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:

1. 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.

PAM BONDI
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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. Id at § (2). Most importantly, the pharmacist shall assume full responsibility for the final product by physically examining and certifying to the products accuracy. Id. 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 Cod*e (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. Id. 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 http://www.flrules.org/Gateway/reference.asp?No=Ref-02297 or on the web at http://www.doh.state.fl.us/mqa/pharmacy.

(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 http://www.flrules.org/Gateway/reference.asp?No=Ref-02298.

(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 http://www.flrules.org/Gateway/reference.asp?No=Ref-02299.

(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 http://www.flrules.org/Gateway/reference.asp?No=Ref-02300.

(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 http://www.flrules.org/Gateway/reference.asp?No=Ref-02301.

(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 http://www.flrules.org/Gateway/reference.asp?No=Ref-02302.

(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 http://www.flrules.org/Gateway/reference.asp?No=Ref-02303.

(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 http://www.flrules.org/Gateway/reference.asp?No=Ref-03142.

(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/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 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.

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

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. 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.

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

COMMUNITY PHARMACY PERMIT

APPLICATION

Application Type – Please choose one of the following:	
____New Establishment ($255.00 fee)	____ Change of Location ($100.00 fee)
____Change of Ownership ($255.00 fee)	____ Stock Transfer (no fee)

SECTION A. Please complete for all Application Types

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. Prescription Department Manager (PDM) Information	
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:_____ Close:_____

8. 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 18?

Yes _____ No _____

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

Yes _____ No _____

d. List all the owners and officers of the corporation. Each person listed below having an ownership interest of 5 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
	/ /		%
	/ /		%
	/ /		%
	/ /		%
	/ /		%

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 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 _____

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 questions #17 and 18. If yes, please provide documents concerning this conviction.)*

Yes _____ No _____

17. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant been in good standing with a state Medicaid program for the most recent five years?
(If yes, please explain on a separate sheet providing accurate details.)

Yes _____ No _____

18. 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 _____

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? *(If yes, please submit proof.)*

Yes _____ No _____

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 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 providing accurate details, if necessary.)*

Yes _____ No _____

Pharmacy Name	State	Status

22. Has any disciplinary action ever been taken against any license, permit or registration issued to the applicant, affiliated person, partner, officer, director, or prescription department manager?
(If yes, explain on a separate sheet providing accurate details.)

Yes _____ No _____

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.)*

Yes _____ No _____

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?

Yes _____ No _____

27. Will the Pharmacy act as a Central Fill Pharmacy?

Yes _____ No _____

SECTION B. Please complete for Change of Location only.

1. Current Practice Location Address

City	State	Zip

Email	Telephone Number

2. New Practice Location Address

City	State	Zip

Email	Telephone Number

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 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 **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.

SIGNATURE _____ DATE_____
(Owner or officer of establishment)

FLORIDA DEPARTMENT OF LAW ENFORCEMENT

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

NOTICE OF:

- **SHARING OF CRIMINAL HISTORY RECORD INFORMATION WITH SPECIFIED AGENCIES,**
- **RETENTION OF FINGERPRINTS,**
- **PRIVACY POLICY, AND**
- **RIGHT TO CHALLENGE AN INCORRECT CRIMINAL HISTORY RECORD**

This notice is to inform you that when you submit a set of fingerprints to the Florida Department of Law Enforcement (FDLE) for the purpose of conducting a search for any Florida and national criminal history records that may pertain to you, the results of that search will be returned to the Care Provider Background Screening Clearinghouse. By submitting fingerprints, you are authorizing the dissemination of any state and national criminal history record that may pertain to you to the Specified Agency or Agencies from which you are seeking approval to be employed, licensed, work under contract, or to serve as a volunteer, pursuant to the National Child Protection Act of 1993, as amended, and Section 943.0542, Florida Statutes. "Specified agency" means the Department of Health, the Department of Children and Family Services, the Division of Vocational Rehabilitation within the Department of Education, the Agency for Health Care Administration, the Department of Elder Affairs, the Department of Juvenile Justice, and the Agency for Persons with Disabilities when these agencies are conducting state and national criminal history background screening on persons who provide care for children or persons who are elderly or disabled. The fingerprints submitted will be retained by FDLE and the Clearinghouse will be notified if FDLE receives Florida arrest information on you.

Your Social Security Number (SSN) is needed to keep records accurate because other people may have the same name and birth date. Disclosure of your SSN is imperative for the performance of the Clearinghouse agencies' duties in distinguishing your identity from that of other persons whose identification information may be the same as or similar to yours.
Licensing and employing agencies are allowed to release a copy of the state and national criminal record information to a person who requests a copy of his or her own record if the identification of the record was based on submission of the person's fingerprints. Therefore, if you wish to review your record, you may request that the agency that is screening the record provide you with a copy. After you have reviewed the criminal history record, if you believe it is incomplete or inaccurate, you may conduct a personal review as provided in s. 943.056, F.S., and Rule 11C8.001, F.A.C. If national information is believed to be in error, the FBI should be contacted at 304-625-2000. You can receive any national criminal history record that may pertain to you directly from the FBI, pursuant to 28 CFR Sections 16.30-16.34. You have the right to obtain a prompt determination as to the validity of your challenge before a final decision is made about your status as an employee, volunteer, contractor, or subcontractor.

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

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

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

Privacy Statement

Authority: The FBI's acquisition, preservation and exchange of information requested by this form is generally authorized under 28 U.S.C. 534. Depending on the nature of your application, supplemental authorities include numerous Federal statutes, hundreds of State statutes pursuant to Pub.L.92-544, Presidential executive orders, regulations and/or orders of the Attorney General of the United States, or other authorized authorities. Examples include, but are not limited to: 5 U.S.C. 9101; Pub.L.94-29; Pub.L.101-604; and Executive Orders 10450 and 12968. Providing the requested information is voluntary; however, failure to furnish the information may affect timely completion of approval of your application.

Social Security Account Number (SSAN): Your SSAN is needed to keep records accurate because other people may have the same name and birth date. Pursuant to the Federal Privacy Act of 1974 (5 USC 552a), the requesting agency is responsible for informing you whether disclosure is mandatory or voluntary, by what statutory or other authority your SSAN is solicited, and what uses will be made of it. Executive Order 9397 also asks Federal Agencies to use this number to help identify individuals in agency records.

Principal Purpose: Certain determinations, such as employment, security, licensing and adoption, may be predicated on fingerprint based checks. Your fingerprints and other information contained on (and along with) this form may be submitted to the requesting agency, the agency conducting the application investigation, and/or FBI for the purpose of comparing the submitted information to available records in order to identify other information that may be pertinent to the application. During the processing of this application, and for as long hereafter as my be relevant to the activity for which this application is being submitted, the FBI(may disclose any potentially pertinent information to the requesting agency and/or to the agency conducting the investigation. The FBI may also retain the submitted information in the FBI's permanent collection of fingerprints and related information, where it will be subject to comparisons against other submissions received by the FBI. Depending on the nature of your application, the requesting agency and/or the agency conducting the application investigation may also retain the fingerprints and other submitted information for other authorized purposes of such agency(ies).

Routine Uses: The fingerprints and information reported on this form may be disclosed pursuant to your consent, and may also be disclosed by the FBI without your consent as permitted by the Federal Privacy Act of 1974 (5 USC 552a(b)) and all applicable routine uses as many be published at any time in the Federal Register, including the routine uses for the FBI Fingerprint Identification Records System (Justice, FBI-009) and the FBI's Blanket Routine Uses (Justice/FBI-BRU). Routine uses include, but are not limited to, disclosures to: appropriate governmental authorities responsible for civil or criminal law enforcement counterintelligence, national security or public safety matters to which the information may be relevant; to State and local governmental agencies and nongovernmental entities for application processing as authorized by Federal and State legislation, executive order, or regulation, including employment, security, licensing, and adoption checks; and as otherwise authorized by law , treaty, executive order, regulation, or other lawful authority. If other agencies are involved in processing the application, they may have additional routine uses.

Additional Information: The requesting agency and/or the agency conducting the application investigation will provide you additional information pertinent to the specific circumstances of this application, which may include identification of other authorities, purposes, uses, and consequences of not providing requested information. In addition, any such agency in the Federal Executive Branch has also published notice.

Electronic Fingerprinting

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

- Background screening results are obtained from the Florida Department of Law Enforcement and the Federal Bureau of Investigation by submitting to a fingerprint scan using the Livescan method;
- You can find a Livescan service provider at: http://www.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:_____ SSN#: _____ - ____ - _____

Aliases:_____

Address: _____ Apt. Number: _____

City:_____ State: _____Zip Code: _____

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

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

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

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

Citizenship: _____

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

Keep this form for your records.

Item #1- 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)**:**
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 Number (TCN) – related to Livescan Fingerprints:		
*****Only provide following information 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 PDM Privacy Statement Acknowledgement

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

I have been provided and read the statement from the Florida Department of Law Enforcement regarding the sharing, retention, privacy and right to challenge incorrect criminal history records and the "Privacy Statement" document from the Federal Bureau of Investigation."

Date:	**Incoming 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

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 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~~

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 Bboard office for your records. When you mail the completed application and fees, use the address noted in the instructions and on the application form.

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

within 30 days if any materials are incomplete.

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

The Board of Pharmacy

COMMUNITY PHARMACY PERMIT APPLICATION INFORMATION

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

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

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

Application Processing

Please read all application instructions before completing your application.

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

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

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

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

Within 30 days of receipt of your application and fees, the board office will notify you of the receipt of your application, any required documents, and your status. If the application is complete, you will be notified that an inspector will contact you to setup an inspection appointment. ~~Please do not contact the board office concerning your inspection date, and allow~~

~~30 days for the inspector to contact you. If you have not been contacted by the inspector within~~

~~30 days, then notify the board~~. If your application is incomplete, you will be notified in writing of what is required to make your application complete.

2) ~~____~~ Submit fingerprint results.

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

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

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

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

- a) If you are an applicant seeking a license for any profession regulated by the Department of Health, which requires a criminal background search as a condition of licensure, you must provide accurate demographic information at the time your fingerprints are taken, ***including your Social Security number***. The Department will not be able to process a submission that does not include your Social Security number.
- 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 http://www.DEAdiversion.usdoj.gov. DEA Form 224 may be obtained in paper form by writing to:

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

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

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

IMPORTANT NOTICE :The Ddepartment 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. 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.

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?

~~PRE-INSPECTION CHECKLIST~~

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

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

_____ Are all required signs displayed?

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

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

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

FLORIDA BOARD OF PHARMACY
P.O. Box 6320
Tallahassee, FL 32314-6320
850-245-4292
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~~

COMMUNITY PHARMACY PERMIT

~~COMMUNITY PHARMACY PERMIT~~ APPLICATION

Application Type – Please choose one of the following:	
___ New Establishment ($255.00 fee)	___ Change of Location ($100.00 fee)
___ Change of Ownership ($255.00 fee)	___ Stock Transfer (no fee)

SECTION A. Please complete for all Application Types

Please list your Federal Employer Identification Number: _____

~~**Application Type – Please choose one of the following:**~~
~~___ New Establishment $255 fee ___ Additional Permit Type $255 fee _____ (existing permit number)~~
~~___ Change of Location $100 fee _____ (existing permit number)~~
~~___ Change of Ownership (a new permit number will be issued) $255 _____ (existing permit number)~~

~~**Will the Pharmacy Dispense Schedule II and/or III Controlled Substances? ___ Yes ___ No**~~
~~**Will the Pharmacy act as a Central Fill Pharmacy? ___ Yes ___ No**~~
~~**Please list your Federal Employer Identification Number: _____**~~

1. Corporate Name	**Telephone Number**
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~~ Prescription Department Manager (PDM) Information

~~Name~~	~~License No.~~	~~Start Date~~	~~PDM Signature~~

~~6. Contact Person~~		~~Telephone Number~~	
~~7. DEA Registration Number~~		~~8. Date ready for inspection (within 90 days)~~	

~~9. Please provide the name, address, telephone number, and permit number of your prescription drug wholesale distributor. (write pending if not known)~~

~~Name~~	~~Telephone Number~~	~~Permit Number~~	
~~Street Address~~	~~City~~	~~State~~	~~Zip~~

~~10. Pharmacy Technician Ratio 2:1 or 3:1 (Optional)~~

~~Rule 64B16-27.410, *Florida Administrative Code*, provides that the prescription department manager or consultant pharmacist of record is required to submit a written request and receive approval from the Board of Pharmacy prior to the pharmacy allowing a pharmacist to supervise more than one registered pharmacy technician. If you would like to apply for the Registered Pharmacy Technician 2:1 or 3:1 ratio, you may do so by checking the appropriate selection below. Selecting an option below serves as your written request to the board office for approval to practice with a 2:1 or 3:1 ratio.~~

Name	License Number

Email	Telephone Number
6. Contact Person	Title
Email	Telephone Number

~~_____ 2:1 Ratio _____ 3:1 Ratio~~
~~(please attach a brief description of the workflow needs that include the operating hours of the pharmacy, number of pharmacist, registered interns and registered pharmacy technicians employed to justify the ratio request)~~

7~~11~~. Operating Hours

~~**Store/Facility Hours**~~

~~Monday-Friday: Open:_____ Close:_____~~

~~Saturday: Open:_____ Close:_____~~

~~Sunday: Open: Close:~~

8~~12~~. Ownership Information

a. Type of Ownership: _____Individual _____Corporation _____Partnership

~~_____Other: _____~~

~~NOTE: If the applicant is a corporation or limited partnership you must include with your application a copy~~

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

Yes _____ No _____

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

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

d. List all the owners and officers of the corporation. Each person listed below having an ownership interest of 5 percent or greater and any person who, directly or indirectly, manages, oversees, or controls the operation of the applicant including officers and members of the board of directors must submit a set of fingerprints and fees unless you answered yes to ~~18~~2c. If 8~~12~~c is yes, please list the owners below and only submit fingerprints for the Prescription Department Manager or Consultant Pharmacist of Record. If 8~~12~~c is yes and the prints are on file with DOH or AHCA and available to the Board of Pharmacy the

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

9~~13~~. Has anyone listed in 8.~~12.~~d had an ownership interest of 5% or more in a pharmacy or any other business permit which was disciplined, suspended, revoked, or closed involuntarily within the past 5 years? *If yes, please provide a signed affidavit disclosing the reason the entity was closed.*

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

9~~13~~a. Has anyone listed in 8~~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? *If yes, please provide a signed affidavit disclosing the reason the entity was closed.*

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

10~~14~~. Has anyone listed in 8~~12~~.d ever obtained a pharmacy permit by misrepresentation or fraud or been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to health care fraud? ? *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~~

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).

Yes No ~~Yes~~ ~~No~~

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?

Yes No ~~Yes~~ ~~No~~

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).*

Yes No ~~Yes~~ ~~No~~

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 ~~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~~8~~. If yes, explain on a separate sheet providing accurate details.)~~)~~*

Yes No ~~Yes~~ ~~No~~ ~~(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

Yes No ~~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?

Yes No

17. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant been in good standing with a state Medicaid program for the most recent five years?
(If yes, please explain on a separate sheet providing accurate details.)

Yes No

18. 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

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? *(If yes, please submit proof.)*

Yes No

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 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

Pharmacy Name	State	Stat

22. Has any disciplinary action ever been taken against any license, permit or registration issued to the applicant, affiliated person, partner, officer, director, or prescription department manager?
(If yes, explain on a separate sheet providing details.)

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

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?

Yes No

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~~
~~Yes No~~

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

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

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

~~No Yes~~

ALL QUESTIONS MUST BE ANSWERED OR YOUR APPLICATION WILL BE RETURNED

****

*** Section 456.013(1), F.S., requires that applicants supplement their applications as needed to reflect any material change in any circumstances or conditions stated in the application, which takes place between the initial filing of the application and the final grant or denial of the license, which might affect the decision of the department.

I certify that the statements contained in this application are true, complete, and correct and I agree that said statements shall form the basis of my application and I do authorize the Florida Board of Pharmacy to make any investigations that they deem appropriate and to secure any additional information concerning me, and I further authorize them to furnish any information they may have or have in the future concerning me to any person, corporation, institution, association, board, or any municipal, county, state, or federal governmental agencies or units, and I understand according to the Florida Board of Pharmacy Statutes that a Pharmacy Permit may be revoked or suspended for presenting any false, fraudulent, or forged statement, certificate, diploma, or other item, in connection with an application for a license or permit, as set forth in Section 465.015(2)(a), F.S.

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

SIGNATURE _____ DATE _____ (Owner or officer of establishmen

SECTION B. Please complete for Change of Location only.

1. Current Practice Location Address

City	**State**	**Zip**
Email	**Telephone Number**	

2. New Practice Location Address

City	**State**	**Zip**
Email	**Telephone Number**	

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 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 **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.

SIGNATURE DATE

(Owner or officer of establishment)

PHARMACY PERMIT APPLICATION CHECKLIST

Keep a copy of the completed application for your records.

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

COMMUNITY PHARMACY PERMIT

_____ Application Completed (all questions answered)

_____ Application signed

_____ Pharmacy Manager Signature

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

_____ Articles of Incorporation from the Secretary of State

_____ Fingerprints have been submitted via livescan for all officers and owners and the prescription department manager

_____ Attach Proof from AHCA that the fingerprints are on file if applicable from the last year

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

_____ Bill of Sale is required for Change of Ownership

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 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 of Birth: _____
(MM/DD/YYYY)

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

Race: _____ Sex: _____
(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*.)

Keep this form for your records.

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

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):
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 Number (TCN) – related to Livescan Fingerprints:		
Only provide following information 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 PDM Privacy Statement Acknowledgement

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

I have been provided and read the statement from the Florida Department of Law Enforcement regarding the sharing, retention, privacy and right to challenge incorrect criminal history records and the "Privacy Statement" document from the Federal Bureau of Investigation."

Date:	Incoming 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

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 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. Institutional Class I Pharmacy – 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. Institutional Class II Pharmacy Permit – 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.

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 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.

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

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 Item #2)?

_____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?

_____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

INSTITUTIONAL PHARMACY PERMIT

APPLICATION

Application Type – Please choose one of the following:	
____New Establishment ($255.00 fee) ____Change of Ownership ($255.00 fee)	____ Change of Location ($100.00 fee) ____ Stock Transfer (no fee)
Pharmacy Permit Type – Please choose one of the following:	
____Institutional Class I ____Institutional Class II	Modified Institutional Class II A _____ Class II B_____ Class II C_____

SECTION A. Please complete for all Application Types

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. Consultant Pharmacist of Record (COR) Information	
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:_____ **Saturday:** Open:_____ Close:_____

8. 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 18?

Yes _____ No _____

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

Yes _____ No _____

d. List all the owners and officers of the corporation. Each person listed below having an ownership interest of 5 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
	/ /		%
	/ /		%
	/ /		%
	/ /		%
	/ /		%

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 _____

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 questions #17 and 18. If yes, please provide documents concerning this conviction.)*

Yes _____ No _____

17. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant been in good standing with a state Medicaid program for the most recent five years?
(If yes, please explain on a separate sheet providing accurate details.)

Yes _____ No _____

18. 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 _____

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? *(If yes, please submit proof.)*

Yes _____ No _____

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 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 providing accurate details, if necessary.)*

Yes _____ No _____

Pharmacy Name	State	Status

22. Has any disciplinary action ever been taken against any license, permit or registration issued to the applicant, affiliated person, partner, officer, director, or consultant pharmacist of record in this state or any other? *(If yes, explain on a separate sheet providing accurate details.)*

Yes _____ No _____

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.)*

Yes _____ No _____

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. If compounding sterile preparations, is your establishment Rule 64B16-27.797, F.A.C. compliant?

Yes _____ No _____

27. Is there any other permit issued by the Department of Health located at the physical location address on this application? *(If yes, explain on a separate sheet providing accurate details.)*

Yes _____ No _____

SECTION B. Please complete for Change of Location only.

1. Current Practice Location Address

City	**State**	**Zip**
Email	**Telephone Number**	

2. New Practice Location Address

City	**State**	**Zip**
Email	**Telephone Number**	

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 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? *NOTE: If yes, please complete **Section C** above and include necessary fee.*

Yes _____ No _____

ALL QUESTIONS MUST BE ANSWERED OR YOUR APPLICATION WILL BE RETURNED

****

Section 456.013(1), F.S., requires that applicants supplement their applications as needed to reflect any material change in any circumstances or conditions stated in the application, which takes place between the initial filing of the application and the final grant or denial of the license, which might affect the decision of the department.

I 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)

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 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 of Birth: _____
(MM/DD/YYYY)

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

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

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

Citizenship: _____

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

Keep this form for your records.

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

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

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

Section A. Consultant Pharmacist of Record (COR) Designation

Applicant/Pharmacy Name:		
Applicant/Pharmacy Mailing Address:		
City	**State**	**Zip**
Incoming COR Name:		**License#:**
		PU
Date Beginning as COR:	**Incoming COR Signature**	
COR Transaction Control Number (TCN) – related to Livescan Fingerprints:		
Only provide following information is there is an Outgoing COR at current pharmacy location.		
Outgoing COR Name:		**License#:**
		PU
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."

Date:	**Incoming COR Signature**

Item #2- Affiliate/Owner Privacy Statement Acknowledgement

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

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

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.

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.

Item #4 - Policy and Procedure Questions

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.

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.

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.

16) 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

~~I~~INSTITUTIONAL PHARMACY PERMIT APPLICATION AND INFORMATION

DH-MQA 1215, 10/17~~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~~ 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~~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

~~Sincerely,~~

~~The Florida Board of Pharmacy~~

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

DH-MQA 1215, 10/17
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. Institutional Class I Pharmacy – 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. Institutional Class II Pharmacy Permit – 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.

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.

~~1) 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

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

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

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) 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.

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.

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:
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.

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.

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.

16) 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.

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 http://www.DEAdiversion.usdoj.gov. ~~DEA Form 224 may be obtained in paper form by writing to:~~

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

~~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. 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.

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 Item #2)?

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?

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

- Are all required signs displayed?

  - Daily operating hours pursuant to Rule 64B16-28.1081, F.A.C.

  - "Consult your pharmacist regarding the availability of a less expensive generically equivalent drug and the requirements of Florida law" pursuant to Section 465.025(7), F.S.

  - Prescription Department Closed pursuant to Rule 64B16-28.109, F.A.C.

  - Pharmacist meal breaks pursuant to Rule 64B16-27.1001(6), F.A.C.

  - Patient Consultation Area pursuant to Rule 64B16-28.1035, F.A.C.

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

- If participating in the Cancer Drug Donation Program, check question #25 on the application and submit a Notice of Participation form with the application.

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) 488-0595~~
~~http://www.doh.state.fl.us/mqa/pharmacy~~

INSTITUTIONAL PHARMACY PERMIT

~~INSTITUTIONAL PHARMACY PERMIT APPLICATION~~ APPLICATION

Application Type – Please choose one of the following:	
____ New Establishment ($255.00 fee) ____ Change of Ownership ($255.00 fee)	____ Change of Location ($100.00 fee) ____ Stock Transfer (no fee)
Pharmacy Permit Type – Please choose one of the following:	
____ Institutional Class I ____ Institutional Class II	____ Modified Institutional Class II A ____ Class II B ____ Class II C ____

SECTION A. Please complete for all Application Types

Please list your Federal Employer Identification Number: ____

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

~~____ New Establishment $255 fee~~
~~____ Change of Location $100 fee _____ (existing permit number)~~
~~____ Change of Ownership (a new permit number will be issued) $255 _____ (existing permit number)~~

~~**Type of Institutional Pharmacy Permit - Please choose one of the following:**~~
~~____ Institutional Class I ____ Institutional Class II ____ Modified Institutional Class II ____ A ____ B ____ C~~

~~**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 Consultant Pharmacist of Record and submit a set of fingerprints with $48 fee.~~

~~Name~~	~~License No.~~	~~Start Date~~	~~Signature~~

~~6. Contact Person~~	~~Telephone Number~~
~~7. DEA Registration Number~~	~~8. Date ready for inspection (must be within 90 days of the date of the application)~~

~~9. Please provide the name, address, telephone number, and permit number of your prescription drug wholesale distributor.~~

~~Name~~	~~Telephone Number~~	~~Permit Number~~	
~~Street Address~~	~~City~~	~~State~~	~~Zip~~

5. Consultant Pharmacist of Record (COR) Information	
Name	License Number
Email	Telephone Number
6. Contact Person	Title
Email	Telephone Number

~~10. Pharmacy Technician Ratio 2:1 or 3:1 (Optional)~~

~~Rule 64B16-27.410, *Florida Administrative Code*, provides that the consultant pharmacist of record be required to submit a request and receive approval from the Board of Pharmacy prior to practicing with either a 2:1 or 3:1 ratio of supervision.~~

~~If you would like to apply for the Pharmacy Technician 2:1 or 3:1 ratio, you may do so by checking the appropriate selection below. Selecting an option below serves as your official notification to the board office that you are requesting approval to practice with a 2:1 or 3:1 ratio. The board will provide notice of application approval or denial.~~

_____ ~~2:1 Ratio~~ _____ ~~3:1 Ratio~~

7~~11~~. Operating Hours

Prescription Department Hours
Monday - Friday: Open: Close:

Saturday: Open: Close: **Sunday:** Open: Close:

~~**Prescription Department Hours**~~

8~~12~~. 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. ~~Type of Ownership: Individual~~

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

Yes _____ No _____

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

Yes _____ No_____

~~If yes, provide attestation from Certified Public Accountant for previous tax year or Florida Corporate Income/Franchise and Emergency Excise Tax~~

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
~~a~~applicant including officers and members of the board of directors must submit a set of fingerprints and fees
unless you answered yes to 8~~12~~c. 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

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

9. Has anyone listed in 8.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? *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 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.)*

Yes_____ No_____

~~**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?**~~

~~Yes No~~

~~**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 _____~~

1~~1~~4a. If "yes" to 1~~1~~4, 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 _____

1~~1~~4 b. If "yes" to 1~~1~~4, 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 _____

1~~1~~4c. If "yes" to 1~~1~~14, 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 _____

1~~1~~14d. If "yes" to 1~~1~~14, 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 _____

1~~2~~5. 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_____

125a. If "yes" to 125, 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_____

136. 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 next question17.) If yes, explain on a separate sheet providing accurate details.)*

Yes No

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

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

158. 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 next two questions. If yes, please provide documents concerning this conviction.)* ~~(If no, do not~~

Yes No

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

169. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant ~~Has the applicant been~~ in good standing with a state Medicaid program or the federal

Yes No

~~(If yes, explain on a separate 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

~~**21. Is the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant currently listed on the United States Department of Health and Human Services Office of**~~

~~Yes~~ **18. Is the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant currently listed on the United States Department of Health and Human Services Office of inspector General's List of Excluded Individuals and Entities?** *(If yes, please submit proof.)*

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. (***A****ttach a separate sheet if necessary.)*

Yes No

State	Permit Type	Permit Number

23. Has the applicant, affiliated persons, partners, officer, directors, or consultant pharmacist of record ever owned a pharmacy? If yes, provide the name of the pharmacy, the state where the pharmacy is located and the status of the pharmacy. *Attach a separate sheet if necessary.*		
Yes No		
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? *(If yes, explain on a separate sheet providing accurate details.)*

Yes No

25. Is there any other permit issued by the Department of Health located at the physical location address on this application? *(If yes, explain on a separate sheet providing accurate details.)*

Yes No

26. If compounding sterile preparations, is your establishment Rule 64B16-27.797, F.A.C. compliant?

Yes No

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

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

Yes No

~~**23. Has the applicant, affiliated persons, partners, officer, directors, or consultant pharmacist of record ever owned a pharmacy? If yes, provide the name of the pharmacy, the state where the pharmacy is located and the status of the pharmacy. *Attach a separate sheet if necessary.***~~

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

~~Pharmacy Name~~	~~State~~	~~Sta~~

~~**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)~~

~~**25. 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)~~

~~**26. If compounding sterile preparations, is your establishment Rule 64B16-27.797, F.A.C. compliant?**~~

~~Yes No~~

~~**27. Is the policy and procedure manual for preventing controlled substances dispensing based on fraudulent representation or invalid practitioner-patient relationship available for inspection by DOH?**~~

~~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?**~~

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

~~**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

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.

INSTITUTIONAL PHARMACY PERMITS

_____ Application Completed (all questions answered)

_____ Application signed

_____ Pharmacy Manager or Consultant Listed with 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 consultant or record.

_____ Attach Proof from AHCA that the fingerprints are on file if applicable

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

_____ Bill of Sale is required for Change of Ownership

SECTION B. Please complete for Change of Location only.

1. Current Practice Location Address		
City	**State**	**Zip**
Email	**Telephone Number**	

2. New Practice Location Address		
City	**State**	**Zip**
Email	**Telephone Number**	

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 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? *NOTE: If yes, please complete **Section C** above and include necessary fee.*

Yes No

ALL QUESTIONS MUST BE ANSWERED OR YOUR APPLICATION WILL BE RETURNED

****

Section 456.013(1), F.S., requires that applicants supplement their applications as needed to reflect any material change in any circumstances or conditions stated in the application, which takes place between the initial filing of the application and the final grant or denial of the license, which might affect the decision of the department.

I 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)

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 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 of Birth: _____
(MM/DD/YYYY)

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 Scan Service provider*.)

Keep this form for your records.

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

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

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

Section A. Consultant Pharmacist of Record (COR) Designation

Applicant/Pharmacy Name:		
Applicant/Pharmacy Mailing Address:		
City	**State**	**Zip**
Incoming COR Name:		**License#:**
		PU
Date Beginning as COR:	**Incoming COR Signature**	
COR Transaction Control Number (TCN) – related to Livescan Fingerprints:		
Only provide following information is there is an Outgoing COR at current pharmacy location.		
Outgoing COR Name:		**License#:**
		PU
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."

Date:	Incoming COR Signature

Item #2- Affiliate/Owner Privacy Statement Acknowledgement

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

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

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.

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.

Item #4 - Policy and Procedure Questions

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.

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.

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.

16) 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

NUCLEAR PHARMACY PERMIT APPLICATION AND INFORMATION

October 2017

DH-MQA 1218, 10/17
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 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..

Application Processing - Please read all application instructions before completing your application.

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 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 http://www.DEAdiversion.usdoj.gov.

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. 465.003(14) or s. 893.02 when the pharmacist knows or has reason to believe that the purported prescription is not based upon a valid practitioner-patient relationship that includes a documented patient evaluation, including history and a physical examination adequate to establish the diagnosis for which any drug is prescribed and any other requirement established by board rule under chapter 458, chapter 459, chapter 461, chapter 463, chapter 464, or chapter 466.

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

PRE-INSPECTION CHECKLIST

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. 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.**

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

NUCLEAR PHARMACY PERMIT

APPLICATION

Application Type – Please choose one of the following:

____ New Establishment $255 fee	____ Change of Location $100 fee
____ Change of Ownership $255 fee	____ Stock Transfer (no fee)

SECTION A. Please complete for all Application Types

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 the Nuclear Pharmacist Department Manager Information:

Name	License Number (PS and NP)

Email	Telephone Number

6. Contact Person	Telephone Number

Email	Phone Number

7. Operating Hours

Prescription Department Hours

Monday-Friday: Open _____ Close: _____

Saturday: Open: _____ Close: _____

Sunday: Open: _____ Close: _____

8. Ownership Information

a. Type of Ownership: _____Individual _____Corporation _____Partnership

_____Other: _____

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

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

Yes _____ No _____

c. Does the corporation have more than $100 million of business taxable assets in this state?

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

d. List all the owners and officers of the corporation. Each person listed below having an ownership interest of 5 percent or greater and any person who, directly or indirectly, manages, oversees, or controls the operation of the applicant including officers and members of the board of directors must submit a set of fingerprints and fees unless you answered yes to 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
	/ /		%
	/ /		%
	/ /		%
	/ /		%
	/ /		%
	/ /		%

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 entity was closed.

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?

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

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?

Yes _____ No _____ If yes, please provide documents concerning this conviction.

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

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

16. 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)

17. 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)

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

Yes _____ No _____ (If yes please submit proof)

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

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

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

No _____ Yes _____ (If yes, explain on a separate sheet providing accurate details and submit documentation from the licensing agency who took the disciplinary action)

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

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

23. 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)

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 28d.

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

24d. Does the applicant, affiliated person, partner, officer, director have a repayment plan approved by the department?

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

City	**State**	**Zip**

Email	**Telephone Number**

2. New Practice Location Address

City	**State**	**Zip**

Email	**Telephone Number**

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

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 the 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)

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 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 of Birth: _____
(MM/DD/YYYY)

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

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

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

Citizenship: _____

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

Keep this form for your records.

Item #1- Nuclear Pharmacist Designation and Privacy Statement Acknowledgement

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

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

Section A. Nuclear Pharmacist Designation

Applicant/Pharmacy Name:		
Applicant/Pharmacy Mailing Address:		
City	**State**	**Zip**
Incoming Nuclear Pharmacist Name:		**License#:**
		PS
Date Beginning:	**Incoming Nuclear Pharmacist Signature**	
PDM Transaction Control Number (TCN) – related to Livescan Fingerprints:		
Only provide following information is there is an Outgoing PDM at current pharmacy location.		
Outgoing Nuclear Pharmacist Name:		**License#:**
		PS
Date Ending as PDM:		

Section B. Incoming PDM Privacy Statement Acknowledgement

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

I have been provided and read the statement from the Florida Department of Law Enforcement regarding the sharing, retention, privacy and right to challenge incorrect criminal history records and the "Privacy Statement" document from the Federal Bureau of Investigation."

Date:	Incoming 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
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		

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:
    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.
    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

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

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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 ~~mqa_pharmacy@doh.state.fl.us~~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..

Application Processing -

Please read all application instructions before completing your application.

1) Mail 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:

Application & Fees:	**Express Mail ONLY**
Department of Health	Department of Health
Board of Pharmacy	Board of Pharmacy
P.O. Box 6320	4052 Bald Cypress Way, Bin C-04
Tallahassee, Florida 32314-6320	Tallahassee, FL 32399-3254

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

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

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

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

~~2)~~ Submit fingerprint results.

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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 Ddepartment?
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.

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 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.

~~4) 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:~~
~~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:

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.

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.

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 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/mqa under "Lookup Licensee."**~~

Drug Enforcement Administration (DEA)

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

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

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

~~Mail completed DEA Form 224 via U.S. Postal service to the address listed on the form.~~
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 ~~D~~department or ~~B~~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

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

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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. Final approval for inspection can not be granted until the application is complete. Faxed applications will not be accepted.

NUCLEAR PHARMACY PERMIT~~:S~~

_____ **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.**

~~INSTITUTIONAL~~
NUCLEAR
PHARMACY
~~PERMIT~~

~~_____ 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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~~F.A.C.?~~

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

~~_____ Are all required signs displayed?~~

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

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

~~_____Does the pharmacy meet the minimum Nuclear Pharmacy requirements in Rule 64B16-28.902, F.A.C?~~

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

~~NUCLEAR PHARMACY PERMIT~~ APPLICATION

Application Type – Please choose one of the following:

~~**Application Type – Please choose one of the following:**~~	
____ New Establishment $255 fee _____~~Additional Permit Type $255 fee~~ _____~~(existing permit number)~~ ____ Change of Ownership ~~Location~~ $255~~100~~ fee _____~~(existing permit number)~~	____ Change of Location $100 fee~~Ownership~~ _____ Stock Transfer (no fee)~~(a new permit number will be issued)~~ ~~$255~~ _____~~(existing permit number)~~

SECTION A. Please complete for all Application Types

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 the Nuclear Pharmacist Department Manager Information:		
Name ~~License No.~~ ~~Start Date~~		~~Signature~~License Number (PS and NP)
Email		Telephone Number

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6. Contact Person	**Telephone Number**
Email	**Phone Number**
~~**7. DEA Registration Number**~~	~~**8. Date ready for inspection (within 90 days)**~~

~~**9. Please provide the name, address, telephone number, and permit number of your prescription drug wholesale distributor.**~~

~~**Name**~~	~~**Telephone Number**~~	~~**Permit Number**~~	
~~**Street Address**~~	~~**City**~~	~~**State**~~	~~**Zip**~~

~~**10. Pharmacy Technician Ratio 2:1 or 3:1 (Optional)**~~

~~Rule 64B16-27.410, *Florida Administrative Code*, provides that the prescription department manager or consultant pharmacist of record is required to of record issubmit a written request and receive approval from the Board of Pharmacy prior to the pharmacy allowing a pharmacist to supervise more than one registered pharmacy technician. If you would like to apply for the Registered Pharmacy Technician 2:1 or 3:1 ratio, you may do so by checking the appropriate selection below. Selecting an option below serves as your written request to the board office for approval to practice with a 2:1 or 3:1 ratio.~~

~~_____ 2:1 Ratio _____ 3:1 Ratio~~
~~(please attach a brief description of the workflow needs that include the operating hours of the pharmacy, number of pharmacist, registered interns and registered pharmacy technicians employed to justify the ratio request)~~

~~Rule 64B16-27.410, *Florida Administrative Code*, provides that the prescription department manager of record isbe required to submit a request and receive approval from the Board of Pharmacy prior to practicing with either a 2:1 or 3:1 ratio of supervision.~~

~~If you would like to apply for the Pharmacy Technician 2:1 or 3:1 ratio, you may do so by checking the appropriate selection below. Selecting an option below serves as your official notification to the board office that you are requesting approval to practice with a 2:1 or 3:1 ratio. The board will provide notice of application approval or denial~~

~~_____ 2:1 Ratio _____ 3:1 Ratio~~

7~~11~~. Operating Hours

~~**Store/Facility Hours**~~

~~Monday-Friday: Open _____ Close: _____~~

~~Saturday: Open: _____ Close: _____~~

~~Sunday: Open: _____ Close: _____~~

Prescription Department Hours

Monday-Friday: Open _____ Close: _____

Saturday: Open: _____ Close: _____

Sunday: Open: _____ Close: _____

8~~12~~. Ownership Information

a. Type of Ownership: _____Individual _____Corporation _____Partnership

_____Other: _____

~~Federal Employer Identification Number: _____~~

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

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

Yes _____ No _____

c. Does the corporation have more than $100 million of business taxable assets in this state?

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

d. List all the owners and officers of the corporation. Each person listed below having an ownership interest of 5 percent or greater and any person who, directly or indirectly, manages, oversees, or controls the operation of the applicant including officers and members of the board of directors must submit a set of fingerprints and fees unless you answered yes to 8~~12~~c. If 8~~12~~c is yes please list the owners below and only submit fingerprints for the Prescription Department Manager or Consultant Pharmacist of Record. If 8~~12~~c 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
	/ /		%
	/ /		%
	/ /		%
	/ /		%
	/ /		%
	/ /		%

9~~13~~. Has anyone listed in 8~~12~~.d had an ownership interest of 5% or more in a pharmacy or any other business permit which was disciplined, suspended, revoked, or closed involuntarily within the past 5 years?

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

9~~13~~a. Has anyone listed in 8~~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.

10~~14~~. Has anyone listed in 8~~12~~.d ever obtained a pharmacy permit by misrepresentation or fraud or been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to health care fraud?

Yes _____ No _____ If yes, please provide documents concerning this conviction.

Pursuant to Section 456.0635(2) and 465.022 (5), Florida Statutes, questions 115 through 1721 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 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 _____

115a. 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?

Yes _____ No _____

115b. 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).

Yes_____ No_____

115c. 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?

Yes_____ No_____

115d. 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).

Yes_____ No _____

12.6. 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 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)**

137. 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)

148. 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)

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 sheet providing accurate details)

1620. 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)

1721. 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)

1822. Is the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant listed on the United States Department of Health Human Services Office of Inspector General's List of Excluded Individuals and Entities?

Yes _____ No _____ (If yes please submit proof)

1923. 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

2024. 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

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

No _____ Yes _____ (If yes, explain on a separate sheet providing accurate details and submit documentation from the licensing agency who took the disciplinary action)

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

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

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

YesNo _____ NoYes _____ (If yes, explain on a separate sheet providing accurate details)

248. 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.

YesNo _____ NoYes _____ (If yes, explain on a separate sheet providing accurate details)

248d. Does the applicant, affiliated person, partner, officer, director have a repayment plan approved by the department?

YesNo _____ NoYes _____ (If yes, explain on a separate sheet providing accurate details)

259. 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?

YesNo _____ NoYes _____

SECTION B. Please complete for a Change of Location only

1. Current Practice Location Address

City	**State**	**Zip**

Email	**Telephone Number**

2. New Practice Location Address

City	**State**	**Zip**

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Email	Telephone Number

~~Please provide the name, address, telephone number, and permit number of your prescription drug wholesale distributor.~~

~~Name~~	~~Permit Number~~	~~Telephone Number~~

~~Street Address~~	~~City~~	~~State~~	~~Zip~~

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

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 the necessary fee

ALL QUESTIONS MUST BE ANSWERED OR YOUR APPLICATION WILL BE RETURNED

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Section 456.013(1), F.S., requires that applicants supplement their applications as needed to reflect any material change any circumstances or conditions stated in the application, which takes place between the initial filing of the application a

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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)

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

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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.

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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).

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/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.

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Name:_____ SSN#: _____-____-_____

Aliases:_____

Address: _____ Apt. Number: _____

City: _____ State: _____ Zip Code: _____

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

Weight: Height: Eye Color: Hair Color: _____

Race: _____ Sex: _____
(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.*)

Keep this form for your records.

Item #1- Nuclear Pharmacist 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):

License #: (if applicable)

Section A. Nuclear Pharmacist Designation

Applicant/Pharmacy Name:		
Applicant/Pharmacy Mailing Address:		
City	**State**	**Zip**
Incoming Nuclear Pharmacist Name:		**License#:**
		PS
Date Beginning:	**Incoming Nuclear Pharmacist Signature**	

PDM Transaction Control Number (TCN) – related to Livescan Fingerprints:		
Only provide following information is there is an Outgoing PDM at current pharmacy location.		
Outgoing Nuclear Pharmacist Name:		**License#:**
		PS
Date Ending as PDM:		
Section B. Incoming PDM Privacy Statement Acknowledgement		
Note: Acknowledgment should be completed by same person listed in Section A above as Incoming PDM.		
I have been provided and read the statement from the Florida Department of Law Enforcement regarding the sharing, retention, privacy and right to challenge incorrect criminal history records and the "Privacy Statement" document from the Federal Bureau of Investigation."		
Date:	**Incoming Nuclear Pharmacist Signature**	

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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

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Affiliate / Owner Name:	**File # (required):**
Applicant Name:	

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From:

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)**

~~**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 Permitist's license 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)~~

Item #3 - Policy and Procedure Questions

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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 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.

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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 cleanin agents, clean towels, hand-washing materials with bactericidal properties, vacuum containers/transf 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.

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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 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 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:
Firm Name:
Doing business as (d/b/a):
Telephone number:
Address:
Permit number (if already licensed as an institutional pharmacy):

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- 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 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.
- 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

DH-MQA 1220, 08/12
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 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 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 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.flhealthsource.gov/background-screening .

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 http://www.DEAdiversion.usdoj.gov. DEA Form 224 may be obtained in paper form by writing to:

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

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. 465.003(14) or s. 893.02 when the pharmacist knows or has reason to believe that the purported prescription is not based upon a valid practitioner-patient relationship that includes a documented patient evaluation, including history and a physical examination adequate to establish the diagnosis for which any drug is prescribed and any other requirement established by board rule under chapter 458, chapter 459, chapter 461, chapter 463, chapter 464, or chapter 466.

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

PRE-INSPECTION CHECKLIST

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

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 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

SPECIAL PHARMACY PERMIT

APPLICATION

Application Type – Please choose one of the following:	
____ New Establishment $255.00 fee	____ Change of Location $100 fee
____ Change of Ownership $255.00 fee	____ Stock Transfer – No fee

Pharmacy Permit Type – Please choose permit type(s) ($255 for each type)

Type of Special Pharmacy Permit - Please choose permit type:

_____Special- Limited Community ____Special- Parenteral and Enteral ____ Special- Closed System Pharmacy
_____Special- ESRD ____ Special- Parenteral/Enteral Extended Scope____ Special- ALF

SECTION A. Please Complete for all Application Types

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**
6. Contact Person	**Title**
Email Address	**Telephone Number**

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 Number	
Street Address	**City**	**State**	**Zip**

8. Operating Hours

Prescription Department Hours

Monday-Friday: Open _____ Close: _____

Saturday: Open: _____ Close: _____

Sunday: Open: _____ Close: _____

8a. Special- Parenteral & Enteral; Provide Toll-Free Telephone Number Below:

(_____) _____- _____

9. Ownership Information

a. Type of Ownership: _____Individual _____Corporation _____Partnership

_____Other: _____

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

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

Yes _____ No _____

c. Does the corporation have more than $100 million of business taxable assets in this state?

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

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 disclosing the reason the 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.

11. Has anyone listed in 9.d ever obtained a pharmacy permit by misrepresentation or fraud or been convicted of, or entered a plea of guilty or nolo contender to, regardless of adjudication, a crime in any jurisdiction which relates to health care fraud?

Yes _____ No _____ If yes, please provide documents concerning this conviction.

Pursuant to Section 456.0635(2) and 465.022(5), *Florida Statutes*, questions 12 through 18 are being asked. If you answer yes to any of the following questions, explain on a separate sheet providing accurate details and submit copies of supporting documentation.

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 _____

12a. If "yes" to 12, 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_____

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_____ No _____(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_____

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 18.)

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

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)

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

Yes _____ No _____

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.*

Yes _____ No _____ (If yes, please list them below, you may provide additional sheet)

Pharmacy Name	State	Status

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

Yes _____ No _____

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

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

24. 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)

25. 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 28a.

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

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

Yes _____ No_____

26. 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 _____

27. Will the Pharmacy Dispense Schedule II and/or III Controlled Substances?

Yes _____ No _____

SECTION B. Please complete for Change of Location ONLY

1. Current Practice Location Address

City	State	Zip

Email Address	Telephone Number

2. New Practice Location Address

City	State	Zip

Email Address	Telephone Number

Please provide your existing Pharmacy Permit Number(s): _____

Please provide your existing Federal DEA Number: _____

SECTION C. Please complete for a Change of Ownership ONLY

1. Are you changing physical locations with this change of ownership?

Yes _____ No _____

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 permit license should be transferred? Note: A copy of the signed letter should be provided with your application

Yes _____ No _____

Please provide your existing Pharmacy Permit Number(s): _____
(Existing permits will be closed and new permit number(s) issued under new ownership)

Please provide your existing Federal DEA Number: _____

SECTION D. Please complete for a Stock Transfer of Ownership ONLY

1. Please provide the date 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 _____

If yes, please complete Section C above and include the necessary fee.

Please provide your existing Pharmacy Permit Number(s): _____

Please provide your existing Federal 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.

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

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 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 of Birth: _____
(MM/DD/YYYY)

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

Race: _____ Sex: _____
(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*.)

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)**:**

Section A. Consultant Pharmacist of Record (COR) or Prescription Department Manager (PDM) Designation

Applicant/Pharmacy Name:		
Applicant/Pharmacy Mailing Address:		
City	**State**	**Zip**
Incoming COR/PDM Name:		**License#:**
Date Beginning as COR/PDM:	**Incoming COR/PDM Signature**	
COR/PDM Transaction Control Number (TCN) – related to Livescan Fingerprints:		
*****Only provide following information 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 Statement Acknowledgement

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

I have been provided and read the statement from the Florida Department of Law Enforcement regarding the sharing, retention, privacy and right to challenge incorrect criminal history records and the "Privacy Statement" document from the Federal Bureau of Investigation."

Date:	**Incoming COR/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/Owner Telephone Number**	
Affiliate/Owner Transaction Control Number (TCN) – related to Livescan Fingerprints:		

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."

_____ _____

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

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:
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:

    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.

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.

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 ~~mqa_pharmacy@doh.state.fl.us~~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 ~~esix~~ight (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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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

~~20~~

~~if you ar~~

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

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

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

~~b)~~ You must provide the correct ORI number.

~~3.~~ Where do I get the ORI number to submit to the vendor?
The ORI number for the pharmacy profession is **EDOH4680Z**~~FL924190Z~~

~~3)~~ 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 policy and procedure manual. The permittee must make available the policy and procedure~~

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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:
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:
a. Used needles and syringes.
b. 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:~~
~~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.~~
~~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/mqa under "Lookup Licensee."**

Drug Enforcement Administration (DEA)

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

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

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

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.

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

~~Are all required signs displayed?~~

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

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

~~You may download a copy of the inspection form from the website at http://doh.state.fl.us/mqa/enforcement/enforce_forms.html~~

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

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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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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 DEPARTMENT OF HEALTH

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

~~INSTITUTIONAL~~ SPECIAL PHARMACY ~~PERMIT~~

~~SPECIAL PHARMACY PERMIT~~ APPLICATION

Application Type – Please choose one of the following:

____ New Establishment $255.00 fee	____ Change of Location $100 fee
____ Change of Ownership $255.00 fee	____ Stock Transfer – No fee

Pharmacy Permit Type – Please choose permit type(s) ($255 for each type)

Type of Special Pharmacy Permit - Please choose permit type:

____ Special- Limited Community ____ Special- Parenteral and Enteral ____ Special- Closed System Pharmacy
____ Special- ESRD ____ Special- Parenteral/Enteral Extended Scope ____ Special- ALF

SECTION A. Please Complete for all Application Types

~~**Application Type – Please choose one of the following:**~~
~~____ New Establishment $255 fee~~
~~____ 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~~

~~____ Community/Special Parenteral and Enteral ____ Special- Closed System Pharmacy/Parenteral and Enteral~~

~~**Will the Pharmacy Dispense Schedule II and/or III Controlled Substances?**~~
~~____ Yes ____ No~~**SECTION A. Please Complete for all Application Types**

Please list your Federal Employer Identification Number:~~er~~ _____

1. Corporate Name	Telephone Number

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

3. Mailing Address

City	State	Zip

4. Physical Address

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City	State	Zip

5. List Prescription Department Manager (PDM) or Consultant Pharmacist of Record

Name	~~License No.~~ ~~Start Date~~ ~~Signature~~License Number
Email Address	Telephone Number
6. Contact Person	~~Telephone Number~~Title
Email Address	Telephone Number
~~7. DEA Registration Number~~	~~8. Date ready for inspection (must be within 90 days of the date of the application)~~

~~9~~. **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 Number	
Street Address	**City**	**State**	**Zip**

~~10. Pharmacy Technician Ratio 2:1 or 3:1 (Optional)~~

~~Rule 64B16-27.410, *Florida Administrative Code*, provides that the prescription department manager or consultant pharmacist of record is required to of record issubmit a written request and receive approval from the Board of Pharmacy prior to the pharmacy allowing a pharmacist to supervise more than one registered pharmacy technician. If you would like to apply for the Registered Pharmacy Technician 2:1 or 3:1 ratio, you may do so by checking the appropriate selection below. Selecting an option below serves as your written request to the board office for approval to practice with a 2:1 or 3:1 ratio.~~

~~_____ 2:1 Ratio _____ 3:1 Ratio~~

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

~~8~~11. Operating Hours	~~8~~11a. Special- Parenteral & Enteral; Provide Toll-Free Telephone Number Below:
Prescription Department Hours	

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Monday-Friday: Open _____ Close: _____ (_____) _____- _____

Saturday: Open: _____ Close: _____

Sunday: Open: _____ Close: _____

912. Ownership Information

a. Type of Ownership: _____Individual _____Corporation _____Partnership

_____Other: _____

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

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

Yes _____ No _____

c. Does the corporation have more than $100 million of business taxable assets in this state?

Yes _____ No _____ If yes, provide attestation from Certified Public Accountant for previous tax year or Florida Corporate Income/Franchise and Emergency Excise Tax Return (F-1120). 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 912c. If 912c. is yes please list the owners below and only submit fingerprints for the Prescription Department Manager or Consultant Pharmacist of Record. If 912c. 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
	/ /		%
	/ /		%
	/ /		%
	/ /		%
	/ /		%

103. Has anyone listed in 912.d had an ownership interest of 5% or more in a pharmacy or any other business permit which was disciplined, suspended, revoked, or closed involuntarily within the past 5 years?

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

103a 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.

114. Has anyone listed in 912.d ever obtained a pharmacy permit by misrepresentation or fraud or been convicted of, or entered a plea of guilty or nolo contender to, regardless of adjudication, a crime in any jurisdiction which relates to health care fraud?

Yes _____ No _____ If yes, please provide documents concerning this conviction.

Pursuant to Section 456.0635(2) and 465.022(5), *Florida Statutes*, questions 125 through 1821 are being asked. If

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you answer yes to any of the following questions, explain on a separate sheet providing accurate details and submit copies of supporting documentation.

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 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 _____

125a. If "yes" to 125, 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_____

125b. If "yes" to 152, 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**_____

125c. If "yes" to 125, 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** _____

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?

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

136a. If "yes" to 136, 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_____~~

Yes_____ No_____

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 18.)

Yes _____ No _____ (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 Medicaid Program for the most recent five years?

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

169. 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)

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

Yes _____ No _____

1720. 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)

1821. 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)

1922. 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)

2023. 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

2124. 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.*

Yes _____ No _____ (If yes, please list them below, you may provide additional sheet)

Pharmacy Name	State	Status

2225. 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? *(If yes, explain on a separate sheet providing accurate details and submit documentation from the licensing agency who took the disciplinary action).*

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Yes _____ No _____ ~~(If yes, explain on a separate sheet providing accurate details and submit documentation from the licensing agency who took the disciplinary action)~~

2326. Has the applicant, or any officer, member or partner ever been convicted of a felony or misdemeanor, excluding minor traffic convictions?

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

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2427. **Is there any other permit issued by the Department of Health located at the physical location address on this application?**
YesNo _____ NoYes _____ (If yes, explain on a separate sheet providing accurate details)
2528. **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 28a.**
YesNo _____ NoYes _____ (If yes, explain on a separate sheet providing accurate details)
25.8a. **Does the applicant, affiliated person, partner, officer, director have a repayment plan approved by the department?**
Yes No_____ YesNo_____
269. **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?**
YesNo _____ NoYes _____
27. Will the Pharmacy Dispense Schedule II and/or III Controlled Substances?
Yes _____ No _____

SECTION B. Please complete for Change of Location ONLY

1. Current Practice Location Address

City	State	Zip

Email Address	Telephone Number

2. New Practice Location Address

City	State	Zip

Email Address	Telephone Number

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Please provide your existing Pharmacy Permit Number(s): _____

Please provide your existing Federal DEA Number: _____

SECTION C. Please complete for a Change of Ownership ONLY

1. **Are you changing physical locations with this change of ownership?**

Yes No

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 permit license should be transferred?** Note: A copy of the signed letter should be provided with your application

Yes No

Please provide your existing Pharmacy Permit Number(s): _____
(Existing permits will be closed and new permit number(s) issued under new ownership)

Please provide your existing Federal DEA Number: _____

SECTION D. Please complete for a Stock Transfer of Ownership ONLY

Please provide the date the transfer of ownership interest took place?

1.

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

If yes, please complete Section C above and include the necessary fee.

Please provide your existing Pharmacy Permit Number(s): _____

Please provide your existing Federal DEA Number: _____

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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 Permit~~ist'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.

COMMUNITY/SPECIAL- PARENTERAL & ENTERAL OR SPECIAL PARENTERAL &ENTERAL

_____ **Application completed (all questions answered)**

_____ **Application signed**

_____ **Consultant Pharmacist of Record/Prescription Department Manager Listed with Signature**

_____ **$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.**

_____ **Attach proof from AHCA of fingerprint results if applicable for 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**

_____ **Bill of Sale is required for Change of Ownership**

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OTICE 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 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,

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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.

Name: _____ SSN#: ___-___-____

Aliases: _____

Address: _____ Apt. Number: _____

City: _____ State: _____ Zip Code: _____

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

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

Race: _____ Sex: _____
(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.)

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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):

Section A. Consultant Pharmacist of Record (COR) or Prescription Department Manager (PDM) Designation

Applicant/Pharmacy Name:		
Applicant/Pharmacy Mailing Address:		
City	**State**	**Zip**
Incoming COR/PDM Name:		**License#:**
Date Beginning as COR/PDM:	**Incoming COR/PDM Signature**	
COR/PDM Transaction Control Number (TCN) – related to Livescan Fingerprints:		

Only provide following information 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:	~~**Outgoing COR/PDM Signature**~~	

Section B. Incoming COR/PDM Privacy Statement Acknowledgement

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

I have been provided and read the statement from the Florida Department of Law Enforcement regarding the sharing, retention, privacy and right to challenge incorrect criminal history records and the "Privacy Statement" document from the Federal Bureau of Investigation."

Date:	Incoming COR/PDM Signature

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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/Owner Telephone Number

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

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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."

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Affiliate/Owner Signature (Required) **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:
   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.

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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.

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.

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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

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@flhealth.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

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 http://www.DEAdiversion.usdoj.gov

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).

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/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.

If controlled substances will be involved in your pharmacy practice, you must make an Application for Registration under the Controlled Substance Act of 1970 with the DEA. If possible, you are encouraged to use the on-line form system provided by the DEA. Information

is available by visiting their website at http://www.DEAdiversion.usdoj.gov. DEA Form 224 may be obtained in paper form by writing to:

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

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. 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**

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

SPECIAL PHARMACY PERMIT

APPLICATION

Application Type – Please choose one of the following:	
____ New Establishment ($255 fee) ____ Change of Ownership ($255 fee)	____ Change of Location $100 fee ____ Stock Transfer (no fee)

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	**Telephone Number**
6. Contact Person	**Telephone Number**
7. DEA Registration Number	

8. Operating Hours

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 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.

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
	/ /		%
	/ /		%
	/ /		%

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 disclosing the reason the entity was closed.

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?

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

12. Has anyone listed in 9.d ever obtained a pharmacy permit by misrepresentation or fraud or been convicted of, or entered a plea of guilty or nolo contender to, regardless of adjudication, a crime in any jurisdiction which relates to health care fraud?

Yes _____ No _____ If yes, please provide documents concerning this conviction.

Pursuant to Section 456.0635(2) and 465.022(5), *Florida Statutes*, questions 14 through 23 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.

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 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 _____

13a. If "yes" to 13, 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_____

13b. If "yes" to 13, 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_____

13c. If "yes" to 13, 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 _____

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 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)

14a. If "yes" to 14, 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. 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)

16. 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 _____

17. 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)

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

Yes _____ No _____

18. Has the applicant been in good standing with a state Medicaid program or the federal Medicare program for the most recent five years?

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

Yes _____ No _____

19. 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 _____

20. 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)

21. 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_____

22. 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 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.*

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

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?

Yes _____ No _____

ALL QUESTIONS MUST BE ANSWERED OR YOUR APPLICATION WILL BE RETURNED

****

Section 456.013(1), F.S., requires that applicants supplement their applications as needed to reflect any material change in any circumstances or conditions stated in the application, which takes place between the initial filing of the application and the final grant or denial of the license, which might affect the decision of the department.

I 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

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/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:_____ SSN#: _____ - ____ - _____

Aliases:_____

Address: _____ Apt. Number: _____

City:_____State: _____Zip Code: _____

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

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

Race: _____ Sex: _____
(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*.)

Keep this form for your records.

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

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

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

Section A. PDM or Consultant of Record

Applicant/Pharmacy Name:		
Applicant/Pharmacy Mailing Address:		
City	**State**	**Zip**
Incoming PDM/Consultant Name:		**License#:**
		PS
Date Beginning as PDM/Consultant:	**Incoming PDM/Consultant Signature**	
PDM/Consultant Transaction Control Number (TCN) – related to Livescan Fingerprints:		
*****Only provide following information is there is an Outgoing PDM at current pharmacy location.*****		
Outgoing PDM/Consultant Name:		**License#:**
		PS
Date Ending as PDM/Consultant:		

Section B. Incoming PDM Privacy Statement Acknowledgement

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

I have been provided and read the statement from the Florida Department of Law Enforcement regarding the sharing, retention, privacy and right to challenge incorrect criminal history records and the "Privacy Statement" document from the Federal Bureau of Investigation."

Date:	**Incoming PDM/Consultant 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

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 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.

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.

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.

9) 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.

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.

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@flhealth.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

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 http://www.DEAdiversion.usdoj.gov

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.

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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 ~~www.doh.state.fl.us/mqa/pharmacy.~~ 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)~~ ~~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).

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~~**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.

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.

9) 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.

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.

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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 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.

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

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

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, 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.~~
- ~~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:

~~http://doh.state.fl.us/mqa/enforcement/enforce_forms.html~~
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. Final approval for inspection cannot be granted until the application is complete. Faxed applications will not be accepted.

_____ **Application completed (all questions answered)**

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_____ 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

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(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.

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

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FLORIDA BOARD OF PHARMACY
P.O. Box 6320
Tallahassee, FL 32314-6320
Telephone (850) 488-0595
http://www.floridaspharmacy.gov
/mqa/pharmacy

SPECIAL PHARMACY PERMIT

~~**STERILE COMPOUNDING PHARMACY PERMIT**~~ **APPLICATION**

Application Type – Please choose one of the following:	
~~Application Type – Please choose one of the following:~~ ____ **New Establishment ($255 fee)** ____ Change of Ownership ($255 fee) ____ ~~Existing Permit (No Fee Required)~~ _____ ~~Existing Permit Number~~	____ **Change of Location $100 fee** _____ ~~(existing sterile compounding permit number)~~ ____ ~~Change of Ownership (a new permit number will be issued) $255~~ _____ ~~(existing sterile compounding permit number)~~ ____ Stock Transfer (no fee)

Please List your Federal Employer Identification Number:
~~Will the Pharmacy Dispense Schedule II and/or III Controlled Substances? ___Yes ___No~~
~~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 Numbero. ~~Start Date~~ ~~Signature~~

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Email	Telephone Number

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6. Contact Person	Telephone Number

7. DEA Registration Number	8. Date ready for inspection (must be within 90 days of the date of the application)

9. 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 Number	
Street Address	**City**	**State**	**Zip**

10. Pharmacy Technician Ratio 2:1 or 3:1 (Optional)

Rule 64B16-27.410, *Florida Administrative Code*, provides that the prescription department manager or consultant pharmacist of record is required to of record issubmit a written request and receive approval from the Board of Pharmacy prior to the pharmacy allowing a pharmacist to supervise more than one registered pharmacy technician. If you would like to apply for the Registered Pharmacy Technician 2:1 or 3:1 ratio, you may do so by checking the appropriate selection below. Selecting an option below serves as your written request to the board office for approval to practice with a 2:1 or 3:1 ratio.

_____ 2:1 Ratio _____ 3:1 Ratio

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

8.911. Operating Hours	11a. Provide Toll Free Telephone Number (If applicable.)
Prescription Department Hours	
Monday-Friday: Open _____ Close: _____	(_____) _____ - _____
Saturday: Open: _____ Close: _____	Sunday: Open: _____ Close: _____
Sunday: Open: _____ Close: _____	

9102. 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. ~~a. Type of Ownership:~~
~~_____Individual _____Corporation _____Partnership~~
~~_____Other: _____~~

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

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

Yes _____ No _____

c. Does the corporation have more than $100 million of business taxable assets in this state?

Yes _____ No _____ If yes, provide attestation from Certified Public Accountant for previous tax year or Florida Corporate Income/Franchise and Emergency Excise Tax Return (F-1120). 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 9~~12~~c. If 9~~12~~c is yes, please list the owners below and only submit fingerprints for the Prescription Department Manager or Consultant Pharmacist of Record. If 9~~12~~c 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
	/ /		%
	/ /		%
	/ /		%

10~~1~~3. Has anyone listed in 9~~10~~2.d had an ownership interest of 5% or more in a pharmacy or any other business permit which was disciplined, suspended, revoked, or closed involuntarily within the past 5 years?

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

11~~2~~3.~~a~~ Has anyone listed in 10~~2~~.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.

12~~3~~4. Has anyone listed in 9~~12~~.d ever obtained a pharmacy permit by misrepresentation or fraud or been convicted of, or entered a plea of guilty or nolo contender to, regardless of adjudication, a crime in any jurisdiction which relates to health care fraud?

Yes _____ No _____ If yes, please provide documents concerning this conviction.

Pursuant to Section 456.0635(2) and 465.022(5), *Florida Statutes*, questions 1~~4~~5 through 23 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.

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 Section 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?

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

Yes _____ No _____

178~~9~~. 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~~1~~ and 21~~2~~)

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

Yes _____ No _____

18~~920~~. Has the applicant been in good standing with a state Medicaid program or the federal Medicare program for the most recent five years?

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

Yes _____ No _____

19~~20~~21. 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 _____

201~~2~~. 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)

212~~3~~. 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_____

223~~4~~. 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

234~~5~~. 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.*

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Yes _____ No _____ (If yes, please list them below, you may provide additional sheet)

Pharmacy Name	State	Status

24~~5~~6. 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~~6~~7. Has the applicant, or any officer, member or partner ever been convicted of a felony or misdemeanor, excluding minor traffic convictions?

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

26~~7~~8. 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~~8~~9. 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~~29a~~. Does the applicant, affiliated person, partner, officer, director have a repayment plan approved by the department?

Yes_____ No_____

29~~30~~. 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?

Yes_____ No_____

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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 Permit~~cist'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

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 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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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: _____ Social Security Number: _____

Aliases: _____

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

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

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

Eye Color: _____ Hair Color: _____

Address: _____ Apt. Number: _____

City: _____ State: _____ Zip Code: _____

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

Keep this form for your records.

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

~~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

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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.

- 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.

Name: _____ SSN#: ___ - ___ - ____

Aliases: _____

Address: _____ Apt. Number: _____

City: _____ State: _____ Zip Code: _____

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

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

Race: _____ Sex: _____
(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.*)

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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
info@floridaspharmacy.gov

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

Section A. PDM or Consultant of Record

Applicant/Pharmacy Name:		
Applicant/Pharmacy Mailing Address:		
City	**State**	**Zip**
Incoming PDM/Consultant Name:		**License#:**
		PS
Date Beginning as PDM/Consultant:	**Incoming PDM/Consultant Signature**	

PDM/Consultant Transaction Control Number (TCN) – related to Livescan Fingerprints:

Only provide following information is there is an Outgoing PDM at current pharmacy location.

Outgoing PDM/Consultant ~~utant~~ Name:	License#:
	PS
Date Ending as PDM/Consultant:	

Section B. Incoming PDM Privacy Statement Acknowledgement

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

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I have been provided and read the statement from the Florida Department of Law Enforcement regarding the sharing, retention, privacy and right to challenge incorrect criminal history records and the "Privacy Statement" document from the Federal Bureau of Investigation."	
Date:	**Incoming PDM/Consultant 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

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."

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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.

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.

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.

9) 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.

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.

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

DH-MQA 1216, 10/17
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 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.

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:

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 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.

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

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. 465.003(14) or s. 893.02 when the pharmacist knows or has reason to believe that the purported prescription is not based upon a valid practitioner-patient relationship that includes a documented patient evaluation, including history and a physical examination adequate to establish the diagnosis for which any drug is prescribed and any other requirement established by board rule under chapter 458, chapter 459, chapter 461, chapter 463, chapter 464, or chapter 466.

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

PRE-INSPECTION CHECKLIST

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

INTERNET PHARMACY PERMIT

APPLICATION

Application Type – Please choose one of the following:	
____ New Establishment $255 fee	____ Change of Location $100 fee
____ Change of Ownership $255 fee	____ Stock Transfer (no fee)

SECTION A. Please complete for all Application Types

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. Prescription Department Manager (PDM) Information

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: _____ Close: _____

8. Ownership Information

a. Type of Ownership: _____Individual _____Corporation _____Partnership

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

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

Yes _____ No _____

c. Does the corporation have more than $100 million of business taxable assets in this state?

Yes _____ No _____ If yes, provide attestation from Certified Public Accountant for previous tax year or Florida Corporate Income/Franchise and Emergency Excise Tax Return (F-1120). 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 8c. If 8c is yes please list the owners below and only submit fingerprint cards for the PDM and the representative who is signing this application. If the representative has prints on file with DOH or AHCA you may provide proof and the requirements to submit 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
	/ /		%
	/ /		%
	/ /		%
	/ /		%
	/ /		%
	/ /		%

Pursuant to Section 456.0635(2), *Florida Statutes*, 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 copies of supporting documentation.

9. 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 21 U.S.C. ss. 801-970 or 42 U.S.C. ss.1395-1396? (If no, do not answer 10.)

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

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 separate sheet providing accurate details)

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 sheet providing accurate details)

12. 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)

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 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 _____ (If yes, explain on a separate 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

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. *Attach a separate sheet if necessary.*

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

Pharmacy Name	State	Status

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

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

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

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

20. **Has the applicant, or any officer, member or partner ever been convicted of a felony or misdemeanor, excluding minor 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 NOT a minor traffic offense for the purposes of this question.)

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.

I hereby have sworn that these statements are true and correct and recognize that providing false information may result in disciplinary action against my license or criminal penalties pursuant to sections 465.016, 775.082, 775.083, and 775.084, F.S.

SIGNATURE _____ DATE_____

(Owner or officer of establishment)

FLORIDA DEPARTMENT OF LAW ENFORCEMENT

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

NOTICE OF:

- **SHARING OF CRIMINAL HISTORY RECORD INFORMATION WITH SPECIFIED AGENCIES,**
- **RETENTION OF FINGERPRINTS,**
- **PRIVACY POLICY, AND**
- **RIGHT TO CHALLENGE AN INCORRECT CRIMINAL HISTORY RECORD**

This notice is to inform you that when you submit a set of fingerprints to the Florida Department of Law Enforcement (FDLE) for the purpose of conducting a search for any Florida and national criminal history records that may pertain to you, the results of that search will be returned to the Care Provider Background Screening Clearinghouse. By submitting fingerprints, you are authorizing the dissemination of any state and national criminal history record that may pertain to you to the Specified Agency or Agencies from which you are seeking approval to be employed, licensed, work under contract, or to serve as a volunteer, pursuant to the National Child Protection Act of 1993, as amended, and Section 943.0542, Florida Statutes. "Specified agency" means the Department of Health, the Department of Children and Family Services, the Division of Vocational Rehabilitation within the Department of Education, the Agency for Health Care Administration, the Department of Elder Affairs, the Department of Juvenile Justice, and the Agency for Persons with Disabilities when these agencies are conducting state and national criminal history background screening on persons who provide care for children or persons who are elderly or disabled. The fingerprints submitted will be retained by FDLE and the Clearinghouse will be notified if FDLE receives Florida arrest information on you.

Your Social Security Number (SSN) is needed to keep records accurate because other people may have the same name and birth date. Disclosure of your SSN is imperative for the performance of the Clearinghouse agencies' duties in distinguishing your identity from that of other persons whose identification information may be the same as or similar to yours.

Licensing and employing agencies are allowed to release a copy of the state and national criminal record information to a person who requests a copy of his or her own record if the identification of the record was based on submission of the person's fingerprints. Therefore, if you wish to review your record, you may request that the agency that is screening the record provide you with a copy. After you have reviewed the criminal history record, if you believe it is incomplete or inaccurate, you may conduct a personal review as provided in s. 943.056, F.S., and Rule 11C8.001, F.A.C. If national information is believed to be in error, the FBI should be contacted at 304-625-2000. You can receive any national criminal history record that may pertain to you directly from the FBI, pursuant to 28 CFR Sections 16.30-16.34. You have the right to obtain a prompt determination as to the validity of your challenge before a final decision is made about your status as an employee, volunteer, contractor, or subcontractor.

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

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

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

Privacy Statement

Authority: The FBI's acquisition, preservation and exchange of information requested by this form is generally authorized under 28 U.S.C. 534. Depending on the nature of your application, supplemental authorities include numerous Federal statutes, hundreds of State statutes pursuant to Pub.L.92-544, Presidential executive orders, regulations and/or orders of the Attorney General of the United States, or other authorized authorities. Examples include, but are not limited to: 5 U.S.C. 9101; Pub.L.94-29; Pub.L.101-604; and Executive Orders 10450 and 12968. Providing the requested information is voluntary; however, failure to furnish the information may affect timely completion of approval of your application.

Social Security Account Number (SSAN): Your SSAN is needed to keep records accurate because other people may have the same name and birth date. Pursuant to the Federal Privacy Act of 1974 (5 USC 552a), the requesting agency is responsible for informing you whether disclosure is mandatory or voluntary, by what statutory or other authority your SSAN is solicited, and what uses will be made of it. Executive Order 9397 also asks Federal Agencies to use this number to help identify individuals in agency records.

Principal Purpose: Certain determinations, such as employment, security, licensing and adoption, may be predicated on fingerprint based checks. Your fingerprints and other information contained on (and along with) this form may be submitted to the requesting agency, the agency conducting the application investigation, and/or FBI for the purpose of comparing the submitted information to available records in order to identify other information that may be pertinent to the application. During the processing of this application, and for as long hereafter as my be relevant to the activity for which this application is being submitted, the FBI(may disclose any potentially pertinent information to the requesting agency and/or to the agency conducting the investigation. The FBI may also retain the submitted information in the FBI's permanent collection of fingerprints and related information, where it will be subject to comparisons against other submissions received by the FBI. Depending on the nature of your application, the requesting agency and/or the agency conducting the application investigation may also retain the fingerprints and other submitted information for other authorized purposes of such agency(ies).

Routine Uses: The fingerprints and information reported on this form may be disclosed pursuant to your consent, and may also be disclosed by the FBI without your consent as permitted by the Federal Privacy Act of 1974 (5 USC 552a(b)) and all applicable routine uses as many be published at any time in the Federal Register, including the routine uses for the FBI Fingerprint Identification Records System (Justice, FBI-009) and the FBI's Blanket Routine Uses (Justice/FBI-BRU). Routine uses include, but are not limited to, disclosures to: appropriate governmental authorities responsible for civil or criminal law enforcement counterintelligence, national security or public safety matters to which the information may be relevant; to State and local governmental agencies and nongovernmental entities for application processing as authorized by Federal and State legislation, executive order, or regulation, including employment, security, licensing, and adoption checks; and as otherwise authorized by law , treaty, executive order, regulation, or other lawful authority. If other agencies are involved in processing the application, they may have additional routine uses.

Additional Information: The requesting agency and/or the agency conducting the application investigation will provide you additional information pertinent to the specific circumstances of this application, which may include identification of other authorities, purposes, uses, and consequences of not providing requested information. In addition, any such agency in the Federal Executive Branch has also published notice.

Electronic Fingerprinting

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

- Background screening results are obtained from the Florida Department of Law Enforcement and the Federal Bureau of Investigation by submitting to a fingerprint scan using the Livescan method;
- You can find a Livescan service provider at: http://www.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:_____ SSN#: _____ - ____ - _____

Aliases:_____

Address: _____ Apt. Number: _____

City:_____ State: _____Zip Code: _____

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

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

Race: _____ Sex: _____ Citizenship: _____
(W-White/Latino(a); B-Black; A-Asian; NA-Native American; U-Unknown) (M=Male; F=Female)

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

Keep this form for your records.

Item #1- PDM Designation and Privacy Statement Acknowledgement

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

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

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 Number (TCN) – related to Livescan Fingerprints:		
Only provide following information 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 PDM Privacy Statement Acknowledgement

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

I have been provided and read the statement from the Florida Department of Law Enforcement regarding the sharing, retention, privacy and right to challenge incorrect criminal history records and the "Privacy Statement" document from the Federal Bureau of Investigation."

Date:	**Incoming 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/Owner Telephone Number**	
Affiliate/Owner Transaction Control Number (TCN) – related to Livescan		

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."

_____ _____

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

DH-MQA 1216, 10/17
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 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.

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:

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 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.

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

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. 465.003(14) or s. 893.02 when the pharmacist knows or has reason to believe that the purported prescription is not based upon a valid practitioner-patient relationship that includes a documented patient evaluation, including history and a physical examination adequate to establish the diagnosis for which any drug is prescribed and any other requirement established by board rule under chapter 458, chapter 459, chapter 461, chapter 463, chapter 464, or chapter 466.

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

PRE-INSPECTION CHECKLIST

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

INTERNET PHARMACY PERMIT

APPLICATION

Application Type – Please choose one of the following:	
____ New Establishment $255 fee	____ Change of Location $100 fee
____ Change of Ownership $255 fee	____ Stock Transfer (no fee)

SECTION A. Please complete for all Application Types

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. Prescription Department Manager (PDM) Information

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: _____ Close: _____

8. Ownership Information

a. Type of Ownership: _____Individual _____Corporation _____Partnership

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

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

Yes _____ No _____

c. Does the corporation have more than $100 million of business taxable assets in this state?

Yes _____ No _____ If yes, provide attestation from Certified Public Accountant for previous tax year or Florida Corporate Income/Franchise and Emergency Excise Tax Return (F-1120). 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 8c. If 8c is yes please list the owners below and only submit fingerprint cards for the PDM and the representative who is signing this application. If the representative has prints on file with DOH or AHCA you may provide proof and the requirements to submit 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
	/ /		%
	/ /		%
	/ /		%
	/ /		%
	/ /		%
	/ /		%

Pursuant to Section 456.0635(2), *Florida Statutes*, 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 copies of supporting documentation.

9. 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 21 U.S.C. ss. 801-970 or 42 U.S.C. ss.1395-1396? (If no, do not answer 10.)

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

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 separate sheet providing accurate details)

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 sheet providing accurate details)

12. 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)

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 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 _____ (If yes, explain on a separate 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

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. *Attach a separate sheet if necessary.*

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

Pharmacy Name	State	Status

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

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

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

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

20. **Has the applicant, or any officer, member or partner ever been convicted of a felony or misdemeanor, excluding minor 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 NOT a minor traffic offense for the purposes of this question.)

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.

I hereby have sworn that these statements are true and correct and recognize that providing false information may result in disciplinary action against my license or criminal penalties pursuant to sections 465.016, 775.082, 775.083, and 775.084, F.S.

SIGNATURE _____ DATE_____

(Owner or officer of establishment)

FLORIDA DEPARTMENT OF LAW ENFORCEMENT

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

NOTICE OF:

- **SHARING OF CRIMINAL HISTORY RECORD INFORMATION WITH SPECIFIED AGENCIES,**
- **RETENTION OF FINGERPRINTS,**
- **PRIVACY POLICY, AND**
- **RIGHT TO CHALLENGE AN INCORRECT CRIMINAL HISTORY RECORD**

This notice is to inform you that when you submit a set of fingerprints to the Florida Department of Law Enforcement (FDLE) for the purpose of conducting a search for any Florida and national criminal history records that may pertain to you, the results of that search will be returned to the Care Provider Background Screening Clearinghouse. By submitting fingerprints, you are authorizing the dissemination of any state and national criminal history record that may pertain to you to the Specified Agency or Agencies from which you are seeking approval to be employed, licensed, work under contract, or to serve as a volunteer, pursuant to the National Child Protection Act of 1993, as amended, and Section 943.0542, Florida Statutes. "Specified agency" means the Department of Health, the Department of Children and Family Services, the Division of Vocational Rehabilitation within the Department of Education, the Agency for Health Care Administration, the Department of Elder Affairs, the Department of Juvenile Justice, and the Agency for Persons with Disabilities when these agencies are conducting state and national criminal history background screening on persons who provide care for children or persons who are elderly or disabled. The fingerprints submitted will be retained by FDLE and the Clearinghouse will be notified if FDLE receives Florida arrest information on you.

Your Social Security Number (SSN) is needed to keep records accurate because other people may have the same name and birth date. Disclosure of your SSN is imperative for the performance of the Clearinghouse agencies' duties in distinguishing your identity from that of other persons whose identification information may be the same as or similar to yours.

Licensing and employing agencies are allowed to release a copy of the state and national criminal record information to a person who requests a copy of his or her own record if the identification of the record was based on submission of the person's fingerprints. Therefore, if you wish to review your record, you may request that the agency that is screening the record provide you with a copy. After you have reviewed the criminal history record, if you believe it is incomplete or inaccurate, you may conduct a personal review as provided in s. 943.056, F.S., and Rule 11C8.001, F.A.C. If national information is believed to be in error, the FBI should be contacted at 304-625-2000. You can receive any national criminal history record that may pertain to you directly from the FBI, pursuant to 28 CFR Sections 16.30-16.34. You have the right to obtain a prompt determination as to the validity of your challenge before a final decision is made about your status as an employee, volunteer, contractor, or subcontractor.

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

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

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

Privacy Statement

Authority: The FBI's acquisition, preservation and exchange of information requested by this form is generally authorized under 28 U.S.C. 534. Depending on the nature of your application, supplemental authorities include numerous Federal statutes, hundreds of State statutes pursuant to Pub.L.92-544, Presidential executive orders, regulations and/or orders of the Attorney General of the United States, or other authorized authorities. Examples include, but are not limited to: 5 U.S.C. 9101; Pub.L.94-29; Pub.L.101-604; and Executive Orders 10450 and 12968. Providing the requested information is voluntary; however, failure to furnish the information may affect timely completion of approval of your application.

Social Security Account Number (SSAN): Your SSAN is needed to keep records accurate because other people may have the same name and birth date. Pursuant to the Federal Privacy Act of 1974 (5 USC 552a), the requesting agency is responsible for informing you whether disclosure is mandatory or voluntary, by what statutory or other authority your SSAN is solicited, and what uses will be made of it. Executive Order 9397 also asks Federal Agencies to use this number to help identify individuals in agency records.

Principal Purpose: Certain determinations, such as employment, security, licensing and adoption, may be predicated on fingerprint based checks. Your fingerprints and other information contained on (and along with) this form may be submitted to the requesting agency, the agency conducting the application investigation, and/or FBI for the purpose of comparing the submitted information to available records in order to identify other information that may be pertinent to the application. During the processing of this application, and for as long hereafter as my be relevant to the activity for which this application is being submitted, the FBI(may disclose any potentially pertinent information to the requesting agency and/or to the agency conducting the investigation. The FBI may also retain the submitted information in the FBI's permanent collection of fingerprints and related information, where it will be subject to comparisons against other submissions received by the FBI. Depending on the nature of your application, the requesting agency and/or the agency conducting the application investigation may also retain the fingerprints and other submitted information for other authorized purposes of such agency(ies).

Routine Uses: The fingerprints and information reported on this form may be disclosed pursuant to your consent, and may also be disclosed by the FBI without your consent as permitted by the Federal Privacy Act of 1974 (5 USC 552a(b)) and all applicable routine uses as many be published at any time in the Federal Register, including the routine uses for the FBI Fingerprint Identification Records System (Justice, FBI-009) and the FBI's Blanket Routine Uses (Justice/FBI-BRU). Routine uses include, but are not limited to, disclosures to: appropriate governmental authorities responsible for civil or criminal law enforcement counterintelligence, national security or public safety matters to which the information may be relevant; to State and local governmental agencies and nongovernmental entities for application processing as authorized by Federal and State legislation, executive order, or regulation, including employment, security, licensing, and adoption checks; and as otherwise authorized by law , treaty, executive order, regulation, or other lawful authority. If other agencies are involved in processing the application, they may have additional routine uses.

Additional Information: The requesting agency and/or the agency conducting the application investigation will provide you additional information pertinent to the specific circumstances of this application, which may include identification of other authorities, purposes, uses, and consequences of not providing requested information. In addition, any such agency in the Federal Executive Branch has also published notice.

Electronic Fingerprinting

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

- Background screening results are obtained from the Florida Department of Law Enforcement and the Federal Bureau of Investigation by submitting to a fingerprint scan using the Livescan method;
- You can find a Livescan service provider at: http://www.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:_____ SSN#: _____ - ____ - _____

Aliases:_____

Address: _____ Apt. Number: _____

City:_____ State: _____Zip Code: _____

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

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

Race: _____ Sex: _____ Citizenship: _____
(W-White/Latino(a); B-Black; A-Asian; NA-Native American; U-Unknown) (M=Male; F=Female)

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

Keep this form for your records.

Item #1- PDM Designation and Privacy Statement Acknowledgement

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

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

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 Number (TCN) – related to Livescan Fingerprints:		
Only provide following information 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 PDM Privacy Statement Acknowledgement

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

I have been provided and read the statement from the Florida Department of Law Enforcement regarding the sharing, retention, privacy and right to challenge incorrect criminal history records and the "Privacy Statement" document from the Federal Bureau of Investigation."

Date:	**Incoming 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/Owner Telephone Number**	
Affiliate/Owner Transaction Control Number (TCN) – related to Livescan		

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."

_____ _____

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