under new ownership.)	Formatted: Font: 10 pt, Not Bold
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	SECTION D. Please complete for a Stock Transfer of Ownership ONLY  —Please provide the date the transfer of ownership interest took place?	Formatted: Numbered + Level: 1 + Numbering Style: 1, 2, 3, + Start at: 1 + Alignment: Left + Aligned at: 0.25" + Indent at: 0.5"
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	2. Did your company's FEIN change as a result of the transfer of ownership interest referenced in	Formatted: Indent: Left: 0.5", No bullets or numbering
_	Section D, question 1 above?  Yes No	Formatted: Numbered + Level: 1 + Numbering Style: 1, 2, 3, + Start at: 1 + Alignment: Left + Aligned at: 0.25" + Indent at: 0.5"
4	yes, please complete Section C above and include the necessary fee,	Formatted: Font: Not Bold
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#### 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 Permiteist's license may be revoked or suspended for presenting any false, fraudulent, or forged statement, certificate, diploma, or other thing, in connection with an application for a license or permit, as set forth in Section 465.015(2)(a), F.S.

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

SIGNATURE	TITLE	DATE

Owner/Officer

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#### 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. Faxed applications will not be accepted.

#### 

prescription department manager or consultant
pharmacist of record. Fingerprint results must be
within one year of the application date.

Attestation for Business Taxable Assets of \$100 million
if applicable

Attach proof from AHCA of fingerprint results if applicable for

\_\_\_\_\_ Bill of Sale is required for Change of Ownership

 ${
m N\over OTICE}$  FOR APPLICANTS SUBMITTING FINGERPRINTS WHERE CRIMINAL RECORD-RESULTS WILL BECOME PART OF THE CARE PROVIDER BACKGROUND SCREENING CLEARINGHOUSE

DH-MQA <u>1220</u>XXXX, <u>08/12</u>10/17 Page 94

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#### **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.

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

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

US Department of Justice, Federal Bureau of Investigation,

DH-MQA <u>1220</u>XXXX,

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<del>08/12</del>10/17 Rule 64B16-28.100, F.A.C. Formatted: Right: 0"

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#### **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.

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#### **Electronic Fingerprinting**

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

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

lame: SSN#:			
Aliases:			_
Address:	Apt. Number:		
City:	State.	Zip Code:	
Date of Birth: / / (MM/DD/YYYY)	Place of Birth:		
Weight: Height:	Eye Color:	Hair Color:	
Race:	Sex:		
(W-White/Latino(a); B-Black; A-Asian; NA-Native American; U-Unknown)	(M=Male; F=Female	)	
Citizenship:			
Transaction Control Number (TCN#):			
(This will be provided to you by the Live	e Scan Service provider.)		

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Rule 64B16-28.100, F.A.C.



Rule 64B16-28.100, F.A.C.

#### **Item #1- Privacy Statement Acknowledgement**

To: Florida Board of Pharmacy Post Office Box 6320 Tallahassee, FL 32314-6320 (850) 245-4292- phone

(850) 413-6982 - fax info@floridaspharmacy.gov File #: (if known):

License #: (if applicable):

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Section A. Consultant Phar	macist of Reco	rd (COR) or Prescription Department	Formatted: Line spacing: Multiple 1.15 li
Manager (PDM) Designation			Formatted Table
Applicant/Pharmacy Name:			
Application flatflacy Name.			
Applicant/Pharmacy Mailing Ac	ldress:		
City	State	Zip	
City	State	<u> </u>	_
Incoming COR/PDM Name:		<u>License#:</u>	
Date Beginning as COR/PDM:	Incoming COR/P	PDM Signature -	Formatted Table
COR/PDM Transaction Control	Number (TCN) - r	elated to Livescan Fingerprints:	_
***Only provide following infor	mation is there is an	Outgoing COR at current pharmacy location.***	
Outgoing COR/PDM Name:		License#: please include PU# if applicable	Formatted: Font: Not Bold
Date Ending as COR/PDM:	Outgoing COR/P	PDM Signature	Formatted Table
Bato Enaing ao COIVI Biii.	Catgoring COTAT	Din Orginaturo	
		tatement Acknowledgement	
Note: Acknowledgment should be com	pleted by same person	n listed in Section A above as Incoming COR.	
		lorida Department of Law Enforcement regarding	
the sharing, retention, privacy and restaurant document from the Federal	right to challenge inc	correct criminal history records and the "Privacy	
			Formatted: Font: (Default) Arial, 11 pt
Date:	Incoming COR/P	PDM Signature	Formatted: Font: (Default) Arial, 11 pt
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#### **Item #2- Affiliate/Owner Privacy Statement** <u>Acknowledgement</u>

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

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

Affiliate / Owner Name:		File # (required):		
Applicant Name:			4	Formatted Table
Affiliate/Owner Mailing Address:				
City	State	Zip		
<u>ony</u>	<u>Otato</u>	<u>=15</u>		
Affiliate/Owner Email	Affiliate/Owne	er Telephone Number		
			-	Formatted Table
	(701)			
Affiliate/Owner Transaction Cont	<u>rol Number (TCN) – r</u>	related to Livescan Fingerpri	nts:	

#### From:

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."

DH-MQA 1220XXXX, 08/1210/17

Rule 64B16-28.100, F.A.C.

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Affiliate/Owner Si	gnature	(Required)
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Date (of signature)

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#### **Item #3 - Policy and Procedure Questions**

Special- Parenteral and Enteral and Special- Parenteral/Enteral Extended Scope Applicants Complete the Following Questions.

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

1) List the following:

Firm Name:

Doing business as (d/b/a):

Telephone number:

Address:

iddi Coo.

Permit number (if already licensed as an institutional pharmacy):

- Explain the practice setting of the proposed facility.
- 3) What are the objectives and purpose of the permittee? Give detailed explanation of the services of the facility scope and practice.
- 4) What are the experience, qualifications, special education, and/or training of the compounding pharmacist? Please provide a resume.
- 5) Address the ratio of supportive personnel to each pharmacist. How will the supportive personnel be utilized? Include a job description for any such supportive personnel.
- 6) What categories of parenteral/enteral products will be prepared (i.e. IV, enteral, irrigating, and oncology products)? Include sample labels.
- 7) What is the policy regarding the delivery of parenteral/enteral products to the patient? Describe methods used and trace the path the product takes from the time it leaves the permittee until it reaches the patient. Describe how products are protected from extreme temperature conditions.
- 8) Address the policy and procedure, special equipment and special techniques to dispense sterile preparations for parenteral therapy/nutrition. If this type of dispensing will not be performed, please state so accordingly.
- Address the policy and procedure, special equipment and special techniques to dispense sterile jejunostomy feeding/sterile irrigation solutions. If this type of dispensing will not be performed, please state so accordingly.
- Address the policy and procedure, special equipment and special techniques to dispense cytotoxic or anti-neoplastic agents. If this type of dispensing will not be performed, please state so accordingly.

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- 11) What is the procedure for the annual review and updating of the policy and procedure manual?
- 12) Include the layout/floor plan of the pharmacy. The drawing must include the dimensions of the clean room and the pharmacy, location of the hood, sink, and other equipment. The drawing must also show the location of the clean room relative to other pharmacy and storage areas.
- 13) Include a sample copy of a patient profile.
- 14) Address the use of aseptic techniques.
- 15) Describe the Quality Assurance Program.
- 16) Describe with detail the policy and procedure for patient education, including the personnel involved.
- 17) Address the policy and procedure for handling waste and returns.
- 18) Describe the type of certified laminar flow hood(s) to be used and the frequency of certification.
- 19) Describe the refrigerator/freezer to be used.
- 20) Describe appropriate waste containers for:
  - a. Used needles and syringes.
  - b. Cytotoxic waste including disposable apparel used in preparation.
- 21) Address the following supplies to be used: gloves, mask, gowns, needles, syringes, disinfectant cleaning agents, clean towels, hand-washing materials with bactericidal properties, vacuum containers/transfer sets, and spill kits for cytotoxic agent spills.
- 22) Address the following references to be used:
  - a. Chapters 465 and 893, F.S., and Rule Title 64B16, F.A.C.
  - b. Authoritative Therapeutic Reference.
  - c. Handbook of Injectable Drugs by American Society of Health-System Pharmacists.
- 23) Occupational Safety and Health Administration guidelines for safe handling of cytotoxic drugs.

### <u>If applying for a Special- Parenteral/Enteral Extended Scope Permit, answer the additional questions below:</u>

- Describe the individual responsibilities of the Special- Parenteral/Enteral Extended Scope Permit and the supplied institutional pharmacy permits, if applicable.
- 25) Address the maintenance of patient profiles and the offer to counsel if dispensing to outpatients.
- 26) Describe the system for the maintenance of compounding records.

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



# SPECIAL STERILE COMPOUNDING PERMIT APPLICATION AND INFORMATION

September 2017

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 in approximately 7-14 days if any materials are incomplete.

If you need to communicate with the board staff, you are encouraged to email the board staff at <a href="MQA.Pharmacy@flhealth.gov">MQA.Pharmacy@flhealth.gov</a>, 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

#### **Special Pharmacy Permit Application Information**

A special sterile compounding permit is a type of special permit, which is required before any permitted pharmacy may engage in the preparation of compounding sterile products. The compounding of sterile products must be in strict compliance with the standards set forth in rules 64B16-27.797 and 64B16-27.700.

All permitees, with the exception of stand alone Special Parenteral/Enteral and Special Parenteral/Enteral Extended Scope, that are currently compounding sterile products are required to submit this application and will be issued a new Special Sterile Compounding permit number (in addition to your usual pharmacy permit).

This permit is not required for those that hold an individual Special Parenteral & Enteral Pharmacy permit or a Special Parenteral & Enteral Extended Scope permit.

Non-Resident pharmacies are not required to obtain this permit at this time.

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) or Consultant Pharmacist of Record.

Chapter 465, F.S., requires Special Pharmacies to be under the professional supervision of the PDM or Consultant Pharmacist of Record licensed in the State of Florida. A Florida licensed pharmacist shall perform compounding and dispensing of medicinal drugs.

Community/Special Parenteral & Enteral, and Special Closed/ Parenteral & Enteral permit holders are required to submit this application and will be issued a new Special Sterile Compounding permit number.

#### **Sterile Compounding Pharmacy Permit Frequently Asked Questions**

- **Q.** Who is required to apply for the new permit?
- **A**. All permitees, with the exception of stand alone Special Parenteral/Enteral and Special Parenteral/Enteral Extended Scope, that are currently compounding sterile products are required to submit this application and will be issued a new Special Sterile Compounding permit number (in addition to your existing pharmacy permit).
- **Q.** What is the fee for the Sterile Compounding Pharmacy permit?
- **A.** There will be no fee required for existing licensees. New establishments are required to submit \$255.00 with the application.
- **Q.** Are existing Special P & E or Extended Scope P & E licensees required to apply for the Sterile Compounding Pharmacy permit?
- **A.** No, these types of pharmacy permits will continue to operate with their existing permit number.
- **Q.** Will a new license number be issued to the pharmacy?
- **A.** Yes, a new license number will be issued for the Sterile Pharmacy Compounding permit.
- Q. Will a background check be required to obtain a Sterile Compounding Pharmacy permit?
- **A.** Fingerprints are not required for existing licensees, however new establishments will be required to submit fingerprints via Live Scan pursuant to Chapter 465.022 Florida Statues
- **Q**. Is a separate pharmacy manager required for the new permit?
- **A.** No, the existing pharmacy manager will be listed as PDM for both permits.
- **Q.** Is an inspection required in order for the permit to be issued?
- **A.** Yes, an inspector will contact you to set up an inspection date. Upon completion of a passing inspection, a new permit number will be issued.
- Q. Will I need a new DEA permit for this license?
- **A.** For information regarding DEA registration please contact the DEA at 1-800-667-9752 or 954-306-4654. You may also visit the DEA website at <a href="http://www.DEAdiversion.usdoj.gov">http://www.DEAdiversion.usdoj.gov</a>

#### **Application Processing**

Please read all application instructions before completing your application.

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 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

\* There is no fee required for existing pharmacies that are currently engaged in the preparation of sterile products from a period of 180 days of adoption of Rule 64B16-28.100, F.A.C.

Within 7-14 days of receipt of your application and fees, the board office will notify you of the receipt of your application, any required documents, and your status. If the application is complete, you will be notified that an inspector will contact you to setup an inspection appointment. Please do not contact the board office concerning your inspection date, and allow 30 days for the inspector to contact you. If the inspector has not contacted you within 30 days, then notify the board. If your application is incomplete, you will be notified in writing of what is required to make your application complete.

2) Submit fingerprint results- For new establishments only.

New Applicants - 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 fingerprints were previously submitted to DOH they are not required to submit them again.

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.flhealthsource.gov/background-screening select Apply for a License, select Pharmacy Permit Information, select Livescan vendor list.

- 2. What information must I provide to the Livescan vendor I choose?
  a) If you are an applicant seeking a license for any profession regulated by the Department of Health, which requires a criminal background search as a condition of licensure, you must provide accurate demographic information at the time your fingerprints are taken, including your Social Security number. The Department will not be able to process a submission that does not include your Social Security number.
  - b) You must provide the correct ORI number.
- 3. Where do I get the ORI number to submit to the vendor?

The ORI number for the pharmacy profession is EDOH4680Z

3) Attestation for Business Taxable Assets- For new establishments only.

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 attesting 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).

#### **<u>Licensure Process-</u>** For new establishments only.

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 15 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/mga 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.

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 <a href="http://www.DEAdiversion.usdoj.gov">http://www.DEAdiversion.usdoj.gov</a>. DEA Form 224 may be obtained in paper form by writing to:

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

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

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

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

#### PRE-INSPECTION CHECKLIST

You may download a copy of the inspection form from the website at:

http://www.floridahealth.gov/licensing-and-regulation/enforcement/inspection-program/inspection-forms.html

#### 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> Faxed applications will not be accepted.

 Application completed (all questions answered)
 Application signed
 Consultant Pharmacist of Record/Prescription Department Manager Listed with Signature
 \$255.00 Fee Attached (Fee required for new establishments only)
 Copy of Articles of Incorporation from the Secretary of State's Office
 Fingerprints have been submitted via live scan for all officers and owners and the prescription department manager or consultant pharmacist of record. (Required for new establishments)
 Attach proof from AHCA of fingerprint results if applicable for prescription department manager or consultant pharmacist of record.
 Attestation for Business Taxable Assets of \$100 million if applicable
 Bill of Sale is required for Change of Ownership

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.



#### FLORIDA BOARD OF PHARMACY

P.O. Box 6320 Tallahassee, FL 32314-6320 Telephone (850) 488-0595 http://www.floridaspharmacy.gov



#### **APPLICATION**

Application Type - Please choo	se one of the fol	llowing:	
New Establishment (\$255 fee)		Change of Location \$100 fee	
Change of Ownership (\$255	fee)	Stock Tra	insfer (no fee)
		1	
Please List your Federal Employer	Identification Nu	mber:	
1. Corporate Name			Telephone Number
2. Doing Business As (d/b/a)			E-Mail Address
3. Mailing Address			
City	State		Zip
•			•
4. Physical Address			
City	State		Zip
5. List Prescription Department	t Manager (PDM)	) or Consultant	Pharmacist of Record
Name		License Number	
Email		Telephone Number	
6. Contact Person		Telephone Number	
or comact rollon.		Totophono itali	
7. DEA Registration Number			

Prescription Department Hours  Monday-Friday: Open Close: Saturday: Open: Close: Sunday: Open: Close:  9. Ownership Information  a. Type of Ownership:Individual Corporation Partnership  NOTE: If the applicant is a 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				
Saturday: Open: Close: Sunday: Open: Close:  9. Ownership Information  a. Type of Ownership:Individual Corporation Partnership  NOTE: If the applicant is a 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				
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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				
	<u> </u>			
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). If no, continue to 12d.	(			
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 9c. If 9c is yes, please list the owners below and only submit fingerprints for the Prescription Department Manager or Consultant Pharmacist of Record. If 9c 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 Ownersh	qiı			
	%			
1 1	%			
	%			
10. Has anyone listed in 9.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 If yes, please provide a signed affidavit disclosing the reason the entity was clos	ed.			
11. Has anyone listed in 10.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?				
other business permit which was voluntarily relinquished or closed voluntarily within the past	5			
other business permit which was voluntarily relinquished or closed voluntarily within the past				
other business permit which was voluntarily relinquished or closed voluntarily within the past years?	ed.			

being asked. If you an providing accurate det 13. Has the applicant of the application, a felony adjudication, a felony of the application, a felony of the application of the appli	nswer yes to any tails and submit or any principal, or entended of, or entended under Chapter 40	of the following questions, explain on a separate sheet copies of supporting documentation. officer, agent, managing employee, or affiliated person of ered a plea of guilty or nolo contendere to, regardless of 09, Chapter 817, or Chapter 893, Florida Statutes; or a or jurisdiction since July 1, 2009? (If yes, provide court
documents concerning		
Yes		
date of the plea, sente	ence and complet	he third degree, has it been more than 10 years from the tion of any subsequent probation? (This question does a under Section 893.13(6)(a), Florida Statutes).
Yes No	0	
	nore than 5 years	he third degree under Section 893.13(6)(a), Florida from the date of the plea, sentence and completion of
Yes N	lo	
affiliated person of the	applicant succe offense being wi	any principal, officer, agent, managing employee, or essfully completed a drug court program that resulted in thdrawn or the charges dismissed? (If "yes", please
Yes	No	
of the applicant been of	convicted of, or e	officer, agent, managing employee, or affiliated person entered a plea of guilty or nolo contendere to, regardless S.C. ss.801-970 or 42 U.S.C. ss. 1395-1396 since July 1,
Yes	No	(If yes, explain on a separate sheet providing accurate details)
		an 15 years before the date of application since the for probation for such conviction or plea ended?
Yes	No	
	een terminated f	officer, agent, managing employee, or affiliated person or cause from the Florida Medicaid Program pursuant to
	la Statutes? (If r	10, do not answer 18.)
Yes		
16. If the applicant or	No any principal, off n terminated, has	(If yes, explain on a separate sheet providing accurate details)  ficer, agent, managing employee, or affiliated person of the applicant been reinstated and in good standing with

	nated for cause, pursuant to the a ral government, from any other st	appeals procedures
Yes No		, ,
18. Has the applicant been in go Medicare program for the most r	ood standing with a state Medicai recent five years?	d program or the federal
Voo No	(If yes, explain on a separate sh	neet providing accurate details)
Yes No	least 20 years prior to the date o	f this application?
19. Did the termination occur at	(If yes, explain on a separate sh	
Yes No		ioot promaing account accame)
	ipal, officer, agent, managing em d States Department of Health Hu uded Individuals and Entities?	
Yes No	(If yes, submit proof)	
Enforcement regarding sharing,	ad the statement from the Florida retention, privacy and right to ch / Statement" document from the l 3 of this application.)	nallenge incorrect criminal
Yes No		
22. Are you currently registered	l or permitted in any other states for each permit. <i>Attach a separa</i>	
Yes No		
State	Permit Type	Permit Number
Pharmacist of Record ever owner	persons, partners, officer, directored a pharmacy? If yes, provide the ated and the status of the pharma	ne name of the pharmacy, the
Yes No	(If yes, please list them belo	w, you may provide additional sheet)
Pharmacy Name	State	Status

24. Has any disciplinary action ever been taken against any license, permit or registration issued to the applicant, affiliated persons, partners, officers, directors or Consultant Pharmacist of Record in this state or any other?
Yes No (If yes, explain on a separate sheet providing accurate details and submit documentation from the licensing agency who took the disciplinary action)
25. Has the applicant, or any officer, member or partner ever been convicted of a felony or misdemeanor, excluding minor traffic convictions?
Yes (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.)
26. Is there any other permit issued by the Department of Health located at the physical location address on this application?
Yes No (If yes, explain on a separate sheet providing accurate details)
27. 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 29a.
Yes No (If yes, explain on a separate sheet providing accurate details)
28a. Does the applicant, affiliated person, partner, officer, director have a repayment plan approved by the department?
Yes No
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?
Yes No
30. Will the Pharmacy dispense Schedule II and/or II controlled substances?

#### 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 thing, in connection with an application for a license or permit, as set forth in Section 465.015(2)(a), F.S.

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

SIGNATURE		TITLE	DATE	
	Owner/Officer		<del></del>	

#### 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 11C-8.001, 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

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

Name:	
Aliases:	
Address:	Apt. Number:
City:	State:Zip Code:
Date of Birth://(MM/DD/YYYY)	Place 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 So	Scan Service provider.)

#### Keep this form for your records.



# Item #1- PDM or Consultant 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 info@floridaspharmacy.gov

File #: (if known):				
Lic	ense #: (if applicable):			

Section A. PDM or Co	nsultant of Record			
Applicant/Pharmacy Nai	ne:			
Applicant/Pharmacy Ma	iling Address:			
City	State	Zip		
Incoming PDM/Consultant Name:		License#:		
		PS		
Date Beginning as PDM/Consultant:	Incoming PDM/Consultant Signature			
PDM/Consultant Transac	tion Control Number (TCN) - related	I to Livescan Fingerprints:		
***Only provide following information is there is an Outgoing PDM at current pharmacy location.***				
Outgoing PDM/Consulta	nt Name:	License#:		
		PS		
Date Ending as PDM/Consultant:				
Section B. Incoming	PDM Privacy Statement Acknowledge	owledgement		
Note: Acknowledgment shoul	d be completed by same person listed in <u>Sec</u>	tion A above as Incoming PDM.		
regarding the sharing, reter	ead the statement from the Florida Depart nation, privacy and right to challenge inco on document from the Federal Bureau of In	rect criminal history records		
Date:	Incoming PDM/Consultant Signa	Incoming PDM/Consultant Signature		



# <u>Item #2- Affiliate/Owner Privacy Statement Acknowledgement</u>

# 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 MQA.Pharmacy@flhealth.gov

From:

Affiliate / Owner Name:	File # (required):			
Applicant Name:				
Affiliate/Owner Mailing Address:				
City	State	Zip		
Affiliate/Owner Email	Affiliate/Owner Telephone Number			
Affiliate/Owner Transaction Control Number (TCN) – related to Livescan Fingerprints				
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 signat	ture)		



#### Item #3 - Policy and Procedure Questions

#### All Applicants Must Complete the Following Questions.

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

List the following:
Firm Name:
Doing business as (d/b/a):
Telephone number:
Address:
Permit number:

- 1) Explain the practice setting of the proposed facility.
- 2) What are the objectives and purpose of the permittee? Give detailed explanation of the services of the facility scope and practice.
- 3) What are the experience, qualifications, special education, and/or training of the compounding pharmacist? Please provide a resume.
- 4) What is the ratio of supportive personnel to each pharmacist? How will the supportive personnel be utilized? Include a job description for any such supportive personnel.
- 5) What categories of parenteral/enteral products will be prepared (i.e. IV, enteral, irrigating, and oncology products)? Include sample labels.
- What is the policy regarding the delivery of parenteral/enteral products to the patient? Describe methods used and trace the path the product takes from the time it leaves the permittee until it reaches the patient. Describe how products are protected from extreme temperature conditions.
- 7) Address the policy and procedure, special equipment and special techniques to dispense sterile preparations for parenteral therapy/nutrition. If this type of dispensing will not be performed, please state so accordingly.
- 8) What are the policy and procedure, special equipment and special techniques to dispense sterile jejunostomy feeding/sterile irrigation solutions? If this type of dispensing will not be performed, please state so accordingly.

- What is the policy and procedure, special equipment and special techniques to dispense cytotoxic or anti-neoplastic agents. If this type of dispensing will not be performed, please state so accordingly.
- 10) What is the procedure for the annual review and updating of the policy and procedure manual?
- 11) Include the layout/floor plan of the pharmacy. The drawing must include the dimensions of the clean room and the pharmacy, location of the hood, sink, and other equipment. The drawing must also show the location of the clean room relative to other pharmacy and storage areas.
- 12) Include a sample copy of a patient profile.
- 13) What aseptic techniques are utilized?
- 14) Describe the Quality Assurance Program.
- 15) Describe with detail the policy and procedure for patient education, including the personnel involved.
- 16) What are the policy and procedures for handling waste and returns?
- 17) Describe the type of certified laminar flow hood(s) to be used and the frequency of certification.
- 18) Describe the refrigerator/freezer to be used.
- 19) Describe appropriate waste containers for:
  - a. Used needles and syringes.
  - b. Cytotoxic waste including disposable apparel used in preparation.
- 20) Address the following supplies to be used: gloves, mask, gowns, needles, syringes, disinfectant cleaning agents, clean towels, hand-washing materials with bactericidal properties, vacuum containers/transfer sets, and spill kits for cytotoxic agent spills.
- 21) How will you utilize the following reference material to ensure patient safety?
  - a. Chapters 465 and 893, F.S., and Rule Title 64B16, F.A.C.
  - b. Authoritative Therapeutic Reference.
  - c. Handbook of Injectable Drugs by American Society of Health-System Pharmacists.
- What steps will be taken to ensure safe handling of cytotoxi drugs related to the Occupational Safety and Health Administration guidelines.
- Describe the individual responsibilities of the Special- Parenteral/Enteral Extended Scope Permit and the supplied institutional pharmacy permits, if applicable.
- 24) What are the protocols for the maintenance of patient profiles and the offer to counsel if dispensing to outpatients?
- 25) Describe the system for the maintenance of compounding records.
- 26) What percentage of your business is related to sterile compounding?
- Describe the types of sterile products you will compound.
- 28) Are the products you will be compounding:
  - a. be pursuant to a patient-specific prescription

- b. be prepared in bulk (compounding multiple doses from a single source or batch)
- c. be prepared in bulk for office use.
- 30) Will your pharmacy ship sterile compounded products to other states? If yes, provide a list of states to which your pharmacy will ship.
- 31) Provide the total number of pharmacy staff and indicate how many will be preparing sterile products;
  - a. Pharmacists
  - b. Pharmacy Interns
  - c. Pharmacy Technicians
- 32) Provide the number of clean rooms in your pharmacy.
- 33) Provide the number of laminar flow hoods in your pharmacy.
- When was the last time your clean room was certified by an independent contractor for National Sanitation Foundation Standard 49? Provide a copy of the most recent inspection and the name and address of the independent contractor.
- 35) When was the last time your laminar flow hood was certified by an independent contractor for National Sanitation Foundation Standard 49? Provide a copy of the most recent inspection and the name and address of the independent contractor.
- 36) Has your company ever recalled a sterile compounded product due to a compounding error? If yes, list the name (s) of the drug and the reason for the recall.

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



## SPECIAL STERILE COMPOUNDING PERMIT APPLICATION AND INFORMATION

May 2013 September 2017

DH-MQA 1270, 5/13 Rule 64B16-28.100 F.A.C. Dear Florida Pharmacy Permit Applicant,

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

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

When your application arrives, your fees will be deposited and verified before the staff review can begin. You will receive a letter acknowledging receipt of your application. The staff will notify you in approximately 7-14 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@fihealth.gov\_MQA\_Pharmacy@doh.state.fl.us, or you may at call us at (850) 245-4292. Phone calls are returned within 24 hours and emails are responded to within 48 hours during normal business hours. Our staff is committed to providing prompt and reliable information to our customers. Many procedures have been streamlined to expedite the processing of applications; we certainly welcome your comments on how our services may be improved.

Sincerely,

The Board of Pharmacy

DH-MQA 1270, 5/13 Rule 64B16-28.100 F.A.C.

#### **Special Pharmacy Permit Application Information**

A special sterile compounding permit is a type of special permit, which is required before any permitted pharmacy may engage in the preparation of compounding sterile products. The compounding of sterile products must be in strict compliance with the standards set forth in rules 64B16-27.797 and 64B16-27.700.

All permitees, with the exception of stand alone Special Parenteral/Enteral and Special Parenteral/Enteral Extended Scope, that are currently compounding sterile products are required to submit this application and will be issued a new Special Sterile Compounding permit number (in addition to your usual pharmacy permit).

This permit is not required for those that hold an individual Special Parenteral & Enteral Pharmacy permit or a Special Parenteral & Enteral Extended Scope permit.

Non-Resident pharmacies are not required to obtain this permit at this time.

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) or Consultant Pharmacist of Record.

Chapter 465, F.S., requires Special Pharmacies to be under the professional supervision of the PDM or Consultant Pharmacist of Record licensed in the State of Florida. A Florida licensed pharmacist shall perform compounding and dispensing of medicinal drugs.

Community/Special Parenteral & Enteral, and Special Closed/ Parenteral & Enteral permit holders are required to submit this application and will be issued a new Special Sterile Compounding permit number.

#### Sterile Compounding Pharmacy Permit Frequently Asked Questions

- Q. Who is required to apply for the new permit?
- **A.** All permitees, with the exception of stand alone Special Parenteral/Enteral and Special Parenteral/Enteral Extended Scope, that are currently compounding sterile products are required to submit this application and will be issued a new Special Sterile Compounding permit number (in addition to your existing pharmacy permit).
- Q. What is the fee for the Sterile Compounding Pharmacy permit?
- **A.** There will be no fee required for existing licensees. New establishments are required to submit \$255.00 with the application.
- **Q.** Are existing Special P & E or Extended Scope P & E licensees required to apply for the Sterile Compounding Pharmacy permit?
- **A.** No, these types of pharmacy permits will continue to operate with their existing permit number.
- Q. Will a new license number be issued to the pharmacy?
- A. Yes, a new license number will be issued for the Sterile Pharmacy Compounding permit.
- Q. Will a background check be required to obtain a Sterile Compounding Pharmacy permit?
- **A.** Fingerprints are not required for existing licensees, however new establishments will be required to submit fingerprints via Live Scan pursuant to <a href="Chapter 465.022 Florida Statues">Chapter 465.022 Florida Statues</a>
- Q. Is a separate pharmacy manager required for the new permit?
- A. No, the existing pharmacy manager will be listed as PDM for both permits.
- Q. Is an inspection required in order for the permit to be issued?
- **A.** Yes, an inspector will contact you to set up an inspection date. Upon completion of a passing inspection, a new permit number will be issued.
- Q. Will I need a new DEA permit for this license?
- **A.** For information regarding DEA registration please contact the DEA at 1-800-667-9752 or 954-306-4654. You may also visit the DEA website at http://www.DEAdiversion.usdoj.gov

#### **Application Processing**

Please read all application instructions before completing your application.

Please mail the application and the \$255.00 application fee (check or moneystorder 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

\* There is no fee required for existing pharmacies that are currently engaged in the preparation of sterile products from a period of 180 days of adoption of Rule 64B16-28.100, F.A.C.

Within 7-14 days of receipt of your application and fees, the board office will notify you of the receipt of your application, any required documents, and your status. If the application is complete, you will be notified that an inspector will contact you to setup an inspection appointment. Please do not contact the board office concerning your inspection date, and allow 30 days for the inspector to contact you. If the inspector has not contacted you within 30 days, then notify the board. If your application is incomplete, you will be notified in writing of what is required to make your application complete.

\_\_\_\_\_2) Submit fingerprint results- For new establishments only.

New Applicants - 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 fingerprints were previously submitted to DOH they are not required to submit them again.

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.

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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 <a href="https://www.deh.state.fl.us/mga/pharmacy">www.deh.state.fl.us/mga/pharmacy</a>.
<a href="https://www.flhealthsource.gov/background-screening-relect Apply">www.flhealthsource.gov/background-screening-relect Apply for a License, select Pharmacy Permit Information, select Livescan vendor list.</a>

- 2. What information must I provide to the Livescan vendor I choose?
  a) If you are an applicant seeking a license for any profession regulated by the Department of Health, which requires a criminal background search as a condition of licensure, you must provide accurate demographic information at the time your fingerprints are taken, including your Social Security number. The Department will not be able to process a submission that does not include your Social Security number.
  - b) You must provide the correct ORI number.
- 3. Where do I get the ORI number to submit to the vendor?

The ORI number for the pharmacy profession is EDOH4680Z

\_\_\_\_3) \_\_Attestation for Business Taxable Assets- For new-establishments only.

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 attesting 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).

#### All Applicants Must Complete the Following Questions.

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

List the following:
Firm Name:
Doing business as (d/b/a):
Telephone number:
Address:
Permit number:

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- 1) Explain the practice setting of the proposed facility.
- 2) What are the objectives and purpose of the permittee? Give detailed explanation of the services of the facility scope and practice.
- What are the experience, qualifications, special education, and/or training of the compounding pharmacist? Please provide a resume.
- 4) What is the ratio of supportive personnel to each pharmacist? How will the supportive personnel be utilized? Include a job description for any such supportive personnel.
- What categories of parenteral/enteral products will be prepared (i.e. IV, enteral, irrigating, and encology products)? Include sample labels.
- 6) What is the policy regarding the delivery of parenteral/enteral products to the patient? Describe methods used and trace the path the product takes from the time it leaves the permittee until it reaches the patient. Describe how products are protected from extreme temperature conditions.
- Address the policy and procedure, special equipment and special techniques to dispense sterile preparations for parenteral therapy/nutrition. If this type of dispensing will not be performed, please state so accordingly.
- 8) What are the policy and procedure, special equipment and special techniques to dispense sterile jejunostomy feeding/sterile irrigation solutions? If this type of dispensing will not be performed, please state so accordingly.
- What is the policy and procedure, special equipment and special techniques to dispense cytotoxic or anti-neoplastic agents. If this type of dispensing will not be performed, please state so accordingly.
- 40) What is the procedure for the annual review and updating of the policy and procedure manual?
- 11) Include the layout/floor plan of the pharmacy. The drawing must include the dimensions of the clean room and the pharmacy, location of the hood, sink, and other equipment. The drawing must also show the location of the clean room relative to other pharmacy and storage areas.
- 12) Include a sample copy of a patient profile.
- 13) What aseptic techniques are utilized?
- 14) Describe the Quality Assurance Program.
- 15) Describe with detail the policy and procedure for patient education, including the personnel involved.
- 16) What are the policy and procedures for handling waste and returns?
- 17) Describe the type of certified laminar flow hood(s) to be used and the frequency of certification.
- 18) Describe the refrigerator/freezer to be used.
- 19) Describe appropriate waste containers for:
  - a. Used needles and syringes.
  - b. Cytotoxic waste including disposable apparel used in preparation.
- 20) Address the following supplies to be used: gleves, mask, gewns, needles, syringes, disinfectant cleaning agents, clean towels, hand washing materials with

- bactericidal properties, vacuum containers/transfer sets, and spill kits for cytotoxic agent spills.
- 21) How will you utilize the following reference material to ensure patient safety?
  - a. Chapters 465 and 893, F.S., and Rule Title 64B16, F.A.C.
  - b. Authoritative Therapeutic Reference.
  - c. Handbook of Injectable Drugs by American Society of Health-System
    Pharmacists
- 22) What steps will be taken to ensure safe handling of cytotoxi drugs related to the Occupational Safety and Health Administration guidelines.
- 23) Describe the individual responsibilities of the Special- Parenteral/Enteral Extended Scope Permit and the supplied institutional pharmacy permits, if applicable.
- 24) What are the protocols for the maintenance of patient profiles and the offer to counsel if dispensing to outpatients?
- 25) Describe the system for the maintenance of compounding records.
- 26) What percentage of your business is related to sterile compounding?
- 27) Describe the types of sterile products you will compound.
- 28) Are the products you will be compounding:
  - a. be pursuant to a patient-specific prescription
  - b. be prepared in bulk (compounding multiple doses from a single source or batch)
  - c. be prepared in bulk for office use.
- 30) Will your pharmacy ship sterile compounded products to other states?

If yes, provide a list of states to which your pharmacy will ship.

- 31) Provide the total number of pharmacy staff and indicate how many will be preparing sterile products;
- ----a. Pharmacists
  - b. Pharmacy Interns
- c. Pharmacy Technicians
- 32) Provide the number of clean rooms in your pharmacy.
- 33) Provide the number of laminar flow hoods in your pharmacy.
- 34) When was the last time your clean room was certified by an independent contractor for National Sanitation Foundation Standard 49? Provide a copy of the most recent inspection and the name and address of the independent contractor.
- 35) When was the last time your laminar flow hood was certified by an independent contractor for National Sanitation Foundation Standard 49? Provide a copy of the most recent inspection and the name and address of the independent contractor.
- 36) Has your company ever recalled a sterile compounded product due to a compounding error? If yes, list the name (s) of the drug and the reason for the recall.

Licensure Process- For new establishments only.

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 15 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/mga 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.

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 <a href="http://www.DEAdiversion.usdoj.gov">http://www.DEAdiversion.usdoj.gov</a>. DEA Form 224 may be obtained in paper form by writing to:

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

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

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

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

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## PRE-INSPECTION CHECKLIST FOR NEW ESTABLISHMENTS

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, Is the pharmacy department equipped an area suitable for private patient counseling if applying for a community pharmacy permit pursuant to Rule 64B16-28.1035, F.A.C.? Are all required signs displayed? • 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. 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: Formatted: Indent: Left: 0", First line: 0" http://doh.state.fl.us/mga/enforcement/enforce\_forms.html Field Code Changed http://www.floridahealth.gov/licensing-and-regulation/enforcement/inspection-Field Code Changed program/inspection-forms.html PHARMACY PERMIT APPLICATION CHECKLIST Formatted: Font: 14 pt 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. Faxed applications will not be accepted.

**Application completed (all questions answered)** 

Application signed
Consultant Pharmacist of Record/Prescription Department Manager Listed with Signature
\$255.00 Fee Attached (Fee required for new establishments only)
Copy of Articles of Incorporation from the Secretary of State's Office
Fingerprints have been submitted via live scan for all officers and owners and the prescription department manager or consultant pharmacist of record. (Required for new establishments)
Attach proof from AHCA of fingerprint results if applicable for prescription department manager or consultant pharmacist of record.
Attestation for Business Taxable Assets of \$100 million if applicable
Bill of Sale is required for Change of Ownership

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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

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#### 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. <u>465.003(14)</u> or s. <u>893.02</u> 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.

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#### FLORIDA BOARD OF PHARMACY

P.O. Box 6320 Tallahassee, FL 32314-6320 Telephone (850) 488-0595 http://www.floridaspharmacy.gov



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#### STERILE COMPOUNDING PHARMACY PERMIT APPLICATION

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Application Type - Please choose one of the Change			of Location \$100 fee	
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	Now Establishment (\$255 fee)	,	of Ownership (a new permit number	Formatted: Font: 9 pt
-	New Establishment (\$255 fee)	be issued) \$25		
	Change of Ownership (\$255 fee)	<del>pe issued) ⊕∠3</del>		
į	Existing Permit (No Fee Required)	compounding pr	dimit number)	Formatted: Right: 0", Space After: 2 pt, Line spacing: At
	Existing Permit Number	Stock T	ransfer (no fee)	least 1.5 pt, Tab stops: Not at 0.55" + 3.63"
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ļ	lease List your Federal Employer Identification			
4	Vill the Pharmacy Dispense Schedule II and		Substances?YesNo	
Į	Please list your Federal Employer Identifica	<del>ition</del>		
į	<del>lumber</del>			
•	. Corporate Name		Telephone Number	
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6. Contact Person	Telephone Number	or .		
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7. DEA Registration Number	8. Date ready for	inspection (mus	st he within 90	
. DEA Registration Number	days of the date o			
<ol> <li>Please provide the name, address prescription drug wholesale distribute</li> </ol>				
Name	Telephone Number			
Street Address	City	State	7in	
street Address	City	<del>State</del>	<del>Zip</del>	
10. Pharmacy Technician Ratio 2:1 or				
Rule 64B16-27.410, Florida Administrativ				<del>) f</del>
consultant pharmacist of record is require approval from the Board of Pharmacy price.				
than one registered pharmacy technician				
Technician 2:1 or 3:1 ratio, you may do s				
ption below serves as your written reque				L .
<del>atio.</del>				
2:1 Ratio	3:1 Ratio			
please attach a brief description of the w	orkflow needs that include the			
harmacy, number of pharmacist, registe	red interns and registered ph	armacy technicia	<del>ins employed to</del>	•
ustify the ratio request) 3.911. Operating Hours	11a Prov	ride Toll-Free Te	lonhono	_
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rescription Department Hours				
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102. Ownership Information				
a Type of Oyunarakiny Individual	Corporation			
a. Type of Ownership: Individual	·	<u>artnership</u>		
OTE: If the applicant is a corporation or limit	ed partnership you must include	with your applicat	ion a copy of the	

Aı			retary of State's office.a. Type of Ownership:				
IndividualCorporationPartnership							
Ť		ther:					
			TNERSHIP YOU MUST INCLUDE WITH YOU		DA		
	ECRETARY OF STATE'S O		OF INCORPORATION ON FILE WITH THE F	<u>-URI</u>	<del>DA</del>		
			sevel aldere members and nertners ever the		~6		
	. Are the applicants, officers	s, directors, sn	areholders, members and partners over the	age	OI		
Т	es No						
C.	Does the corporation have	more than \$10	00 million of business taxable assets in this	state	e?		
	-		If yes, provide attestation from Certified Public Accountant for				
ľ	es No		year or Florida Corporate Income/Franchise and Emergency E Return (F-1120). If no, continue to 12d.				
d	L List all the owners and c		orporation. Each person listed below havir	ng an			
			and any person who, directly or indirectly, n				
			pplicant including officers and members of				
			gerprints and fees unless you answered yes				
			and only submit fingerprints for the Prescri				
			Board of Pharmacy the requirement to sub-				
	rints for this person is met.						
	Owner/Officer-Title	Date of Birth	Mailing Address, City State, Zip Code		of ership		
		1 1		OWII	%		
		1 1			%		
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			ownership interest of 5% or more in a pharn				
		hich was disci <sub>l</sub>	plined, suspended, revoked, or closed invol	unta	rily		
W	ithin the past 5 years?						
Ψ	es No		If yes, please provide a signed affidavit disclosing the reason the er	ntity was	closed:		
1			ii yes, piease provide a signed amdavit disclosing the reason the er	ility was	cioseu.		
1:	123.a Has anyone listed in	1 <u>0</u> 2.d had an o	ownership interest of 5% or more in a pharn	nacy	or		
		hich was volur	ntarily relinquished or closed voluntarily wit	hin t	he		
pa	ast 5 years?						
Y	es No		If yes, please provide a signed affidavit disclosing the reason the en	ntity was	closed.		
1:	234. Has anyone listed in 9	12.d ever obtai	ined a pharmacy permit by misrepresentation	on or			
			ea of guilty or nolo contender to, regardless				
			ich relates to health care fraud?				
Y	es No _		If yes, please provide documents concerning this conviction.				
Ť			, , ,				
P	Pursuant to Section 456.0635(2) and 465.022(5), Florida Statutes, questions 145 through 23 are						
b	eing asked. If you answer y	es to any of th	ne following questions, explain on a separat				
þ	roviding accurate details ar	nd submit copi	es of supporting documentation.				

1345. 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 in another state or jurisdiction since July 1, 2009? (If yes, provide court documents concerning this conviction)	
Yes No	
1345a. If "yes" to 1345, 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	
1345b. If "yes" to 1345, 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	
1345c. If "yes" to 1345, 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).	
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Yes No	
1456. 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)	
1456a. If "yes" to 1456, has it been more than 15 years before the date of application since the sentence and any subsequent period of probation for such conviction or plea ended?	
Yes No	
1567. 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 \$ection 409.913, Florida Statutes? (If no, do not answer 189.)	
(If yes, explain on a separate sheet providing accurate details) Yes No	
1678. 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?	

No.	(If yes, explain on a separate	sheet providing accurate details)						
Yes No  1789. 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 201 and 212)								
Yes No	(If yes, explain on a separate	sheet providing accurate details)						
18920. Has the applicant been i Medicare program for the most	n good standing with a state Merecent five years?	edicaid program or the fede	ral					
		sheet providing accurate details)						
Yes No								
192024. Did the termination occ	cur at least 20 years prior to the	• • •						
Yes No	(ii yes, expiain on a separate	sheet providing accurate details)						
2042. Is the applicant or any pri of the applicant listed on the Un Inspector General's List of Excl	ited States Department of Healt							
	(If yes, submit proof)	orida Department of Law						
2123. I have been provided and read the statement from the Florida Department of Law Enforcement regarding sharing, retention, privacy and right to challenge incorrect criminal history records and the "Privacy Statement" document from the Federal Bureau of Investigation. (Found on Page 8 of this application.)								
Yes No								
2234. Are you currently register permit type, and permit number	ite,							
Yes No								
State	Permit Type	Permit Number						
2345. Has the applicant, affiliate Pharmacist of Record ever own state where the pharmacy is locarecessary	ed a pharmacy? If yes, provide	the name of the pharmacy,	the					
necessary.								
Yes No	(If yes, please list them be	elow, you may provide additional sheet						
Pharmacy Name	State	Status						
DH-MQA, 1270, <u>10/17</u> 0 <del>5/13</del>	Page 5 <del>-of 10</del>	_1						

2456. Has any disciplinary action ever been taken against any license, perm issued to the applicant, affiliated persons, partners, officers, directors or Co	
Pharmacist of Record in this state or any other?	Distillant
Yes No (If yes, explain on a separate sheet providing	g accurate details and submit
l documentation from the licensing agency who took the disciplinary action)	
2567. Has the applicant, or any officer, member or partner ever been convic	cted of a felony or
misdemeanor, excluding minor traffic convictions?	
Yes (You must include all misdemear adjudication was withheld by the court, so that you would not have a record of conviction. Driving under the i	
impaired is <u>NOT</u> a minor traffic offense for the purposes of this question.)	influence or driving while
· - · · · · · · · · · · · · · · · · · ·	
2678. Is there any other permit issued by the Department of Health located a location address on this application?	at the physical
Yes No (If yes, explain on a separate sheet providing accurate	e details)
2789. Does the applicant, affiliated person, partner, officer, director have any	y outstanding fines,
liens or overpayments assessed by a final order of the department? If yes,	please answer 29a.
Yes No (If yes, explain on a separate sheet providing accurate	e details)
18a29a. Does the applicant, affiliated person, partner, officer, director have a approved by the department?	a repayment plan
Yes No	
1930. Is the policy and procedure manual for preventing controlled substan	nce dispensing
based on fraudulent representation or invalid practitioner-patient relationsh	nip available for
inspection by DOH?	
ves No	
Yes No  30. Will the Pharmacy dispense Schedule II and/or II controlled substances?	Formatted: Font: 12 pt, Bold

# 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. Ilcertify 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 Permiteist's license may be revoked or suspended for presenting any false, fraudulent, or forged statement, certificate, diploma, or other thing, in connection with an application for a license or permit, as set forth in Section 465.015(2)(a), F.S. Under penalty of perjury I have read the foregoing document and that the facts stated in it are true. I recognize that providing false information may result in disciplinary action against my license or criminal penalties.

\_\_\_\_\_DATE\_\_\_\_

SIGNATURE \_\_\_\_

Owner/Officer

#### **PHARMACY PERMIT APPLICATION CHECKLIST**

Keep a copy of the completed application for your records.

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

Application completed (all questions answered)
Application signed
Consultant Pharmacist of Record/Prescription Department Manager Listed with Signature
\$255.00 Fee Attached (Fee required for new establishments only)
Copy of Articles of Incorporation from the Secretary of State's Office
Fingerprints have been submitted via live scan for all officers and
pharmacist of record. (Required for new establishments)
Attach proof from AHCA of fingerprint results if applicable for
prescription department manager or consultant
pharmacist of record.
Attestation for Business Taxable Assets of \$100 million if applicable
Bill of Sale is required for Change of Ownership

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

Name:	Soci	al Security Number:
Aliases:		
Date of Birth:(MM/DD	Place of Birth:	
Citizenship:	Race:	(W-White/Latino (a); B-Black; A-Asian; NA-Native American; U-Unknown)
Sex: (M=Male; F=F	Weight:	Height:
Eye Color:	Hair Color:	
Address:		Apt. Number:
City:	State:	Zip Code:
Transaction Control No.		evided to you by the Live Scan Service provider.

Keep this form for your records.

DH-MQA, 1270, <u>10/17</u>05/13 Rule 64B16-28.100, F.A.C.

#### 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 Elduran 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 11C-8.001, 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

#### US Department of Justice, Federal Bureau of Investigation, **Criminal Justice Information Services Division**

**Privacy Statement** 

**Privacy Statement** 

Authority: The FBI's acquisition, preservation and exchange of information requested by this form is Formatted: Justified, Right: -0.31" 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

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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.

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

Name:			SSN#:	Formatted: Font: 11 pt	
Aliases:				Formatted: Font: 11 pt	
Address:			Apt. Number:	Formatted: Font: 11 pt	
City:		State:	Zip Code:	 Formatted: Font: 11 pt	
Date of Birth: (M	/ / IM/DD/YYYY)	Place of Birth:		 Formatted: Font: 11 pt	
Weight:	Height:	Eve Color:	Hair Color:		

(W-White/Latino(a); B-Black; A-Asian; (M=Male; F=Female)

NA-Native American; U-Unknown)

Citizenship:

Transaction Control Number (TCN#):

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

DH-MQA, 1270, <u>10/17</u>05/13 Rule 64B16-28.100, F.A.C.

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#### Keep this form for your records.



# Item #1- PDM or Consultant 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

File #: (if known):
l icense #: (if applicable):
Liberioe III (II applicable):
License #: (if applicable):

<u>IIIIO@IIOIIdaspiia</u>	arriacy.gov			
Section A. PDM or Con	sultant of Record	4	(	Formatted: Line spacing: Double
Applicant/Pharmacy Name				
Applicant/Pharmacy Mailin	ng Address:			
City	<u>State</u>	Zip		
Incoming PDM/Consultant	· Name:	License#:		
mooning i Dimoonsuitant	. Hame.			
		<u>PS</u>		
Date Beginning as	Incoming PDM/Consultant Signa	<u>ture</u> ←	(	Formatted Table
PDM/Consultant:				
PDM/Consultant Transaction	on Control Number (TCN) – related	to Livescan Fingerprints:	_	Formatted: Pattern: Clear (Gray-15%)
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***Only provide following info	ormation is there is an Outgoing PDM at			
Outgoing PDM/Constultan	t <del>utant </del> name.	<u>License#:</u>		
		<u>PS</u>		
<b>Date Ending as PDM/Cons</b>	s <mark>lu</mark> ltant:	4	(	Formatted Table
Outrain PDM/Ourantee	O'mat			

DH-MQA, 1270, <u>10/1705/13</u> Rule 64B16-28.100, F.A.C.

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

Section B. Incoming PDM Privacy Statement Acknowledgement

I have been provided and read the regarding the sharing, retention, and the "Privacy Statement" documents and the sharing statement of the sharing	privacy and right to challe	nge incorrect criminal history re	
Date: In	coming PDM/Consultan	t Signature	
			4 Camputed Nov
			Formatted: None
	Affiliate/Owner Prive	acy Statement	Formatted: Left, Indent: Left: 0"
ACKHOWI	eugement.		
HEALTH To be co	mpleted by EACH A	ffiliate/Owner listed in	Formatted: Left, Indent: Left: 0"
the appl	<u>Cation.</u>		
To: Florida Board of Ph Post Office Box 632			
Tallahassee, FL 323	14-6320		
(850) 245-4292- pho (850) 413-6982 - fax	<u>ne</u>		
MQA.Pharmacy@flh	ealth.gov		Formatted: Indent: First line: 0.63", Tab stops: 0.63", Lef
-			Field Code Changed
From:			Formatted: Indent: First line: 0", Tab stops: 0.63", Left
Affiliate / Owner Name:		File # (required):	Formatted: No underline
Applicant Name:			Formatted Table
Affiliate (Occurred Marilian Antology			
Affiliate/Owner Mailing Addre	<u>ss:</u>		
City	<u>State</u>	Zip	
Affiliate/Owner Email	Affiliate/Own	er Telephone Number	
			Formatted Table
Affiliate/Owner Transaction C	ontrol Number (TCN) -	related to Livescan Fingern	rinte
Annatorowici Transaction C	ontrol Number (1014)	Total Carlo El Vessail I I III ger p	Times.
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I have been provided and re	ad the statement from	the Florida Department of	Formatted: Justified, Indent: Left: 0"
Law Enforcement regarding			
challenge incorrect crimina			
document from the Federal I	sureau of investigation."		
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Affiliate/Owner Signature	(Required)	Date (of signature)	



#### Item #3 - Policy and Procedure Questions

#### All Applicants Must Complete the Following Questions.

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

List the following:
Firm Name:
Doing business as (d/b/a):
Telephone number:
Address:
Permit number:

- 1) Explain the practice setting of the proposed facility.
- What are the objectives and purpose of the permittee? Give detailed explanation of the services of the facility scope and practice.
- 3) What are the experience, qualifications, special education, and/or training of the compounding pharmacist? Please provide a resume.
- 4) What is the ratio of supportive personnel to each pharmacist? How will the supportive personnel be utilized? Include a job description for any such supportive personnel.
- 5) What categories of parenteral/enteral products will be prepared (i.e. IV, enteral, irrigating, and oncology products)? Include sample labels.
- 6) What is the policy regarding the delivery of parenteral/enteral products to the patient? Describe methods used and trace the path the product takes from the time it leaves the permittee until it reaches the patient. Describe how products are protected from extreme temperature conditions.
- 7) Address the policy and procedure, special equipment and special techniques to dispense sterile preparations for parenteral therapy/nutrition. If this type of dispensing will not be performed, please state so accordingly.
- 8) What are the policy and procedure, special equipment and special techniques to dispense sterile jejunostomy feeding/sterile irrigation solutions? If this type of dispensing will not be performed, please state so accordingly.

- What is the policy and procedure, special equipment and special techniques to dispense cytotoxic or anti-neoplastic agents. If this type of dispensing will not be performed, please state so accordingly.
- 10) What is the procedure for the annual review and updating of the policy and procedure manual?
- 11) Include the layout/floor plan of the pharmacy. The drawing must include the dimensions of the clean room and the pharmacy, location of the hood, sink, and other equipment. The drawing must also show the location of the clean room relative to other pharmacy and storage areas.
- 12) Include a sample copy of a patient profile.
- 13) What aseptic techniques are utilized?
- 14) Describe the Quality Assurance Program.
- Describe with detail the policy and procedure for patient education, including the personnel involved.
- 16) What are the policy and procedures for handling waste and returns?
- 17) Describe the type of certified laminar flow hood(s) to be used and the frequency of certification.
- 18) Describe the refrigerator/freezer to be used.
- 19) Describe appropriate waste containers for:
  - a. Used needles and syringes.
  - b. Cytotoxic waste including disposable apparel used in preparation.
- 20) Address the following supplies to be used: gloves, mask, gowns, needles, syringes, disinfectant cleaning agents, clean towels, hand-washing materials with bactericidal properties, vacuum containers/transfer sets, and spill kits for cytotoxic agent spills.
- 21) How will you utilize the following reference material to ensure patient safety?
  - a. Chapters 465 and 893, F.S., and Rule Title 64B16, F.A.C.
  - b. Authoritative Therapeutic Reference.
  - c. Handbook of Injectable Drugs by American Society of Health-System Pharmacists.
- 22) What steps will be taken to ensure safe handling of cytotoxi drugs related to the Occupational Safety and Health Administration guidelines.
- 23) Describe the individual responsibilities of the Special- Parenteral/Enteral Extended Scope Permit and the supplied institutional pharmacy permits, if applicable.
- 24) What are the protocols for the maintenance of patient profiles and the offer to counsel if dispensing to outpatients?
- <u>25)</u> Describe the system for the maintenance of compounding records.
- 26) What percentage of your business is related to sterile compounding?
- 27) Describe the types of sterile products you will compound.
- 28) Are the products you will be compounding:
  - a. be pursuant to a patient-specific prescription

- b. be prepared in bulk (compounding multiple doses from a single source or batch)
- c. be prepared in bulk for office use.
- 30) Will your pharmacy ship sterile compounded products to other states?

If yes, provide a list of states to which your pharmacy will ship.

- 31) Provide the total number of pharmacy staff and indicate how many will be preparing sterile products:
  - a. Pharmacists
- b. Pharmacy Interns
  - c. Pharmacy Technicians
- 32) Provide the number of clean rooms in your pharmacy.
- 33) Provide the number of laminar flow hoods in your pharmacy.
- 34) When was the last time your clean room was certified by an independent contractor for National Sanitation Foundation Standard 49? Provide a copy of the most recent inspection and the name and address of the independent contractor.
- 35) When was the last time your laminar flow hood was certified by an independent contractor for National Sanitation Foundation Standard 49? Provide a copy of the most recent inspection and the name and address of the independent contractor.
- 36) Has your company ever recalled a sterile compounded product due to a compounding error? If yes, list the name (s) of the drug and the reason for the recall.

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



# INTERNET PHARMACY PERMIT APPLICATION AND INFORMATION

October 2017



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

#### **Internet 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).

An Internet Pharmacy as authorized by Section 465.0197, F.S., is required for any location not otherwise licensed or issued a permit under this chapter, within or outside this state that uses the Internet to communicate with or obtain information from consumers and uses the information to fill or refill prescriptions or to dispense, distribute, or otherwise engage in the practice of pharmacy in this state.

The Internet Pharmacy Permit is open at least 6 days per week for a minimum of 40 hours per week. A toll-free telephone number shall be provided to facilitate communication between patients in this state and a pharmacist in the pharmacy who has access to the patient's records.

# <u>Application Processing - Please read all application instructions before completing your application.</u>

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:

#### **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 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 pharmacist 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 within one year of the receipt date of the application and are available to the Department. 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.

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 principle 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 for you to sign this affirmation is included as an addendum to the application as Item #1.

#### **Licensure Process**

Once the application is deemed complete, the board staff authorizes an inspection. Upon completion of the inspection, the inspector notifies the board office as to whether the inspection was satisfactory or unsatisfactory. If the inspection is satisfactory, a permit number is issued within 10 days. Please wait 10 days from your satisfactory inspection before checking on the status of your permit. You may look up your license number on our website at <a href="http://www.flhealthsource.com/">http://www.flhealthsource.com/</a> under "Verify a License."

#### **Drug Enforcement Administration (DEA)**

The DEA will not issue a registration until the Florida Board of Pharmacy has issued a pharmacy permit.

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 <a href="http://www.DEAdiversion.usdoj.gov">http://www.DEAdiversion.usdoj.gov</a>. DEA Form 224 may be obtained in paper form by writing to:

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

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. <u>465.003(14)</u> or s. <u>893.02</u> 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

To prepare for your inspection, please review the inspection form. You may download a copy of the inspection form from the website at

http://www.floridahealth.gov/licensing-and-regulation/enforcement/inspection-program/inspection-forms.html

#### **INTERNET 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 can not be granted until the application is complete</u>. Faxed applications will not be accepted.

#### **INTERNET PHARMACY PERMIT:**

 Application completed (all questions answered)
 Application signed
 Nuclear Pharmacist Manager Signature
 \$255.00 Fee Attached (Permit fee includes \$250 application fee and \$5.00 unlicensed activity fee)
 Certificate of Status for the Corporation from the Secretary of State
 Fingerprints have been submitted via livescan for all officers and owners and the prescription department manager
 Attestation for Business Taxable Assets of \$100 million if applicable
 PDM Designation and Privacy Statement Acknowledgement Provided
 Affiliate/Owner Privacy Statement Acknowledgement provided for each affiliate/owner (Application Item #2)
 Applicant/affiliate/owner supplemental documents provided explaining any previous ownership, disciplinary actions, voluntary relinquishments and/or criminal activity.
 Applicant/Affiliate/Owner pharmacy permit questions answered and supplemental documents provided.



#### FLORIDA BOARD OF PHARMACY

P.O. Box 6320 Tallahassee, FL 32314-6320 Telephone (850) 488-0595 http://www.floridaspharmacy.gov



#### **APPLICATION**

Application Type - Please choose	one of the following	<u>ng:</u>		
New Establishment \$255 fee		Change of Location \$100 fee		
Change of Ownership \$255 fee		Stock Transfer (no fee)		
SECTION A. Please comple	ete for all Appl	ication Type	es	
Please list your Federal Employ	ver Identification	Number:		
1. Corporate Name			Telephone Number	
•				
2. Doing Business As (d/b/a)			E-Mail Address	
3. Mailing Address				
City	State		Zip	
4. Physical Address				
City	State		Zip	
5. Prescription Department Mar	l nager (PDM) Info	rmation		
Name			License Number	
Email			Telephone Number	
6. Contact Person			Title	
Email			Telephone Number	

7. Operating Hours				
Prescription Department Hours				
Monday-Friday: Open	Close:			
Saturday: Open:	Close:	Sunday:	Open:0	Close:
8. Ownership Information				
a. Type of Ownership:Indiv	/idual	Corporation	Partnership	
NOTE: IF CORPORATION OR LIMITED PAR	TNERSHIP YOU	J MUST INCLUDE WITH YOUR A		THE ARTICLES OF
INCORPORATION ON FILE WITH THE FLOR	RIDA SECRETA	RY OF STATE'S OFFICE.		
b. Are the applicants, officer	s director	rs shareholders men	nhers and nartne	rs over the age of
18?	o, un coto	o, ondi choldero, men	ibers and partie	13 Over the age of
Yes No _				
c. Does the corporation have	e more tha	n \$100 million of busi	iness taxable ass	ets in this state?
Yes No		If yes, provide attestation		ccountant for previous tax
		year or Florida Corporate Return (F-1120). If no, c		Emergency Excise Tax
d. List all the owners and of	ficers of the	he corporation. Each	person listed be	low having an
ownership interest of 5 perce				<b>.</b>
oversees, or controls the ope				
board of directors must subr 8c is yes please list the owner				
representative who is signing				
or AHCA you may provide proof and the requirements to submit prints for this person is met.				
Attach a separate sheet if necess	ary. Date of			% of
Owner/Officer-Title	Birth	Mailing Address	, City, State, Zip Cod	de Ownership
	1 1			%
	1 1			%
	1 1			%
	1 1			%
	1 1			%
	/ /		0.41	<u> </u>
Pursuant to Section 456.0635 you answer yes to any of the	• • •	• •		
accurate details and submit			-	n providing
9. Has the applicant or any p				affiliated person of
the applicant been convicted of, or entered a plea of guilty or nolo contendere to, regardless of				
adjudication, a felony under	•	•	•	a Statutes; or 21
U.S.C. ss. 801-970 or 42 U.S.	U. 33.1383	•	•	ough if palitudication
		withheld by the court, so	that you would not have	
Yes No _		Driving under the influence offense for the purposes		red is <u>NOT</u> a minor traffic

10. Has it been more than 15 years prior to the date of this application since the sentence and completion of any subsequent period of probation for such conviction?				
Yes No	(If yes, explain on a separa	te sheet providing accurate details)		
of the applicant ever been t	y principal, officer, agent, managing erminated for cause from the Florida atutes? (If no, do not answer 12.)	• • •		
Yes No	(If yes, explain on a separate s	sheet providing accurate details)		
the applicant has been term	rincipal, officer, agent, managing en ninated, has the applicant been reins nm for the most recent five years?	tated and in good standing with		
Yes No	(If yes, explain on a separate s	sheet providing accurate details)		
13. 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 14 and 15)				
Yes No	(If yes, explain on a separate s	sheet providing accurate details)		
14. Has the applicant been in good standing with a state Medicaid program or the federal Medicare program for the most recent five years?				
Yes No (If yes, explain on a separate sheet providing accurate details)				
15. Did the termination occ	ur at least 20 years prior to the date	of this application?		
Yes No	(If yes, explain on a separate s	sheet providing accurate details)		
16. 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		
47 Has the applicant offil:	atad warran mantus attions discontain	a succession and a sub-assession of the		
17. 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. <i>Attach a separate sheet if necessary.</i>				
	(If yes, explain on a separate shee	t providing accurate details)		
Pharmacy Name	State	Status		

		on ever been taken against any license, permit or registration ited person, partner, officer, director, or prescription department
No	Yes	(If yes, explain on a separate sheet providing accurate details)
	nny other permit nis application?	issued by the Department Health located at the physical location
No	Yes	(If yes, explain on a separate sheet providing accurate details)
	• • • •	officer, member or partner ever been convicted of a felony or or traffic convictions?
No	Yes	(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 <a href="NOT">NOT</a> a minor traffic offense for the purposes of this question.)
ALL (	QUESTIONS MUST	Γ BE ANSWERED OR YOUR APPLICATION WILL BE RETURNED
circumstances or c	conditions stated in the a	plicants supplement their applications as needed to reflect any material change in any application, which takes place between the initial filing of the application and the final grant or e decision of the department.
basis of my applica secure any addition future concerning n agencies or units, a suspended for pres	ation and I do authorize nal information concern me to any person, corpo and I understand accord	his application are true, complete, and correct and I agree that said statements shall form the the Florida Board of Pharmacy to make any investigations that they deem appropriate and to ing me, and I further authorize them to furnish any information they may have or have in the pration, institution, association, board, or any municipal, county, state, or federal governmental ding to the Florida Board of Pharmacy Statutes that a Pharmacy Permit may be revoked or ulent, or forged statement, certificate, diploma, or other thing, in connection with an application ion 465.015(2)(a), F.S.
		s are true and correct and recognize that providing false information may result in disciplinary lties pursuant to sections 465.016, 775.082, 775.083, and 775.084, F.S.
SIGNATURE	(Owner or office	DATE cer 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.doh.state.fl.us/mqa/background.html;
- Failure to submit background screening will delay your application;
- Applicants may use any Livescan service provider approved by the Florida
   Department of Law Enforcement to submit their background screening to the department;
- If you do not provide the correct Originating Agency Identification (ORI) number to the livescan service provider the Board office <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)*;
- If you do not have a SSN you will need to contact the Board office for a fingerprint card then return the card to the Board office:
- The ORI number for the Board of Pharmacy is EDOH4680Z
- Typically background screening results submitted through a Livescan service provider are received by the Board within 24-72 hours of being processed.
- If you obtain your livescan from a service provider who does not capture your photo you may be required to be reprinted by another agency in the future.

Name:			
Aliases:			
Address:			Apt. Number:
City:		State:	Zip Code:
	/ <u>/</u> /YYYY)	Place of Birth:	
Weight: F	leight:	Eye Color:	Hair Color:
Race:	k; A-Asian;	Sex: (M=Male; F=Female)	Citizenship:
Transaction Control N (This will be provided to yo			

## Keep this form for your records.



# Item #1- PDM 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 info@floridaspharmacy.gov

File #:	File #: (if known):		
Licens	Se #: (if applicable)		

	on Department Manager (PD	M) Designation	
Applicant/Pharmacy Na	ime:		
Applicant/Pharmacy Ma	ailing Address:		
7 ponound narmady me	ining / idai ooo.		
City	Ctata	7:	
City	State	Zip	
Incoming PDM Name:		License#:	
		PS	
Date Beginning as PDM	I: Incoming PDM Signature		
DDM Tuesday Contr	and Named are (TON) and a feed to differ		
PDW Transaction Contr	ol Number (TCN) – related to Live	escan Fingerprints:	
	information is there is an Outgoing PD	M at current pharmacy location.*** License#:	
Outgoing PDM Name:			
		PS	
Date Ending as PDM:	Outgoing PDM Signature		
Section B. Incoming	g PDM Privacy Statement Ac	knowledgement	
	ıld be completed by same person listed in		
I have been provided and r	ead the statement from the Florida De	epartment of Law Enforcement	
regarding the sharing, rete	ntion, privacy and right to challenge i	ncorrect criminal history records	
and the "Privacy Statemen	t" document from the Federal Bureau	of Investigation."	
Date:	Incoming PDM Signature		



# <u>Item #2- Affiliate/Owner Privacy Statement</u> <u>Acknowledgement</u>

# 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

MQA.Pharmacy@flhealth.gov

Affiliate / Owner Name:		File # (required):		
Applicant Name:				
Affiliate/Owner Mailing Address:				
City	State	Zip		
Affiliate/Owner Email	Affiliate/Owner Telep	hone Number		
Affiliate/Owner Transaction Control Nu	umber (TCN) - related	to Livescan		
From:				
have been provided and read the statement from the Florida Department of Law Enforcement regarding the sharing, retention, privacy and right to challenge ncorrect criminal history records and the "Privacy Statement" document from the Federal Bureau of Investigation."				
Affiliate/Owner Signature (Required)	Date (of signature	)		

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



# INTERNET PHARMACY PERMIT APPLICATION AND INFORMATION

October 2017



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

### **Internet 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).

An Internet Pharmacy as authorized by Section 465.0197, F.S., is required for any location not otherwise licensed or issued a permit under this chapter, within or outside this state that uses the Internet to communicate with or obtain information from consumers and uses the information to fill or refill prescriptions or to dispense, distribute, or otherwise engage in the practice of pharmacy in this state.

The Internet Pharmacy Permit is open at least 6 days per week for a minimum of 40 hours per week. A toll-free telephone number shall be provided to facilitate communication between patients in this state and a pharmacist in the pharmacy who has access to the patient's records.

# <u>Application Processing - Please read all application instructions before completing your application.</u>

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:

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 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 pharmacist 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 within one year of the receipt date of the application and are available to the Department. 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.

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 principle 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 for you to sign this affirmation is included as an addendum to the application as Item #1.

#### **Licensure Process**

Once the application is deemed complete, the board staff authorizes an inspection. Upon completion of the inspection, the inspector notifies the board office as to whether the inspection was satisfactory or unsatisfactory. If the inspection is satisfactory, a permit number is issued within 10 days. Please wait 10 days from your satisfactory inspection before checking on the status of your permit. You may look up your license number on our website at <a href="http://www.flhealthsource.com/">http://www.flhealthsource.com/</a> under "Verify a License."

### **Drug Enforcement Administration (DEA)**

The DEA will not issue a registration until the Florida Board of Pharmacy has issued a pharmacy permit.

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 <a href="http://www.DEAdiversion.usdoj.gov">http://www.DEAdiversion.usdoj.gov</a>. DEA Form 224 may be obtained in paper form by writing to:

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

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. <u>465.003(14)</u> or s. <u>893.02</u> 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

To prepare for your inspection, please review the inspection form. You may download a copy of the inspection form from the website at

http://www.floridahealth.gov/licensing-and-regulation/enforcement/inspection-program/inspection-forms.html

### **INTERNET 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 can not be granted until the application is complete</u>. Faxed applications will not be accepted.

### **INTERNET PHARMACY PERMIT:**

 Application completed (all questions answered)
 Application signed
 Nuclear Pharmacist Manager Signature
 \$255.00 Fee Attached (Permit fee includes \$250 application fee and \$5.00 unlicensed activity fee)
 Certificate of Status for the Corporation from the Secretary of State
 Fingerprints have been submitted via livescan for all officers and owners and the prescription department manager
 Attestation for Business Taxable Assets of \$100 million if applicable
 PDM Designation and Privacy Statement Acknowledgement Provided
 Affiliate/Owner Privacy Statement Acknowledgement provided for each affiliate/owner (Application Item #2)
 Applicant/affiliate/owner supplemental documents provided explaining any previous ownership, disciplinary actions, voluntary relinquishments and/or criminal activity.
 Applicant/Affiliate/Owner pharmacy permit questions answered and supplemental documents provided.



### FLORIDA BOARD OF PHARMACY

P.O. Box 6320 Tallahassee, FL 32314-6320 Telephone (850) 488-0595 http://www.floridaspharmacy.gov



### **APPLICATION**

Application Type - Please choose	one of the following	<u>ng:</u>		
New Establishment \$255 fee		Change of Location \$100 fee		
Change of Ownership \$255 fee		Stock Tr	_ Stock Transfer (no fee)	
SECTION A. Please comple	ete for all Appl	ication Type	es	
Please list your Federal Employ	ver Identification	Number:		
1. Corporate Name			Telephone Number	
•				
2. Doing Business As (d/b/a)			E-Mail Address	
3. Mailing Address				
City	State		Zip	
4. Physical Address				
City	State		Zip	
5. Prescription Department Mar	l nager (PDM) Info	rmation		
Name	go: (. 2,		License Number	
Email			Telephone Number	
6. Contact Person			Title	
Email			Telephone Number	

7. Operating Hours				
Prescription Department Hours				
Monday-Friday: Open	Close:			
Saturday: Open:	Close:	Sunday:	Open:	Close:
8. Ownership Information				
a. Type of Ownership:Indiv	/idual	Corporation	Partnership	
NOTE: IF CORPORATION OR LIMITED PAR	TNERSHIP YOU	J MUST INCLUDE WITH YOUR A	•	THE ARTICLES OF
INCORPORATION ON FILE WITH THE FLOR	RIDA SECRETA	RY OF STATE'S OFFICE.		
b. Are the applicants, officer	rs director	rs shareholders men	nhers and nartne	rs over the age of
18?	o, an coto	o, onarcholacio, men	inders and partite	13 Over the age of
Yes No _				
c. Does the corporation have	e more tha	n \$100 million of bus	iness taxable ass	sets in this state?
Yes No		If yes, provide attestation		ccountant for previous tax
		year or Florida Corporate Return (F-1120). If no, c		Emergency Excise Tax
d. List all the owners and of	fficers of the	he corporation. Each	person listed be	low having an
ownership interest of 5 perce				
oversees, or controls the ope		• •	_	
board of directors must subr 8c is yes please list the owner				
representative who is signing			<u>-</u>	
or AHCA you may provide pr	oof and th			
Attach a separate sheet if necess	ary. Date of			, % of
Owner/Officer-Title	Birth	Mailing Address	, City, State, Zip Coo	de Ownership
	1 1			%
	1 1			%
	1 1			%
	1 1			%
	1 1			%
D 450 0001	(0) 51-3	1-04-4-4	0.41	%
Pursuant to Section 456.0635(2), <i>Florida Statutes</i> , questions 9 through 15 are being asked. If you answer yes to any of the following questions, explain on a separate sheet providing				
accurate details and submit	_		-	it providing
9. Has the applicant or any p				affiliated person of
the applicant been convicted of, or entered a plea of guilty or nolo contendere to, regardless of				
adjudication, a felony under U.S.C. ss. 801-970 or 42 U.S.	-	•	•	a Statutes; or 21
0.3.0. 33. 001-370 01 42 0.3.	o. 33.1333	•	•	o oven if adjudication was
		withheld by the court, so	that you would not have	
Yes No _		Driving under the influen offense for the purposes		ired is <u>NOT</u> a minor traffic

10. Has it been more than 15 years prior to the date of this application since the sentence and completion of any subsequent period of probation for such conviction?					
Yes No _	(If yes, explain on a separa	te sheet providing accurate details)			
of the applicant ever been ter	11. 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 12.)				
Yes No _	(If yes, explain on a separate s	sheet providing accurate details)			
the applicant has been terming the Florida Medicaid Program	ncipal, officer, agent, managing em ated, has the applicant been reinst for the most recent five years?	ated and in good standing with			
Yes No _	(If yes, explain on a separate s	sheet providing accurate details)			
13. Has the applicant or any of the applicant ever been ter established by the state or fe	orincipal, officer, agent, managing minated for cause, pursuant to the deral government, from any other s f no, do not answer 14 and 15)	employee, or affiliated person appeals procedures			
Yes No _	(If yes, explain on a separate s	sheet providing accurate details)			
14. Has the applicant been in good standing with a state Medicaid program or the federal Medicare program for the most recent five years?					
Yes No (If yes, explain on a separate sheet providing accurate details)					
15. Did the termination occur at least 20 years prior to the date of this application?					
Yes No _	No (If yes, explain on a separate sheet providing accurate details)				
	red or permitted in any other states er for each permit. Attach a separa	• • •			
Yes No _					
State	Permit Type	Permit Number			
47 Use the englished offiliate	ad novom novinou affices diseases	aver evened a pharmacy 2 If			
17. 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. <i>Attach a separate sheet if necessary.</i>					
	(If yes, explain on a separate shee	providing accurate details)			
Pharmacy Name	State	Status			

		been taken against any license, permit or registration son, partner, officer, director, or prescription department
No	Yes	(If yes, explain on a separate sheet providing accurate details)
19. Is there any o address on this a		by the Department Health located at the physical location
No	Yes	(If yes, explain on a separate sheet providing accurate details)
	icant, or any officer, cluding minor traffic	member or partner ever been convicted of a felony or convictions?
No	Yes	(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 <a href="NOT">NOT</a> a minor traffic offense for the purposes of this question.)
ALL QUES	STIONS MUST BE ANS	SWERED OR YOUR APPLICATION WILL BE RETURNED
circumstances or condition		oplement their applications as needed to reflect any material change in any which takes place between the initial filing of the application and the final grant or of the department.
basis of my application a secure any additional info future concerning me to a agencies or units, and I u suspended for presenting	nd I do authorize the Florida ormation concerning me, and any person, corporation, inst understand according to the l	on are true, complete, and correct and I agree that said statements shall form the Board of Pharmacy to make any investigations that they deem appropriate and to d I further authorize them to furnish any information they may have or have in the itution, association, board, or any municipal, county, state, or federal governmental Florida Board of Pharmacy Statutes that a Pharmacy Permit may be revoked or ged statement, certificate, diploma, or other thing, in connection with an application $5(2)(a)$ , F.S.
		nd correct and recognize that providing false information may result in disciplinary ant to sections 465.016, 775.082, 775.083, and 775.084, F.S.
SIGNATURE	(Owner or officer of estab	DATE plishment)

### 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.doh.state.fl.us/mqa/background.html;
- Failure to submit background screening will delay your application;
- Applicants may use any Livescan service provider approved by the Florida
   Department of Law Enforcement to submit their background screening to the department;
- If you do not provide the correct Originating Agency Identification (ORI) number to the livescan service provider the Board office <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)*;
- If you do not have a SSN you will need to contact the Board office for a fingerprint card then return the card to the Board office:
- The ORI number for the Board of Pharmacy is EDOH4680Z
- Typically background screening results submitted through a Livescan service provider are received by the Board within 24-72 hours of being processed.
- If you obtain your livescan from a service provider who does not capture your photo you may be required to be reprinted by another agency in the future.

Name:			
Aliases:			
Address:			Apt. Number:
City:		State:	Zip Code:
	/ <u>/</u> /YYYY)	Place of Birth:	
Weight: F	leight:	Eye Color:	Hair Color:
Race:	k; A-Asian;	Sex: (M=Male; F=Female)	Citizenship:
Transaction Control N (This will be provided to yo			

## Keep this form for your records.



# Item #1- PDM 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 info@floridaspharmacy.gov

File #:	(if known):
Licens	se #: (if applicable):

	on Department Manager (PD	M) Designation	
Applicant/Pharmacy Na	ime:		
Applicant/Pharmacy Ma	ailing Address:		
7 ponound narmady me	ining / idai ooo.		
City	Ctata	7:	
City	State	Zip	
Incoming PDM Name:		License#:	
		PS	
Date Beginning as PDM	I: Incoming PDM Signature		
DDM Tuesday Contr	and Named are (TON) and a feed to differ		
PDW Transaction Contr	ol Number (TCN) – related to Live	escan Fingerprints:	
	information is there is an Outgoing PD	M at current pharmacy location.*** License#:	
Outgoing PDM Name:			
		PS	
Date Ending as PDM:	Outgoing PDM Signature		
Section B. Incoming	g PDM Privacy Statement Ac	knowledgement	
	ıld be completed by same person listed in		
I have been provided and r	ead the statement from the Florida De	epartment of Law Enforcement	
regarding the sharing, rete	ntion, privacy and right to challenge i	ncorrect criminal history records	
and the "Privacy Statemen	t" document from the Federal Bureau	of Investigation."	
Date:	Incoming PDM Signature		



# <u>Item #2- Affiliate/Owner Privacy Statement</u> <u>Acknowledgement</u>

# 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

MQA.Pharmacy@flhealth.gov

Affiliate / Owner Name:		File # (required):
Applicant Name:		
Affiliate/Owner Mailing Address:		
City	State	Zip
Affiliate/Owner Email	Affiliate/Owner Telep	hone Number
Affiliate/Owner Transaction Control Number (TCN) – related to Livescan		
From:		
have been provided and read the statement from the Florida Department of Law Enforcement regarding the sharing, retention, privacy and right to challenge ncorrect criminal history records and the "Privacy Statement" document from the Federal Bureau of Investigation."		
Affiliate/Owner Signature (Required)	Date (of signature	)