



**STATE OF FLORIDA  
DEPARTMENT OF HEALTH  
INVESTIGATIVE SERVICES  
INV406 - Special Closed System 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**

**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**

License #	Licensee Name
License Type	
License #	Licensee Name
License Type	
License #	Licensee Name
License Type	
License #	Licensee Name
License Type	
License #	Licensee Name
License Type	
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**

**RX DPT MGR/COR/POR**

	License #
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**INV 406 - Special Closed System Pharmacy  
Special - Closed System Pharmacy Requirements**

## INV406 - Special Closed System Pharmacy

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Pharmacist on Duty when Rx Department open [64B16-28.109, F.A.C.]	
Pharmacy technicians and interns properly identified and supervised [64B16-27.100(4) F.A.C.] [64B16-27.4001 F.A.C.] [64B16-27.410 F.A.C.] [64B16-27.420 F.A.C.]	
Written policy/procedure manual regarding the number of technical positions and their utilization. [64B16-27.410(2)(a), F.A.C.]	
Documentation signed by Pharmacy technician acknowledging review of the Policy and Procedure manual within 90 days of hire. [64B16-27.410(2)(b) F.A.C.]	
Documentation that Pharmacy Technician has been trained in the established job description [64B16-27.410(2)(c), F.A.C.]	
Pharmacy licenses are current. [465.015(1)(a), F.S.]	
Pharmacists, interns and technicians have proof of current licensure. [465.014 F.S.] [465.015 (2)(b)]	
A verbal and written offer of counsel is made to the patient or patient's agent with each new or refilled prescription when appropriate [64B16-27.820(1) F.A.C.]	
Generic Equivalent sign posted. [465.025 (7) F.S.]	
Prescription department is clean and safe, has a sink with running water convenient to the prescription department, and references and equipment necessary to the professional practice of pharmacy. [64B16-28.102 F.A.C.]	
Medication properly labeled. [499 F.S.] [64B1628.108 F.A.C.] [893.04(1)(e) F.S.] [21CFR1306.24] [21CFR1306.14]	
Expired medications removed from the shelves. [64B16-28.110 F.A.C.] [64B16-28.1191 F.A.C.]	
Continuous Quality Improvement Program described in the Pharmacy policy and procedure manual and summarization of Quality -Related Events which have been reviewed by the CQI committee quarterly are available for inspection. [64B16-27.300 F.A.C.] [766.101(1)(a)(l) F.S.]	
Policy and Procedure available and implemented to prevent the fraudulent dispensing of controlled substances [465.022(4) F.S.]	
Pharmacy maintains patient profile records. [64B16-27.800, F.A.C.]	
Written prescriptions for controlled substances are on counterfeit-proof pads from Department-approved vendors. [893.065 F.S.] [456.42(2) F.S.]	
All controlled substance prescriptions (electronic, faxed, verbal and written) contain required information. [893.04(a)(b)(c) F.S.] [21CFR1306.05]	
Controlled substance inventory taken on a 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 and Rx information in computer system are retrievable. [21CFR1304.04] [21CFR1306.22] [64B16-28.140 F.A.C.]	
Controlled substance records are maintained for 4 years [465.022(12) (b) F.S.] [64B16-28.140 F.A.C.]	
Controlled substance prescriptions have the date dispensed and dispensing pharmacist. [893.04(1) F.S.] [21CFR1306.22(c)] [64B16-28.140(3) F.A.C.]	
Certified daily log or signed printout maintained. [21CFR1306.22(f)(3)] [64B16-28.140(3)(d) &(e) F.A.C]	
Pharmacy is reporting to law enforcement any instance of fraudulent prescriptions within 24 hours or close of business on the next business day of learning of instance. Reports include all required information. [465.015(3) F.S.]	
Record of theft or significant loss of all controlled substances is being maintained and is being reported to the sheriff within 24 hours of discovery. [893.07(5), F.S.] [465.015, F.S.]	
Pharmacy is reporting to the PDMP within 24 hours of dispensing a controlled substance. [893.055(4) F.S.]	
Compounding records properly maintained. [64B28.140(4), F.A.C.]	
All prepacking is done in accordance with procedures set up by the PDM and Records of returns of unit dose medications are properly maintained. [465.016(1) F.S.] [64B16-28.118 F.A.C.] [64B16-28.120(3)]	
The pharmacy maintains an audit trail for all drugs from receipt or acquisition to sale or disposition. [499.005 F.S.] [61N-1.012 F.A.C.]	
Invoices for medications purchased from a Florida licensed wholesaler/distributor are retrievable for inspection. [499.005(14) F.S.]	
Label on the immediate container of a repackaged medication or multiple unit prepackaged medication includes the name, strength, dosage form, name of the manufacturer, expiration date and lot number of the medication. [64B16-28.108(3) F.A.C.]	
Customized patient medication packages are labeled with separate serial number for each medicinal drug dispensed, name, strength, quantity and physical description of each drug product, date of preparation, name of each prescriber, and all other requirements in the rule. [64B16-28.108(6)(b) F.A.C.]	
Customized packages are assigned a beyond use date that is not more than 60 days from the date of preparation, but not later than the expiration of any medication in the package. [64B16-28.108(6)(b)(9) F.A.C.]	
Pharmacy provides a 24-hour emergency and on-call service [64B16-28.830(3) F.A.C.]	
Pharmacy is dispensing only to individuals in custodial care facilities utilizing a closed delivery system as allowed by rule. [64B16-28.830(1) F.A.C.]	
Policy and procedure manual includes drug procurement, storage, handling, compounding, dispensing, record keeping and disposition. [64B1628.830(2) 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.

Inspector Signature:

Representative:

Date:

Date: