



**STATE OF FLORIDA  
DEPARTMENT OF HEALTH  
INVESTIGATIVE SERVICES  
INV362 – Mod Class II Institutional Pharmacy**



File #  
Insp #

<b>NAME</b>	<b>PERMIT NUMBER</b>	<b>DATE OF INSPECTION</b>	
<b>DOING BUSINESS AS</b>			
<b>STREET ADDRESS</b>		<b>TELEPHONE #</b>	<b>EXT</b>
<b>CITY</b>	<b>COUNTY</b>	<b>STATE/ZIP</b>	

**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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**INV362 – Mod Class II Institutional Pharmacy**

**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.]	
Current DEA registration. [21CFR 1301.11] [465.023(1)(c), F.S.]	
Records reflect on-site consultations by consultant pharmacist at least monthly. [64B16-28.702(2)(b)(c)(d), F.A.C.]	
All medication properly labeled. [64B16-28.108, F.A.C.]	
Pharmacy Services Committee meets at least annually. [64B16-28.702(6), F.A.C.]	
Separate logs for records of emergency box use including the utilization of separate logs for record keeping. [64B16-28.702(6), F.A.C.]	
Secure ordering, storage and record keeping of all medicinal drugs at facility. [64B16-28.702(6), F.A.C.]	
Continuous Quality Improvement Program described in the Pharmacy policy and procedure manual and quarterly summarization of Quality-Related Events are available for inspection. [64B16-27.300, F.A.C.] [766.101(1)(a)(l), F.S.]	
Outdated medications removed from active stock. [64B16-28.110, F.A.C.]	

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**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), F.A.C.]	
Proof of use forms used for all medicinal drugs, controlled and non-controlled, within the facility that include the patient's name, date of administration, initials of person administering the drug, and all pertinent controls required. [64B16-28.702(7), F.A.C.]	
Drugs stocked in establishment are those employed for treatment of primary condition or medical objective set forth in policy and procedures manual. [64B 16-28.702(6), F.A.C.]	
Pharmacy stocks no more than 15 medicinal drugs excluding those in the emergency box. [64B16-28.702(2)(b), F.A.C.]	
Controlled substances inventory taken on biennial basis and available for inspection. [893.07(1)(a), F.S.] [21CFR 1304.11]	
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)] [21CFR 1305.22(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, F.A.C.]	

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

Utilization of perpetual inventory system for all controlled substances. [64B 16-28.702(6)(b)(4), F.A.C.]	
Controlled substances inventory taken on biennial basis and available for inspection. [893.07(1)(a), F.S.] [21CFR 1304.11]	
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)] [21CFR 1305.22(g)]	
Controlled substance records are maintained for 4 years [465.022(12)(b), F.S.] [64B16-28.140, F.A.C.]	
Utilization of a medication administration record (MAR) for all medicinal drugs administered to patients of the facility. [64B16-28.702(6)(c)4., F.A.C.]	

**Remarks:**

I have read and have had this inspection report and the law 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: