



STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
INV359 – Community Pharmacy



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 Pharmacy

Signage Requirements

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 Pharmacy General Requirements

Outdated medications removed from active stock.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.]	
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.]	
Pharmacy has a designated Prescription Department manager with a current and active Florida license. [64B16-27.450, F.A.C.]	
Pharmacists, pharmacy technicians, and interns have proof of current licensure [465.014, F.S.] [64B16-27.100, F.A.C.]	
Pharmacists, pharmacy technicians, and interns are properly identified and supervised. [64B16-27.100(1)(2), F.A.C.] [64B16-27.4001, F.A.C.] [64B16-27.420, F.A.C.]	
Written policy and procedure manual regarding the number of technician positions and their utilization. [64B16-27.4001(3)(4), 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.]	

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Generic equivalent sign is posted. [465.025(7), F.S.]	
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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.]	
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.]	
Human Use Compounded Drug Products: Compounding of drug products and compounding practices such as patient-specific, anticipatory, office stock or office use, and other legally permissible forms, strictly adheres to relevant federal regulations, including but not limited to 21 USC 353a and 21 USC 353b. [64B16-27.700(4), 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.]	

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.

Inspector Signature

Representative:

Date:

Date: