



**STATE OF FLORIDA  
DEPARTMENT OF HEALTH  
INVESTIGATIVE SERVICES  
INV407 – Special Limited Community Pharmacy**



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**

**Basic License Data - PSD**

DEA Reg #	
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**Optional Information**

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**Business Operation Hours**

M-T-W-Th-F	Weekly hours
Monday	Tuesday
Wednesday	Thursday
Friday	Saturday
Saturday Hours	Sunday
Sunday Hours	

**License Relations**

**Pharmacy Affiliate**

	Licensee #
	Licensee #
	Licensee #
	Licensee #
	Licensee #
	Licensee #

**RX DPT MGR/COR/POR**

	License #
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**INV 407 – Special Limited Community Pharmacy**

Pharmacist on duty when Prescription Department open [64B16-28.109, F.A.C.]	
Technicians properly identified. [64B16-27.100(2), F.A.C.] [64B16-27.4001, F.A.C.] [64B16-27.410, F.A.C.] [64B16-27.420, F.A.C.]	
Pharmacy maintains a written policy and procedure manual regarding the number of registered pharmacy technician positions and the pharmacy operates within the established ratio as defined by rule. [64B16-27.410(2)(a), F.A.C.]	
Pharmacists, technicians, and interns are licensed in the State of Florida. [465.015(1)(a), F.S.]	
A verbal and written offer of counsel is made to the patient or patient's agent with each new or refilled prescription. [64B16-27.820(1), F.A.C.]	
Generic Equivalent sign posted. [465.025(7), F.S.]	
Prescription department is operating under clean, sanitary, and uncrowded health conditions. [64B16-28.102, F.A.C.]	
Pharmacy has a working sink with running water easily accessible to the prescription counter. [64B16-28.102, F.A.C.]	
Medication is properly labeled for dispensing to patient, return to stock, or manufacturer containers. [64B16-28.108, F.A.C.] [499, F.S.] [64B16-28.108, F.A.C.] [893.04(1)(e) F.S.]	

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Outdated medications removed from active stock. [64B16-28.110, F.A.C.] [64B16-28.1191, F.A.C.]	
Continuous Quality Improvement Program described in the Pharmacy policy and procedure manual and quarterly summarization of Quality - Related Events are available for inspection. [64B16-27.300, F.A.C.] [766.101(1)(a)(l), F.S.]	
Certified daily log or signed printout maintained. [21CFR1306.22(f)(3)] [64B16-28.140(3)(d) & (e), F.A.C.]	
Compounding Records properly maintained including compounding date, lot number, expiration date, name and manufacturer of ingredients, package size, number of units, technician compounding and pharmacist verifying the final compound. [64B16-28.140(4), 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.]	
Medicinal drugs dispensed are for employees, medical staff and their dependents for personal use, patients obtaining services in the emergency room, and discharged patients for continuation of a course of therapy as provided for under the permit. [64B16-28.810, F.A.C.]	
Medicinal drugs dispensed to patients of the hospital are for continuation of therapy and do not exceed three day's supply except for multi-dose medicinal drugs intended for continuation of therapy provided in containers that may exceed 3 day's supply. [64B16-28.810(4)(e), F.A.C.]	
Consultant pharmacist provides medication management services and has a written collaborative practice agreement. [465.0125, F.S.]	

**Controlled Substances**

Pharmacy maintains patient profile records. [64B16-27.800, F.A.C.]	
Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a), F.S.] [21CFR1304.11]	
DEA 222 forms properly completed or records of CSOS orders electronically completed, linked to the original order, archived and retrievable. [893.07(2), F.S.] [21CFR 1305.13(e)] [21CFR 1305.22(g)]	
Controlled substance records and prescription information in computer system are retrievable and maintained for 4 years. [21CFR1304.04] [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 the 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(1)(b), F.S.]	
Pharmacy is reporting to the PDMP within 24 hours of dispensing a controlled substance. [893.055(4), F.S.]	
Compounding Records properly maintained [64B16-28.140(4), 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.]	
Medicinal drugs dispensed are for employees, medical staff and their dependents for personal use, patients obtaining services in the emergency room, and discharged patients for continuation of a course of therapy as provided for under the permit. [64B16-28.810, F.A.C.]	
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**Remarks:**

I have read and have had this inspection report and the law and regulations concerned herein explained and do affirm that the information given herein is true and correct to the best of my knowledge.

Inspector Signature:

Representative:

Date:

Date: