



**STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES**

**Florida
HEALTH**

WWW.DOH.STATE.FL.US

SPECIAL - CLOSED SYSTEM PHARMACY

File # _____
Insp # _____

ROUTINE CHANGE LOC NEW CURRENTLY NOT OPERATING CHANGE OWNER

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

NAME OF ESTABLISHMENT						PERMIT NUMBER			DATE OF INSPECTION						
DOING BUSINESS AS						DEA NUMBER			PRESCRIPTION DEPARTMENT MANAGER						
STREET ADDRESS						TELEPHONE #			EXT #						
CITY			COUNTY			STATE/ZIP			PRESCRIPTION DEPARTMENT MANAGER LICENSE #						
PRESCRIPTION DEPARTMENT HOURS								REGISTERED PHARMACIST/INTERN/TECHNICIAN				LICENSE #			
	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday	1.							
Open								2.							
Close								3.							
											SATISFACTORY	N/A	YES	NO	
1	Current permits, registrations, and licenses displayed. [21CFR 1301.11] [465.018(1)(2), F.S.] [64B16-27.100, F.A.C.]											<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2	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.]											<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3	Written policy/procedure manual for pharmacy technicians. [64B16-27.440,F.A.C.] [64B16-27.410(5), F.A.C.]											<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4	Written offer to counsel when appropriate. [64B16-27.820,F.A.C.]											<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5	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.]											<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6	Prescription department clean and safe. [64B16-28.102, F.A.C.]											<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7	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.]											<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8	CQI Policy and Procedures and proof of quarterly meetings. (protected under [766.101,F.S]) [64B16-27.300, F.A.C.]											<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9	Medication properly labeled. [64B16-28.108, F.A.C.]											<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10	Outdated pharmaceuticals removed from active stock. [64B16-28.110, F.A.C]											<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11	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.]											<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12	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.]											<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13	Pharmacy maintains patient profiles and complete records of dispensing. [64B16-27.800, F.A.C.] [64B16-28.140, F.A.C.]											<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14	All controlled substance prescriptions contain information required and are written on counterfeit-proof prescription pads. [893.04, F.S.] [456.42(2), F.S.]											<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15	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.]											<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16	Controlled substance inventory taken on biennial basis and available for inspection. [893.07(1)(a),F.S.]											<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17	DEA 222 order forms properly completed. [893.07(2), F.S.]											<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18	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.]											<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19	Certified daily log OR printout maintained as required by section. [64B16-28.140(3)(c) or (e), F.A.C.]											<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20	Provides 24-hour emergency and on-call service. [64B16-28.830(3), F.A.C.]											<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
21	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.]											<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
22	Dispensing only to individuals as allowed by rule for Special-Closed Systems Pharmacy permit. [64B16-28.830, F.A.C.]											<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
23	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.] [465.016(1)(1), F.S.]											<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
24	Pharmacy is reporting to PDMP within 7 days of dispensing controlled substance where required. [893.005, F.S.]											<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
25	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.]											<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
26	Policy and Procedure manual includes drug procurement, storage, handling, compounding, dispensing, record keeping, and disposition. [64B16-28.830, F.A.C.]											<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
27	Compounding records properly maintained. [64B28.140(4), F.A.C.]											<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Note: If establishment is engaged in parenteral/enteral compounding, license must so indicate and a separate inspection form completed.

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.

PRINT NAME OF RECIPIENT _____

ID _____

Institutional Representative _____

Date _____

Investigator/Sr. Pharmacist Signature _____