



**STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
INV406 – Special Closed System Pharmacy**



File #
Insp #

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

Additional Information

Basic License Data - PSD

DEA Reg #	
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Business Operation Hours

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

License Relations

Pharmacy Affiliate

	License #
	License #
	License #
	License #
	License #
	License #

RX DPT MGR/COR/POR

	License #
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INV 406 – Special Closed System Pharmacy

Special - Closed System Pharmacy Requirements

Pharmacists, interns, and technicians properly identified and licensed in the State of Florida. [465.013, F.S.] [64B16-26.400, F.A.C.] [64B16-26.2032(4)(6), F.A.C.] [64B16-27.410, F.A.C.] [465.014(1), F.S.] [64B16-27.100, 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.]	
Written offer to counsel when appropriate. [64B16-27.820, F.A.C.]	
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.]	
Continuous Quality Improvement Program described in the Pharmacy policy and procedure manual and quarterly summarization of Quality-Related Events [64B 16-27.300, F.A.C.] [766.101(1)(a)(I), F.S.]	
Medication is properly labeled for dispensing to patient, return to stock, or manufacturer containers. [64B16-28.108, F.A.C.]	
Customized medication packages are labeled properly and assigned a beyond use date of not more than 120 days from the date of preparation, but not later than the beyond use date for any of the medications in the package. [64B16-28.108(6), F.A.C.]	
Prepackaged medication labels include, lot number, drug name, strength, dosage form, manufacturer name, and expiration date not more than 1 year from date of prepackaging or the manufacturers expiration date; and records of prepacking are maintained. [64B16-28.108 (3), F.A.C.] [64B16-28.120, F.A.C.]	
Outdated pharmaceuticals removed from active stock. [64B16-28.110, F.A.C.]	
Pharmacy maintains patient profiles with allergy information and medications dispensed. [64B16-27.800, F.A.C.] [64B16-28.140, F.A.C.]	

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Certified daily log OR printout maintained as required by section. [64B16-28.140(3)(c) or (e), F.A.C.]	
Provides 24-hour emergency and on-call service. [64B16-28.830(3), F.A.C.]	
Dispensing only to individuals in nursing homes, jails, ALFs, and ICFs, or other custodial care facilities. [64B16-28.830, F.A.C.]	
Returned/unused medications are correctly labeled and do not include compounded or controlled substance medications. [64B16-28.830(2), F.A.C.] [64B16-28.118, F.A.C.] [64B16-28.120(3), F.A.C.]	
Compounding records include compounding date, lot number, expiration date, name and manufacturer of ingredients, package size, number of units, technician compounding and pharmacist verifying the final compound. [64B28.140(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.]	

Controlled Substances

Controlled substance inventory taken on biennial basis and available for inspection. [893.07(1)(a), F.S.]	
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. [465.022(12)(b), F.S.] [465.018(7), F.S.] [21CFR 1306.22] [21CFR 1304.04] [64B16-28.140, F.A.C.]	
Pharmacy is reporting to PDMP within 24 hours of dispensing controlled substance. [893.055, F.S.]	
Record of theft or significant loss of all controlled substances is being maintained and is being reported to the sheriff and the board within 24 hours of discovery. [893.07(5), F.S.] [465.015, F.S.]	

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.	

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.	

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: