



**STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
INV359 – Community Requirements**



File #
Insp #

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

Additional Information

Basic License Data - PSD

DEA Reg #	
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Optional Information

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Business Operation Hours

M-T-W-TH-F	Weekly Hours
Monday	Tuesday
Wednesday	Thursday
Friday	Saturday
Saturday Hours	Sunday
Sunday Hours	

License Relations

Pharmacy Affiliate

	License #
	License #
	License #
	License #
	License #
	License #

RX DPT MGR/COR/POR

	License #
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INV 359 – Community Requirements

Signage Requirements Section

Signage stating the hours the pharmacy department is open. [64B16-28.1081(2), F.A.C.]	
"Prescription Department Closed" sign with bold letters not less than 2 inches in width and height is displayed in a prominent place where it is easily read by patrons. [64B16-28.109, F.A.C.]	
Patient Consultation Area sign is posted. [64B16-30.003, F.A.C] [64B16-28.1035, F.A.C.]	

Community Requirements General Section

Outdated medications removed from active stock. [64B16-28.110, F.A.C.] [64B16-28.1191, F.A.C.]	
Prescription Department is open for a minimum of 20 hours per week. [64B16-28.1081(1), F.A.C.]	
All controlled substance prescriptions (electronic, faxed, verbal and written) contain required information. [893.04(a)(b)(c), F.S.] [21CFR1306.05]	
Certified daily log or signed printout maintained. [21CFR1306.22(f)(3)] [64B16-28.140(3)(d), F.A.C.]	

INV 359 – COMMUNITY REQUIREMENTS

Insp #

File #

Prescription department has current copy of laws and rules, references and equipment necessary to the professional practice of pharmacy. [64B16-28.102(5)(a), F.A.C.]	
Technicians properly identified. [64B16-27.100(2), F.A.C.] [64B16-27.4001, F.A.C.] [64B16-27.410, F.A.C.] [64B16-27.420, F.A.C.]	
Legend drugs properly stored within confines of pharmacy department and maintained at appropriate temperature to preserve therapeutic activity. [64B16-28.118, F.A.C.]; [64B16-28.120, F.A.C.]; [64B16-28.102, F.A.C.]	
Documentation of destruction or return of controlled substances. [64B16-28.303, F.A.C.]	
Generic equivalent sign is posted. [465.025(7), F.S.]	

Additional Community Requirements

Prescription department is operating under clean, sanitary, and uncrowded health conditions. [64B16-28.102, F.A.C.]	
Prescription department has a sink with running water easily accessible to the prescription counter. [64B16-28.102, F.A.C.]	
Pharmacist is on the premises and on duty when the prescription department is open. [64B16-28.109, F.A.C.]	
Pharmacy maintains a written policy and procedure manual regarding the number of registered pharmacy technician positions and the pharmacy operates within the established ratio as defined by rule. [64B16-27.410(2)(a), F.A.C.]	
Pharmacists, technicians, and interns are licensed in the State of Florida. [465.015(1)(a), F.S.]	
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.]	
Medication is properly labeled for dispensing to patient. [64B16-28.108, F.A.C.]	
Unclaimed prescriptions are maintained in stock for no more than one year past dispensing date. [64B16-28.1191, F.A.C.]	
Manufacturer containers are properly labeled. [499.003(26), F.S.]	
Customized medication packages are labeled properly with beyond use date of not more than 120 days from the date of preparation but not later than the beyond use date for any of the medications in the package. [64B16-28.108(6)9., 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.]	
Pharmacy maintains patient profile with allergy information and medications dispensed. [64B16-27.800, F.A.C.]	
Compounding records include compounding date, lot number, expiration date, name and manufacturer of ingredients, package size, number of units, technician compounding and pharmacist verifying the final compound. [64B16-28.140(4), F.A.C.]	
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.]	
Facility engaged in non-sterile office use compounding for human use is registered with FDA as an outsourcing facility. [64B16-27.700(3)(g), F.A.C.]	
Signage indicating that any patient receiving testing, screening, or treatment services is advised to seek follow-up care from his or her primary care physician. [465.1895(9), F.S.]	
Human Trafficking signage is posted in a conspicuous place accessible to employees that is at least 11 inches by 15 inches in size, printed in a clearly legible font and in at least a 32-point type which gives instructions in English and Spanish on how to report to the National Human Trafficking Resource Center. [456.0341, F.S.]	

Requirements for Dispensing Controlled Substances

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 prescription information in computer system are retrievable and maintained for 4 years. [465.022(12)(a), F.S.] [64B16-28.140, F.A.C.] [21CFR1306.22] [21CFR1304.04]	
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.]	
Record of theft or significant loss of all controlled substances is being maintained and reported to the sheriff and board within 24 hours of discovery. [893.07(5)(b), F.S.] [465.022(11)(b), F.A.C.]	
Pharmacy is reporting to the PDMP within 24 hours of dispensing controlled substance. [893.055(4)(3)(a), F.S.]	

Pharmacy Ships Medicinal Drugs to Patients [64B16-28.10801, F.A.C.]

Pharmacy has policies and procedures in place to ensure that medicinal drugs are not adulterated at the time of receipt by the patient or their agent.	
Pharmacy has policies and procedures in place to provide instructions to the patient on reporting concerns with delivery and storage of medicinal drugs.	

Pharmacy Engages in Centralized Prescription Filling [64B16-28.450, 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.	
The originating pharmacy is identified with pharmacy name and address on the prescription container label.	
The central fill pharmacy is identified by name and address or a by a code available at the originating pharmacy.	
If a controlled substance, the word "central fill" appears on the face of the original prescription.	

INV 359 – COMMUNITY REQUIREMENTS

Insp #

File #

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.	
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Automated Pharmacy System [465.0235, F.S.]

Pharmacy maintains a record of the medicinal drugs dispensed, including the identity of the pharmacist responsible for verifying the accuracy of the dosage and directions and providing patient counseling.	
Pharmacy maintains written policies and procedures to ensure the proper, safe, and secure functioning of the automated pharmacy system for a minimum of 4 years.	

Internet Pharmacy

A toll-free telephone number is provided to facilitate communication between patients in this state and a pharmacist at the pharmacy who has access to the patient's records. [465.0197(3)(e), F.S.]	
Toll free number is disclosed on the label affixed to each container of dispensed medicinal drugs. [465.0197(3)(e), F.S.]	
Documentation of a valid, unexpired pharmacy license, permit or registration in the state in which the dispensing facility is located and from which the medicinal drugs shall be dispensed. [465.0197(3)(a), F.S.]	

HIV Infection Prevention Drugs

Pharmacists are screening, ordering or dispensing HIV postexposure prophylaxis drugs under a written Collaborative Practice Agreement. [465.1861, F.S.]	
An access-to-care plan has been submitted to the board office and is in place to assist patients in gaining access to appropriate care settings when they present to a pharmacist for HIV screening and indicate that they lack regular access to primary care. [465.1861, F.S.]	

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: