



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



INSPECTION AUTHORITY: CHAPTER 465.017, CHAPTER 893.09 AND CHAPTER 456, FLORIDA STATUTES

File #
Insp #

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

Additional Information

Business Operation Hours

M-T-W-TH-F	Weekly 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

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ACS Manager

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Optional Information

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Basic License Data-PSD

DEA Reg #	
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License Relations

RX DPT MGR/COR/POR

	License #
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Special Sterile Compounding

	License #
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INV 406 - Special Closed System Pharmacy

Special - Closed System Pharmacy Requirements

Current permits, registrations, and licenses displayed. [21CFR 1301.11] [465.018(1)(2), F.S.] [64B16-27.100, F.A.C.]	
Interns and technicians properly registered, identified, and supervised. [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.]	
Written policy/procedure manual for pharmacy technicians. [64B16-27.440,F.A.C.] [64B16-27.410(5), F.A.C.]	
Written offer to counsel when appropriate. [64B16-27.820,F.A.C.]	
Rx. dept. is clean and safe, has sink/running water easily accessible to prescription department and sufficient equipment to adequately, safely, and accurately fulfill the duties related to prescriptions. [64B16-28.102, F.A.C.]	
Prescription department clean and safe. [64B16-28.102, F.A.C.]	
Current reference books and current copy of laws and rules in hard copy or in a readily available electronic data format. [64B16-28.102, F.A.C.]	

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Insp #

File #

CQI Policy and Procedures and proof of quarterly meetings. (protected under [766.101,F.S] [64B16-27.300, F.A.C.]	
Medication properly labeled. [64B16-28.108, F.A.C.]	
Outdated pharmaceuticals removed from active stock. [64B16-28.110, F.A.C.]	
Customized patient medication packages are labeled properly and assigned a beyond use date that is not more than 60 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.]	
All medicinal drug prescriptions have date dispensed and the initials of the dispensing pharmacist. [893.04(1)(c)(6), F.S.] [64B16-28.140(3), F.A.C.]	
Pharmacy maintains patient profiles and complete records of dispensing. [64B16-27.800, F.A.C.] [64B16-28.140, F.A.C.]	
All controlled substance prescriptions contain information required and are written on counterfeit-proof prescription pads. [893.04, F.S.] [456.42(2), F.S.]	
Prescriptions not filled or refilled in excess of one year (or six months for controlled substances in schedule 3-5) from date written. [893.04(1)(g), F.S.] [64B16-27.211, F.A.C.]	
Controlled substance inventory taken on biennial basis and available for inspection. [893.07(1)(a),F,S.]	
DEA 222 order forms properly completed. [893.07(2), F.S.]	
Controlled substance records and prescriptions retrievable and maintained for 4 years. [465.022(12)(b), F.S.] [465.018(7), F.S.] [21CFR1306.22] [21CFR1304.04] [64B16-28.140, F.A.C.]	
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.]	
Prepackaged medication labels include the expiration date and lot number and records of prepacking are maintained. [64B16-28.108, F.A.C.] [64B16-28.120, F.A.C.]	
Dispensing only to individuals as allowed by rule for Special-Closed Systems Pharmacy permit. [64B16-28.830, F.A.C.]	
Appropriate records of returned/unused unit dose medicinal drugs maintained/available. [64B16-28.830(2), F.A.C.] [64B16-28.118, F.A.C.] [64B16-28.120(3), F.A.C.]	
Pharmacy is reporting to PDMP within 7 days of dispensing controlled substance where required. [893.005, 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.]	
Policy and Procedure manual includes drug procurement, storage, handling, compounding, dispensing, record keeping, and disposition. [64B16-28.830, F.A.C.]	
Compounding records properly maintained. [64B28.140(4), F.A.C.]	

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.

Investigator/Sr. Pharmacist Signature:

Representative:

Date:

Date: