



**STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
INV364 - Special P&E and Extended Scope**



File #
Insp #

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

Additional Information

Business Operation Hours

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Registered Pharmacist / Intern / Tech

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ACS Manager

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Optional Information

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Basic License Data - PSD

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License Relations

RX DPT MGR/COR/POR

	License #
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Special P&E and Extended Scope Requirements

Board of Pharmacy notified in writing of current Rx department manager. [64B16-28.820(3)(a), F.A.C.]	
Current DEA registration. [21CFR 1301.11]	
Pharmacist license/renewal certificate displayed. [64B16-27.100(1), F.A.C.]	
Pharmacy Technicians Current Registration Properly Displayed [64B16-27.100(4), F.A.C.]	
Pharmacy technicians properly identified and supervised. [64B16-27.420(4)(a), F.A.C.]	
Pharmacist and pharmacy interns properly identified [64B16-27.100(3), F.A.C.]	
Interns properly registered and supervised. [465.013, F.S.] [64B16-26.400, F.A.C.]	
Licensed pharmacist certifies accuracy of final preparation and documents in a manner that responsibility can be traced to the pharmacist. [64B16-27.1001, F.A.C.]	
Board approved policy and procedure manual available for inspection. [64B16-28.820(3)(d), F.A.C.]	
Working sink convenient to the clean room. [64B16-28.820(5)(c)3, F.A.C.]	
Refrigeration/freezer/sink/appropriate waste containers for used needles/ syringes. [64B16-28.820(5)(c), F.A.C.]	
Other equipment as is necessary to meet the needs of the professional practice of pharmacy. [64B16-28.102, F.A.C.]	
Current chapter of Florida Statutes: 465 and 499 and 893, and Board Rules [64B16-28.820(5)(e)1-4, F.A.C.]	
Current edition of the Handbook of Injectable Drugs by American Society of Healthsystem Pharmacists. [64B16-28.820(5)(e)6, F.A.C.]	
Practice Guidelines for Personnel Dealing with Cytotoxic Drugs* [64B16-28.820(5)(e)7, F.A.C.]	
Prescriptions may not be filled in excess of one year or six months from date written for controlled substances [64B16-27.211, F.A.C.] [893.04(1)(g), F.S.]	
CQI Policy and Procedures and proof of quarterly meetings [64B16-27.300, F.A.C.]	
Parenteral/Enteral Extended Scope Permit if compounding in conjunction with institutional pharmacy permits [64B16-28.860, F.A.C.]	

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Pharmaceutical stock examined at least every four months and deteriorated or outdated items removed. [64B16-28.110, F.A.C.]	
Medication properly labeled. [64B16-28.108, F.A.C.]	
Pedigree records are retrievable [61N-1.012(3), F.A.C.]	
Written offer to counsel. [64B16-27.820, F.A.C.]	
Special handling/packing/labeling/delivery of prescriptions with telephone accessibility to pharmacist at all hours. [64B16-28.820(3)(b), F.A.C.]	
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.]	
Pharmacy is reporting to the PDMP within 24 hours of dispensing controlled substance. [893.055(4), F.S.]	
Prescriber's name/address/DEA # on all controlled substance prescription. [F.S. 893.04(1)(c)2, F.A.C.]	
Initials of pharmacist filling controlled substance prescriptions on prescription. [893.04(1)(c)6, F.S.]	
Controlled substance inventory taken on biennial basis and available for inspection. [893.07(1)(a), F.S.]	
DEA 222 order forms properly completed. [893.07, F.S.]	
Certified daily log OR printout maintained as required by section. [64B16-28.140(3)(c) or (e), F.A.C.]	
Dispensing done pursuant to prescriptions with patient profiles maintained. [64B16-28.820(3) (c), F.A.C.]	
Results of quality assurance program available for inspection. [64B16-28.820(3)(d), F.A.C.]	

Pharmacy Ships Medicinal Drugs to Patients

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.	

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: