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

<table>
<thead>
<tr>
<th>NAME</th>
<th>PERMIT NUMBER</th>
<th>DATE OF INSPECTION</th>
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<th>DOING BUSINESS AS</th>
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<tr>
<th>STREET ADDRESS</th>
<th>TELEPHONE #</th>
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<tr>
<th>CITY</th>
<th>COUNTY</th>
<th>STATE/ZIP</th>
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### Additional Information

#### Business Operation Hours

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<th>Day</th>
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<tr>
<td>M-T-W-TH-F</td>
<td>Weekly Hours</td>
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<td>Monday</td>
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<td>Friday</td>
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<td>Sunday</td>
<td>Saturday Hours</td>
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#### Registered Pharmacist / Intern / Tech

<table>
<thead>
<tr>
<th>License #</th>
<th>Licensee Name</th>
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#### ACS Manager


#### Optional Information


#### Basic License Data - PSD

<table>
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<tr>
<th>DEA Reg #</th>
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#### License Relations

#### Pharmacy Affiliate

<table>
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### INV 362 - Mod Class II & III 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.]
- 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.]
Compliance with USP <797> and administration begins not later than 1 hour from start of preparation.

Institutional Pharmacy permits under [64B16-27.797 FAC]

The policy and procedures contain the drugs and strengths stocked. [64B16-28.702(6)(a), 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]

Expired medications removed from the shelves. [64B16-28.110, 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.]

Mod Class III Institutional Pharmacy

Mod Class III permit. [465.019(2)(d), F.S.] [64B16-28.750 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 Preparing, 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.]


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.]

Remarks:

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 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. [64B16-28.702(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.]; [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.]; [21CFR1305.13(e)]; [21CFR1305.22(g)]

Controlled substance records are maintained for 4 years [465.022(b) F.S.]; [64B16-28.140 F.A.C.]

The policy and procedures contain the drugs and strengths stocked. [64B16-28.702(6)(a), F.A.C.]

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), 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. [64B16-28.702(6), F.A.C.]

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.]; [21CFR1305.13(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, F.A.C.]

Remarks:

Mod Class III Institutional Pharmacy

Current Class III permit. [465.019(2)(d), F.S.] [64B16-28.750 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 Preparing, 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.]


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.]

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. I have received a copy of the Licensee Bill of Rights.

Inspector Signature:  

Representative:  

Date:  

Date: