



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



WWW.DOH.STATE.FL.US

**SPECIAL - CLOSED SYSTEM PHARMACY**

File # \_\_\_\_\_

ROUTINE  CHANGE LOC  NEW  CURRENTLY NOT OPERATING  CHANGE OWNER

Insp # \_\_\_\_\_

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							
	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday	1.	LICENSE #		
Open								2.			
Close								3.			
				SATISFACTORY	N/A	YES	NO				
								SATISFACTORY	N/A	YES	NO
1	Board of Pharmacy office notified of current pharmacy manager. [64B16-28.830(5),F.A.C.] [465.018,F.S.]			<input type="checkbox"/>	<input type="checkbox"/>	22	Pharmacy maintains patient profile records. [64B16-27.800(3), 64B16-28.140(3),F.A.C.]			<input type="checkbox"/>	<input type="checkbox"/>
2	Current DEA registration. [21CFR 1301.11] [465.023(1),F.S.]			<input type="checkbox"/>	<input type="checkbox"/>	23	Controlled substance records readily available. [ 893.07,F.S.]			<input type="checkbox"/>	<input type="checkbox"/>
3	Interns properly registered and supervised. [465.013,F.S.] [64B16-26.400,F.A.C.]			<input type="checkbox"/>	<input type="checkbox"/>	24	Initials of pharmacist filling cont. sub. Rx on the Rx. [893.04(1)(c)6,F.S.]			<input type="checkbox"/>	<input type="checkbox"/>
4	Proper pharmacist technician ratio. If 2:1 or 3:1 Pharmacy Manager has Board of Pharmacy approval. [64B16-27.410] [64B16-27.420,F.A.C.]			<input type="checkbox"/>	<input type="checkbox"/>	25	Date controlled substance Rx was filled on the Rx. [893.04(1)(c)6,F.S.]			<input type="checkbox"/>	<input type="checkbox"/>
5	Pharmacy technicians properly identified and supervised. [64B16-27.410,F.A.C.]			<input type="checkbox"/>	<input type="checkbox"/>	26	Patient's name/address on controlled substance Rx. [893.04(1)(c)1,F.S.]			<input type="checkbox"/>	<input type="checkbox"/>
6	Written policy/procedure manual for pharmacy technicians. [64B16-27.440,F.A.C.]			<input type="checkbox"/>	<input type="checkbox"/>	27	Prescriber's name/address/DEA# on all controlled substance prescriptions. [893.04(1)(c)2,F.S.]			<input type="checkbox"/>	<input type="checkbox"/>
7	Pharmacist license/renewal certificate displayed. [64B16-27.100(1),F.A.C.]			<input type="checkbox"/>	<input type="checkbox"/>	28	All controlled substance prescriptions must have drug prescribed, quantity and directions for use. [893.04(1)(c)4,F.S.]			<input type="checkbox"/>	<input type="checkbox"/>
8	Pharmacist on duty when Rx department open. [64B16-27.1001(4),F.A.C.]			<input type="checkbox"/>	<input type="checkbox"/>	29	Date of refills on controlled substance prescriptions. [893.04(1)(c)6,F.S.]			<input type="checkbox"/>	<input type="checkbox"/>
9	Written offer to counsel when appropriate. [64B16-27.820,F.A.C.]			<input type="checkbox"/>	<input type="checkbox"/>	30	Pharmacist's initials on controlled substance Rx refills. [893.04(1)(c)6,F.S.]			<input type="checkbox"/>	<input type="checkbox"/>
10	Rx dept. has sink/running water convenient to Rx dept. [64B16-28.102,F.A.C.]			<input type="checkbox"/>	<input type="checkbox"/>	31	Controlled substance refills limited to 5 in 6 months from original date of prescription. [893.04(1)(g),F.S.]			<input type="checkbox"/>	<input type="checkbox"/>
11	Prescription department has drug refrigeration storage. [64B16-28.102,F.A.C.]			<input type="checkbox"/>	<input type="checkbox"/>	32	Controlled substance inventory taken on biennial basis and available for inspection. [ 893.07(1)(a),F.S.]			<input type="checkbox"/>	<input type="checkbox"/>
12	Prescription department clean and safe. [64B16-28.102,F.A.C.]			<input type="checkbox"/>	<input type="checkbox"/>	33	DEA 222 order forms properly completed. [893.07(2),F.S.]			<input type="checkbox"/>	<input type="checkbox"/>
13	Prescription balance and weights, counting tray, graduates, spatulas, mortars, and pestles. [64B16-28.102,F.A.C.]			<input type="checkbox"/>	<input type="checkbox"/>	34	Controlled substance Rx information in computer system is retrievable. [CFR 1306.22] [893.07,F.S.] [64B16-28.140,F.A.C.]			<input type="checkbox"/>	<input type="checkbox"/>
14	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"/>	35	Controlled substance records maintained for 2 years. [893.07(4)(b),F.S.] [CFR 1304.04 & 1306.22]			<input type="checkbox"/>	<input type="checkbox"/>
15	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"/>	36	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"/>
16	Medication properly labeled. [64B16-28.108,F.A.C.]			<input type="checkbox"/>	<input type="checkbox"/>	37	Provides 24-hour emergency and on-call service. [64B16-28.830(3),F.A.C.]			<input type="checkbox"/>	<input type="checkbox"/>
17	Outdated pharmaceuticals removed from active stock. [64B16-28.110,F.A.C.]			<input type="checkbox"/>	<input type="checkbox"/>	38	Prepackaged medication with proper expiration date. [64B16-28.120,F.A.C.]			<input type="checkbox"/>	<input type="checkbox"/>
18	Expiration date on prescription label or provided in other written form. [64B16-28.108,F.A.C.]			<input type="checkbox"/>	<input type="checkbox"/>	39	Log of prepacking. [64B16-28.120,F.A.C.]			<input type="checkbox"/>	<input type="checkbox"/>
19	All medicinal drug prescriptions require date dispensed. [64B16-28.108,F.A.C.]			<input type="checkbox"/>	<input type="checkbox"/>	40	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"/>
20	All medicinal drug prescriptions require initials of pharmacist and date of refill. [64B16-28.140(3)(b),F.A.C.]			<input type="checkbox"/>	<input type="checkbox"/>	41	Appropriate records of returned/unused unit dose medicinal drugs maintained/available. [64B16-28.830(2),F.A.C.] [64B16-28.118,F.A.C.] [64B-12.012(1)(a),F.A.C.] [465.016(1)(l),F.S.]			<input type="checkbox"/>	<input type="checkbox"/>
21	Complete prescription records of pharmacy. [64B16-28.140,F.A.C.]			<input type="checkbox"/>	<input type="checkbox"/>	* Questions with (*) may be answered n/a (not applicable).					

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.

PRINT NAME OF RECIPIENT \_\_\_\_\_

ID \_\_\_\_\_

Institutional Representative \_\_\_\_\_

Date \_\_\_\_\_

Investigator/Sr. Pharmacist Signature \_\_\_\_\_

Save