STATE OF FLORIDA  
DEPARTMENT OF HEALTH  
INVESTIGATIVE SERVICES  
INV359 - Community Requirements

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

Business Operation Hours

M-T-W-TH-F  
Monday

Monday Hours

Tuesday Hours

Tuesday Hours

Wednesday Hours

Thursday Hours

Friday Hours

Friday Hours

Saturday Hours

Saturday Hours

Sunday

Registered Pharmacist / Intern / Tech

ACS Manager

Optional Information

Basic License Data - PSD

License Relations

Pharmacy Affiliate

License #

INV 359 - Community Requirements

Community Requirements General Section

Pharmacist on duty when Rx department open. [64B16-28.109, F.A.C.]

When a pharmacist is not on duty, the prescription department is securely locked, no other personnel remain in the department, and a sign not less than 2 inches in width and height is displayed in a prominent place where it is easily read by patrons stating "Prescription Department Closed". [64B16-28.109 F.A.C.]

Rx Department is open for a minimum of 20 hours per week. [64B16-28.1081F.A.C.]

Pharmacy technicians and interns properly identified and supervised [64B16-27.100 (3) & (4) F.A.C.]; [64B16-27.4001 F.A.C.]; [64B16-27.410 F.A.C.]; [64B16-27.420 F.A.C.].

Written policy and procedure manual regarding the number of technician 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)].

Private consultation area available [6416-28.1035 F.A.C.]
### Generic equivalent sign posted. [465.025(7), F.S.]

A sign has been prominently posted indicating the specific hours of the day during which meal breaks may be taken by the pharmacist and assuring patients that the pharmacist is available for consultation upon request during the meal break. [64B16-27.1001 F.A.C.]

Upon receipt of a new or refill prescription, a verbal and printed offer to counsel is made to the patient or the patient’s agent. [64B16-27.820(1), F.A.C.]

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.]


Expired medications removed from the shelves. [64B16-28.110 F.A.C.]; [64B16-28.1191 F.A.C.]

Continuously Quality Improvement Program described in the Pharmacy policy and procedure manual and summarized in Quality-Related Events which have been reviewed by the CQI committee quarterly are available for inspection. [64B16-28.300 F.A.C.]; [766.101(1)(a)(i) 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.]; [465.42(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(a)]; [21CFR1305.22(g)]

Controlled substance records and Rx information in computer system are retrievable. [21CFR1304.04]; [465.022(12)(a) F.S.]; [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 next business day of learning of instance. Reports include all required information. [465.015(3), F.S.]

Pharmacy is reporting to the PDMP within 24 hours of dispensing controlled substance. [893.055(4), F.S.]

Pharmacy with a retail pharmacy wholesaler permit is reporting sales to the Controlled Substance Reporting system monthly by the 20th of the following month. [499.0121(14), F.S.]


All compounding 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. [64B16-28.120 F.A.C.]

Medication properly labeled. [499.005(2), F.S.]; 64B16-28.140(3) F.A.C.]

Invoices for medications purchased from a Florida licensed wholesaler/distributor are retrievable. [64B16-28.140(2)(b) F.A.C.]

Expiration medications removed from the shelves. [64B16-28.110 F.A.C.]; [64B16-28.1191 F.A.C.]

Controlled substance records and Rx information in computer system are retrievable. [21CFR1304.04]; [465.022(12)(a) F.S.]; [21CFR1306.22]; [64B16-28.140 F.A.C.]

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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.]

Administration begins not later than 1 hour following start of immediate use CSPs preparation. [64B16-27.797 F.A.C.]

### Pharmacies have the same owner or have a written contract specifying the services to be provided by each pharmacy.

Current P&P Manual available for inspection designating at minimum: types of medications that may be filled, procedures for communicating orders, procedures for securely transporting the filled prescriptions.

Central Fill and originating pharmacy shall each be identified on the prescription container label.

The word “central fill” appears on the face of the original prescription and the originating pharmacy’s pharmacist transmitting the prescription, and the date of transmission.

The originating pharmacy keeps a record of receipt of the filled prescription, including the date of receipt, method of delivery and the name of the originating pharmacy’s employee accepting delivery.

### 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: ____________

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