



**STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
INV361 - Class II Institutional 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

Pharmacy Affiliate

	License #

RX DPT MGR/COR/POR

	License #
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Special Sterile Compounding

	License #
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INV 361 - Class II Institutional Pharmacy

Class II Institutional Pharmacy General Requirements

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Current Class II Institutional Pharmacy permit. [465.019(2)(b), F.S.]	
Current professional supervision of a consultant pharmacist. [465.019(5), F.S.] [64B16-28.501, F.A.C.]	
Current DEA registration. [21 CFR 1301.11] & [465.023(1)(c), F.S.]	
Sufficient daily operating hours to adequately serve patients of institution. [64B16-28.603, F.A.C.]	
Current pharmacists' and registered pharmacy technicians' licenses displayed. [64B16-27.100(1), F.A.C.]	
Pharmacy interns properly registered, identified and supervised [465.013 F.S.] [64B16-26.400(4), F.A.C.] [64B16-26.2032(4), F.A.C.]	
Pharmacy technicians properly registered, supervised, and visibly identified as registered pharmacy technicians [64B16-27.410(3), F.A.C.] [64B16-27.420(4), F.A.C.]	
Policy and Procedures for utilization of registered pharmacy technicians including scope of responsibilities, supervision, on going training. [64B16-27.410(5), F.A.C.] [64B16-27.420, F.A.C.] [64B16-27.440, F.A.C.]	
The pharmacy has adequate sanitation, a sink with running water, refrigeration, space and equipment necessary to accurately fulfill the duties related to prescriptions. [64B16-28.102(1) F.A.C.]	
14 Current reference sufficient to meet professional practice of pharmacy and current Florida Laws and Rules, hard copy or electronic. [64B16-28.102(5)(a), F.A.C.]	
Policy and procedures for destruction of unusable controlled substances. [64B16-28.303, F.A.C.]	
Controlled substance records readily retrievable. [893.07(4), F.S.]	
Controlled substance records maintained for 4 years. [CFR 1304.04 & 1306.22] [893.07(4)(b), F.S.] [465.022(12)(b), F.S.] [64B16-28.140, F.A.C.]	
DEA 222 forms properly completed or records of receipt of CSOS orders electronically completed and linked to original order and archived. [21CFR 1305.22(g)] [893.07(2) F.S.]	
Controlled substance inventory taken on biennial basis and available for inspection. [893.07(1)(a), F.S.] [21CFR1304.11] <i>CS inventory 8-14-2014.</i>	
Policy and procedures for removal of a single dose of medication for administration to a patient when no pharmacist is on duty. [64B16-28.602(1), F.A.C.] NA	
Prepacking of medication either unit dose or multiple dose according to policy and procedures by consultant pharmacist. [64B16-28.120(3), F.A.C.]	
Unit dose medication properly labeled. [64F-12.006, F.A.C.] [61N-1.006(1)(a) F.A.C.]	
Prepacking and labeling of unit dose or multiple dose medication is checked by Florida licensed pharmacist. [64B16-27.430 F.A.C.] [64B16-28.108(4), F.A.C.] [64B16-28.120(3), F.A.C.]	
Pharmaceutical stock examined at least every four months and deteriorated or outdated items removed. [64B16-28.110, F.A.C.]	
Florida licensed pharmacist doing the compounding or is physically present and certifies the accuracy of the finished product. [64B16-27.1001(2), F.A.C.]	
Florida licensed pharmacist certifying the final parenterals, and bulk solutions and medication orders and documenting processing so that professional responsibility can be traced to a pharmacist. [64B16-27.1001(2), F.A.C] [64B16-27.1001(3) F.A.C]	
Emergency Department dispensing records properly maintained. [64B16-28.6021, F.A.C.]*	
Continuous Quality Improvement Program described in Pharmacy policy and procedure manual and summarization of Quality - Related Events which have been reviewed by the Continuous Quality Improvement Committee quarterly. [64B16-27.300, F.A.C.] [766.101(1)(a)l, F.S.] <i>Most recent CQI meeting 1-26-2015.</i>	
Pharmacy contracted with Special P&E Ext Scope Pharmacy has Policy and Procedures manual that delineates duties and responsibilities of each entity. [64B16-28.602(2) F.A.C]	
All medicinal drugs provided by Special P&E EXT Scope pharmacy inspected and logged by institution. [64B16-28.602(2)(a)2. F.A.C]	
Multidisciplinary Committee provides oversight of decentralized automated medication system [64B16-28.605(3), F.A.C]	
Policies and procedures for decentralized automated medication system and criteria for determining medications that qualify as override medications. [64B16-28.605(2)(a), F.A.C]	
Pharmacist conducts daily audit of medications placed or to be placed in decentralized automated medication systems that includes random sampling; or bar code or electronic verification utilized. [64B16-28.605(4) F.A.C]	
Required records related to audits of stocking and output of automated medication system readily retrievable and maintained 60 days. [64B16-28.605(7) F.A.C]	
QA program for automated medication system provides for review of override medication utilization; med errors and discrepancies [64B16-28.605(8) F.A.C]	
Pharmacies utilizing remote medication order processing by pharmacists not employed by the institution have a compliant written agreement with pharmacist or entity employing pharmacist. [64B16-28.606(2) F.A.C]	
Policy and Procedure for remote medication order processing compliant and available for review. [64B16-28.606(3) F.A.C]	

Facility Performing Immediate Use Compounding Only

Preparation time does not exceed 1 hour when preparing, and administration begins not later than 1 hour following start of Immediate use CSPs. [64B16-27.797(1)(j), F.A.C.]	
Preparation is properly labeled if preparer does not administer or witness administration when preparing immediate-use CSPs. [64B16-27.797(1) (j), F.A.C.]	

Speical P&E Extended Scope Requirements

Pharmacy has current list of name, address, telephone number and license number of each pharmacist involved in remote medication order processing. [64B16-28.606(3)(d) F.A.C]	
Pharmacy maintains records for 2 years that identify the name, initials or code of each person performing a processing function for every remote medication order. [64B16-28.606(4) F.A.C]	

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.

Investigator/Sr. Pharmacist Signature:

Representative:

Date:

Date: