



STATE OF FLORIDA  
DEPARTMENT OF HEALTH  
INVESTIGATIVE SERVICES  
INV362 - Mod Class II & Class III Institutional  
Pharmacy



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	Tuesday
Wednesday	Thursday
Friday	Saturday
Sunday	Saturday Hours
Sunday Hours	

Registered Pharmacist / Intern / Tech

License #	Licensee Name
License Type	

ACS Manager

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Optional Information

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Basic License Data - PSD

DEA Reg #	
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License Relations

Pharmacy Affiliate

	License #
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RX DPT MGR/COR/POR

	License #
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Mod Class II Institutional Pharmacy Requirements

Current modified Class II Institutional Pharmacy permit. [465.019(2)(c), F.S.]	
Current professional supervision of a consultant pharmacist. [465.019(5), F.S.]	
Consultant pharmacist provides medication management services and has a written collaborative practice agreement. [465.0125, F.S.]	
Current DEA registration. [21CFR 1301.11] [465.023(1)(c), F.S.]	
Pharmacy has policy and procedures manual available for inspection. [64B16-28.702(5), FAC.]	
Records reflect on-site consultations by consultant pharmacist at least monthly unless otherwise directed by Board. [64B16-28.702(2)(b)(c)(d), FAC.]	
All medication properly labeled. [64B16-28.108 F.A.C.]	

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Pharmacy Services Committee meets at least annually. [64B16-28.702(6), FAC.]	
Provisions for handling of emergency box including the utilization of separate logs for record keeping. [64B16-28.702(6), FAC.]	
Provision for secure ordering, storage and record keeping of all medicinal drugs at facility. [64B16-28.702(6), FAC.]	
Secure storage of the medicinal drugs. [64B16-28.702(6), FAC.]	
Records of consultations for the facility for not less than four years available for inspection. [64B16-28.702(6), FAC.]	
Records within the pharmacy of drugs administered to patients of institutional program. [64B16-28.702(1), FAC.]	
CQI Policy and Procedures and proof of quarterly meetings. [766.101, F.S.] [64B16-27.300, FAC]	
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]	
Expired medications removed from the shelves. [64B16-28.110, F.A.C.]	
Pharmacy has established institutional formulary if necessary for the substitution of medicinal drugs. [465.025 (9), F.S]	

### Type "A" Mod Class II Institutional Pharmacy

Quantity of controlled substances stocked does not exceed 100 dosage units PER CONTAINER unless approved by Board. [64B16-28.702(7), FAC.]	
Proof of use forms used for all medicinal drugs, controlled and non-controlled, within the facility that include the patient name, date of administration, initials of person administering the drug, and all pertinent controls required. [64B16-28.702(7), FAC.]	
Drugs stocked in establishment are those employed for treatment of primary condition or medical objective set forth in policy and procedures manual. [64B16-28.702(6), FAC.]	
Pharmacy stocks no more than 15 medicinal drugs excluding those in the emergency box. [64B16-28.702(2)(b), FAC.]	
Controlled substances inventory taken on biennial basis and available for inspection. [893.07(1) (a), F.S.] [21CFR1304.11]	
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)]	
Controlled substance records are maintained for 4 years [465.022(12) (b) F.S.] [64B16-28.140 F.A.C.]	
The policy and procedures contain the drugs and strengths stocked. [64B16-28.702(6)(a)1, FAC.]	

### Type "B" Mod Class II Institutional Pharmacy

Utilization of perpetual inventory system for all controlled substances; for injectables and other medicinal drugs as required by the pharmacy committee. [64B16-28.702(6)(b)(4), FAC.]	
Drugs stocked in establishment are those employed for treatment of primary condition or medical objective set forth in policy and procedures manual. [64B16-28.702(6), FAC.]	
Controlled substances inventory taken on biennial basis and available for inspection. [893.07(1)(a), F.S.]; [21CFR1304.11]	
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)]	
Controlled substance records are maintained for 4 years [465.022(12) (b) F.S.] [64B16-28.140 F.A.C.]	

### Type "C" Mod Class II Institutional Pharmacy

Utilization of a medication administration record (MAR) for all medicinal drugs administered to patients of the facility. [64B16-28.702(6)(c)4, FAC.]	
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### Class III Institutional Pharmacy

Current Class III permit. [465.019(2)(d), F.S.] [64B1628.750 F.A.C]	
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 prepackaging, 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, prepackaging, 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 healthcare 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.]	

### 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:**

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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.

Inspector Signature:

Representative:

Date:

Date: