



**STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES**
INV 456 – Modified Institutional Class III
Affiliation



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

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Optional Information

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Business Operation Hours

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

License Relations

Pharmacy Affiliate

	License #
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RX DPT MGR/COR/POR

	License #
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Modified Institutional Class III Pharmacy Requirements

Current Class III permit. [465.019(2)(d), F.S.] [64B1628.750 F.A.C.]	
Current professional supervision of a consultant pharmacist. [465.019(5), F.S.] [64B16-28.501, F.A.C.]	
Consultant pharmacist provides medication management services and has a written collaborative practice agreement. [465.0125, F.S.]	
Records reflect on-site consultations by consultant pharmacist at least monthly unless otherwise directed by Board. [64B16-28.501(3) FAC.]	
Current DEA registration. [21 CFR 1301.11] & [465.023(1)(c), F.S.]	
Policy and procedures for destruction of unusable controlled substances. [64B16-28.303, F.A.C.]	
Controlled substance records are readily retrievable. [893.07(4) F.S.]; [21CFR1304.04]; [465.022(12) (a) F.S.]; [21CFR1306.22]; [64B16-28.140 F.A.C.]	
Controlled substance inventory taken on a biennial basis and available for inspection [893.07(1)(a), F.S.] [21CFR1304.11]	
Controlled substance records are maintained for 4 years [465.022(12) (b) F.S.] 64B16-28.140 F.A.C.	
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)]; [21CFR1305.22(g)]	
Provision for utilization of perpetual inventory system for Controlled Substances. [64B16-28.750(5)(a)(8), F.A.C]	
Provision for secure ordering, storage, and record keeping of all medicinal drugs at facility. [64B16-28.750(5)(a)(9), F.A.C]	
Pharmacy has a policy and procedure for development of a formulary. [64B16-28.750(5)(a)(6), F.A.C]	

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Pharmacy Services Committee meets annually. [64B16-28.750(5)(a)(7), F.A.C.]	
Expired medications removed from shelves. [64B16-28.110, FAC]	
All medication is properly labeled. [61N-1.006(1)(a) F.A.C.]; [64B16-28.108(3) F.A.C.]	
Immediate Use sterile compounds are prepared in compliance with USP <797> and administration begins not later than 1 hour from start of preparation. [64B16-27.797 FAC]	
CSP is properly labeled if preparer does not administer or witness the administration of the Immediate Use CSP [64B16-797 FAC]	
CQI Policy and Procedures and proof of quarterly meetings. [766.101, F.S.] [64B16-27.300, FAC]	
Pharmacy is affiliated with a hospital or is a hospital providing services to affiliated institutional pharmacies under common control. [465.019(2)(d)(1) F.S.]	
All prepacking, compounding, dispensing, distribution and provision of pharmaceutical services is among permitted entities under common control. [465.019(2)(d) F.S.]	
Policy and Procedure for maintenance of drug records to monitor the movement, dispensing, distribution and transportation of drugs [465.019 F.S.]; [64B16-28.750(5)(a)(3) F.A.C.]	
Policy and Procedure for safe practices for the preparation, dispensing, prepackaging, distribution, and transportation of all medicinal drugs. [465.019, F.S.] [64B16-28.750(5)(a)(2) F.A.C.]	
Provisions for maintaining records of pharmacy staff responsible for each step in the preparation, dispensing, prepacking, transportation, and distribution of drugs. [465.019(2)(d)(2)(d), F.S.]; [64B16-28.750(5)(a)(4) F.A.C.]	
Pharmacy has procedure for Identification of drugs products that may not be safely distributed among Class III Institutional Pharmacies and health care establishment permittees. [64B16-28.750(5)(a)(5) F.A.C.]	
Documentation is available for inspection: of the hospital with which the permittee is affiliated, all other Class III Institutional Pharmacy permits under common control with the permittee, all health care clinic establishments under common control with the permittee, and the manner in which the permittee and other entities are under common control. [64B16-28.750(5)(a) (13) (c) 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.

Inspector Signature

Representative:

Date:

Date: