



**STATE OF FLORIDA  
DEPARTMENT OF HEALTH  
INVESTIGATIVE SERVICES  
INV359 - Community Requirements**



File #

Insp #

<b>NAME</b>	<b>PERMIT NUMBER</b>	<b>DATE OF INSPECTION</b>	
<b>DOING BUSINESS AS</b>			
<b>STREET ADDRESS</b>		<b>TELEPHONE #</b>	<b>EXT</b>
<b>CITY</b>	<b>COUNTY</b>	<b>STATE/ZIP</b>	

**Additional Information**

**Business Operation Hours**

Monday	Monday Hours
Tuesday	Tuesday Hours
Wednesday	Wednesday Hours
Thursday	Thursday Hours
Friday	Friday Hours
Saturday	Saturday Hours
Sunday	Sunday Hours

**Registered Pharmacist / Intern / Tech**

License #	Licensee Name
License Type	

**ACS Manager**

--	--

**Optional Information**

--	--

**Basic License Data - PSD**

--	--

**License Relations**

**Pharmacy Affiliate**

	License #
--	-----------

**RX DPT MGR/COR/POR**

	License #
--	-----------

**INV 359 - Community Requirements**

**Community Requirements General Section**

Pharmacist on duty when Rx department open. [64B16-28.109, F.A.C.]	
Rx department hours open 5 days for 40 hours per week. [64B16-28.1081, F.A.C.]	
Pharmacy technicians properly identified and supervised. [64B16-27.420, F.A.C.]	
Written policy and procedure manual regarding the number of technician positions and their utilization. [64B16-27.410(2) (a), F.A.C.]	
Documentation signed by Pharmacy technician acknowledging review of the Policy and Procedure manual within 90 days of hire. [64B16-27.410(2) (b), F.A.C.]	
Documentation that Pharmacy technician has been trained in the established job description. [64B16-27.410(2)(c), F.A.C.]	
Current license of pharmacist, technicians and interns are conspicuously displayed in a place easily read by patrons. [465.025(7), FS] [64B16-27.100, F.A.C.]	

## INV359 - Community Requirements

Insp #

File #

Private consultation area available. [465.025(7), FS] [64B16-28.1035, F.A.C.]	
Generic equivalent sign posted. [465.025(7), FS]	
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. [64B16-27.1001, F.A.C.]	
Upon receipt of a new or refill prescription, a verbal and printed offer to counsel is made to the patient or the patient's agent. [64B16-27.820(1), F.A.C.]	
Prescription department is clean and safe, has sink/running water convenient to prescription department and adequate equipment as is necessary to the professional practice of pharmacy. [64B16-28.102, F.A.C.]	
Medication properly labeled. [499.007, F.S.] [64B16-28.108, F.A.C.]	
Expired medications removed from the shelves. [64B16-28.110, F.A.C.]	
Continuous Quality Improvement Program described in Pharmacy policy and procedure manual and summarization of Quality - Related Events which have been reviewed by the Continuous Quality Improvement Committee quarterly. [64B16-27.300, F.A.C.] [766.101(1)(a)l, F.S.]	
Policy and Procedure available and implemented to prevent the fraudulent dispensing of controlled substances. [465.022(4), F.S.]	
Pharmacy maintains patient profile records. [64B16-27.800, F.A.C.]	
All controlled substance prescriptions contain information required and are written on counterfeit-proof prescription pads unless exempt. [893.04, F.S.] [456.42(2), F.S.]	
Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a), F.S.]	
DEA 222 forms properly completed or records of receipt of CSOS orders electronically completed, archived and retrievable. [21CFR 1305.22(g)] [893.07(2) F.S.]	
Controlled substance records and Rx information in computer system is retrievable. [21CFR 1306.22] [64B16-28.140, F.A.C.]	
Controlled substance records maintained for 4 years. [465.022(12)(b), F.S.]	
Controlled prescriptions have the date dispensed and dispensing pharmacists. [893.04(1)(c) 6, F.S.] [64B16-28.140(3)(b), F.A.C.]	
Certified daily log OR printout maintained. [21CFR 1306.22(b)(3)] [64B16-28.140(3)(b), 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 is being reported to the sheriff within 24 hours of discovery. [893.07(5), F.S.] [465.015, F.S.]	
Pharmacy is reporting to the PDMP within 7 days of dispensing controlled substance. [893.055(4), F.S.]	
Pharmacy with a retail pharmacy wholesaler permit is reporting sales to the Controlled Substance Reporting system monthly by the 20th of the following month. [499.0121(14), F.S.]	
Compounding records properly maintained. [64B16-28.140(4), F.A.C.]	
Unit dose records properly maintained. [465.016(1)(l), F.S.] [64B16-28.118, F.A.C.]	
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.]	
Prescriptions for controlled substances are on counterfeit-proof prescription pads or blanks purchased from a Department-approved vendor and the quantity and date meet the requirements of 456.42, F.S. [893.065, F.S.]	
Preparation time does not exceed 1 hour when preparing, and administration begins not later than 1 hour following start of Immediate use CSPs. [64B16-27.797, F.A.C.]	
Compliant office use compounding agreement between practitioner and pharmacy available for review. [64B16-27.700 (3)(d)]	
Complete office use compounding records available for review. [64B16-27.700 (3)(e)]	

**Is there an onsite drug disposal receptacle? Or does the facility take back any drugs for destruction?**

Are they an authorized collector by DEA (modifier on their DEA registration)?	
Is DEA form 41 complete and maintained?	

**Pharmacy engages in Centralized Prescription Filling? [64B16-28.450]**

Pharmacies have the same owner or have a written contract specifying the services to be provided by each pharmacy.	
Current P&P Manual available for inspection designating at minimum: types of medications that may be filled, procedures for communicating orders, procedures for securely transporting the filled prescriptions.	
Central Fill and originating pharmacy shall each be identified on the prescription container label.	
The word "central fill" appears on the face of the original prescription and the originating pharmacy's pharmacist transmitting the prescription, and the date of transmittal.	
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.	

**Remarks:**

## INV359 - Community Requirements

Insp #

File #

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.

Investigator/Sr. Pharmacist Signature:

Representative:

Date:

Date: