## INV 359 - Community Requirements

### Signage Requirements Section

- Signage stating the hours the pharmacy department is open. [64B16-28.1081 (2) F.A.C.]
- "Prescription Department Closed" sign with bold letters not less than 2 inches in width and height is displayed in a prominent place where it is easily read by patrons. [64B16-28.109 F.A.C.]
- Patient Consultation Area sign is posted. [64B16-30.003, F.A.C.] [64B16-28.1035, F.A.C.]
Pharmacist has a written collaborative practice agreement. [465.1865, F.S.]

F.A.C.

have been reviewed by the CQI committee quarterly are available for inspection. [64B16-27.300 F.A.C.; [766.101(1)(a)(l) F.S.]

The central fill pharmacy is identified by name and address or a by a code available at the originating pharmacy.

The originating pharmacy is identified with pharmacy name and address on the prescription container label.

Procedures for securely transporting the filled prescriptions.

Pharmacies have the same owner or have a written contract specifying the services to be provided by each pharmacy.

Pharmacy has policies and procedures in place to provide instructions to the patient on reporting concerns with delivery and storage of medicinal drugs.

Pharmacy has policies and procedures in place to ensure that medicinal drugs are not adulterated at the time of receipt by the patient or their agent.

Physician. [465.1895 (9) F.S.]

Signage indicating that any patient receiving testing, screening, or treatment services is advised to seek followup care from his or her primary care physician. 

Administration begins not later than 1 hour following start of immediate use CSPs preparation. [64B16-27.797 F.A.C.]

Invoices for medications purchased from a Florida licensed wholesaler/distributor are retrievable for inspection. [499.005 (14) F.S.]

The pharmacy maintains an audit trail for all drugs from receipt or acquisition to sale or disposition [499.005 F.S.] [61N-1.012 F.A.C.]

Compounding records properly maintained. [64B16-28.140(4), F.A.C.]

Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a) F.S.]; [21CFR1304.11]

Controlled substance records are maintained for 4 years [465.022(12) (b) F.S.]; [64B16-28.140 F.A.C.]

Pharmacy is reporting to the PDMP within 24 hours of dispensing controlled substance. [893.055(4) (3)(a), F.S.]; [893.07(5)(b) F.S.]; [465.022(11) (b) F.A.C.]

Record of theft or significant loss of all controlled substances is being maintained and reported to the sheriff and board within 24 hours of discovery. [893.07(2) (b), F.S.]; [64B16-28.140 F.A.C.]

Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a) F.S.]; [21CFR1304.11]

Controlled substance records and Rx information in computer system are retrievable. [21CFR1304.04]; [465.022(12) (a) F.S.]; [21CFR1306.22]; [64B16-28.140 F.A.C.]

Pharmacy is reporting to law enforcement any instance of fraudulent prescriptions within 24 hours or close of business on next business day of learning of instance. Reports include all required information. [465.015(3), F.S.]

Record of theft or significant loss of all controlled substances is being maintained and reported to the sheriff and board within 24 hours of discovery. [893.07(5)(b) F.S.]; [465.022(11) (b) F.A.C.]

Pharmacy is reporting to the PDMP within 24 hours of dispensing controlled substance. [893.055(4) (3)(a), F.S.]

Compounding records properly maintained. [465.1865, F.S.]

The pharmacy maintains an audit trail for all drugs from receipt or acquisition to sale or disposition [499.005 F.S.] [61N-1.012 F.A.C.]

Invoices for medications purchased from a Florida licensed wholesaler/distributor are retrievable for inspection. [499.005 (14) F.S.]

Administration begins not later than 1 hour following start of immediate use CSPs preparation. [64B16-27.797 F.A.C.]

Facility engaged in non-sterile office use compounding for human use is registered with FDA as an outsourcing facility [F.A.C 64B16-27.700(3)(g)]

Signage indicating that any patient receiving testing, screening, or treatment services is advised to seek followup care from his or her primary care physician. [465.1895 (9) F.S.]

Pharmacist has a written collaborative practice agreement. [465.1865, F.S.]

Pharmacy Ships Medicinal Drugs to Patients [ 64B16-28.10801, F.A.C.]

Pharmacy has policies and procedures in place to ensure that medicinal drugs are not adulterated at the time of receipt by the patient or their agent.

Pharmacy has policies and procedures in place to provide instructions to the patient on reporting concerns with delivery and storage of medicinal drugs.
If a controlled substance, the word "central fill" appears on the face of the original prescription.

The originating pharmacy keeps a record of receipt of the filled prescription, including the date of receipt, method of delivery and the name of the originating pharmacy’s employee accepting delivery.

Automated Pharmacy System [465.0235, F.S.]

- Pharmacy maintains a record of the medicinal drugs dispensed, including the identity of the pharmacist responsible for verifying the accuracy of the dosage and directions and providing patient counseling.
- Pharmacy maintains written policies and procedures to ensure the proper, safe, and secure functioning of the automated pharmacy system for a minimum of 4 years.

Internet Pharmacy

- A toll-free telephone number is provided to facilitate communication between patients in this state and a pharmacist at the pharmacy who has access to the patient’s records. [465.0197 (3)(e), F.S.]
- Toll free number is disclosed on the label affixed to each container of dispensed medicinal drugs. [465.0197 (3)(e), F.S.]
- Documentation of a valid, unexpired pharmacy license, permit or registration in the state in which the dispensing facility is located and from which the medicinal drugs shall be dispensed. [465.0197(3)(a) F.S]

Remarks:

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge. I have received a copy of the Licensee Bill of Rights.

Inspector Signature: ___________________________ Representative: ___________________________

Date: ___________________________ Date: ___________________________