



**STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES**
INV 361 - Class II & III Institutional Pharmacy



File #
Insp #

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|--------------------------|----------------------|---------------------------|------------|
| 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

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| | License # |
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Class II Institutional Pharmacy General Requirements

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| Current Class II Institutional Pharmacy permit. [465.019(1)F.S.] | |
| Current professional supervision of a consultant pharmacist. [465.019(5), F.S.] [64B16-28.501, F.A.C.] | |
| Consultant pharmacist provides medication management services and has a written collaborative practice agreement. [465.0125, F.S.] | |
| Current DEA registration. [21 CFR 1301.11] & [465.023(1)(c), F.S.] | |
| Sufficient daily operating hours to adequately serve patients of institution. [64B16-28.603, F.A.C.] | |
| Pharmacists, interns and technicians have proof of current licensure [465.014 F.S.], [465.015(2)(b)]. | |
| Pharmacy technicians and interns properly identified and supervised[64B16-27.100 (1) & (2) F.A.C.]; [64B16-27.4001 F.A.C.]; [64B16-27.410 F.A.C.]; [64B16-27.420 F.A.C.]. [64B16-26.400(4) F.A.C.] | |
| Written policy and procedure manual regarding the number of technician positions, their utilization and on-going training and documentation signed by Pharmacy technician acknowledging review of the Policy and Procedure manual within 90 days of hire. [[64B16-27.410(2)(a) F.A.C.] [64B16-27.410(2)(b) F.A.C.] | |
| Pharmacy is clean and safe, has a sink with running water, current references and equipment necessary to the professional practice of pharmacy. [64B16-28.102 F.A.C.] | |
| Policy and procedures for destruction of unusable controlled substances. [64B16-28.303, F.A.C.] | |
| Controlled substance records are readily retrievable. [893.07(4) F.S.] [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.] | |
| 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 inventory taken on biennial basis and available for inspection. [893.07(1)(a), F.S.] [21CFR1304.11] | |
| Policy and procedures for removal of a single dose of medication for administration to a patient when no pharmacist is on duty. [64B16-28.602(1), F.A.C.] | |
| All prepacking, either unit dose or multiple dose, is done in accordance with policies and procedures set up by consultant pharmacist. [64B16-28.120(3) F.A.C.] | |

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| Unit dose medication is properly labeled. [61N-1.006(1)(a) F.A.C.]; [64B16-28.108(3) F.A.C.] | |
| Prepacking and labeling of unit dose or multiple dose medication is checked by Florida licensed pharmacist. [64B16-28.608(4) F.A.C.] | |
| A pharmacist is conducting the compounding or is physically present and gives direction to the registered pharmacy technician for reconstitution, addition of additives, or for bulk compounding of the parenteral solution. [64B16-27.1001(2) F.A.C.] | |
| Florida licensed pharmacist certifying the final parenterals, and bulk solutions and medication orders and documenting processing so that professional responsibility can be traced to a pharmacist. [64B16-27.1001(2), F.A.C] [64B16-27.1001(3) F.A.C] | |
| Emergency Department dispensing records properly maintained. [64B16-28.6021, 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.] | |
| Pharmacy contracted with Special P&E Ext Scope Pharmacy has Policy and Procedures manual that delineates duties and responsibilities of each entity. [64B16-28.602(2) F.A.C] | |
| All medicinal drugs provided by Special P&E EXT Scope pharmacy inspected and logged by institution. [64B16-28.602(2)(a)2. F.A.C] | |
| Multidisciplinary Committee that includes at least one pharmacist provides oversight of decentralized automated medication systems. [64B16-28.605(3) F.A.C.] | |
| Policies and procedures for decentralized automated medication system and criteria for determining medications that qualify as override medications. [64B16-28.605(3)(b)(2) F.A.C.] | |
| Pharmacy has procedures compliant with rule to assure the accuracy of stocking or restocking of decentralized automated medication system. [64B16-28.605(4) F.A.C.] | |
| Required records related to audits of stocking and output of automated medication system readily retrievable and maintained 60 days. [64B16-28.605(7) F.A.C] | |
| Pharmacy has a quality assurance program for automated medication system that provides for a review of overrides, investigation of medications error related to the automated medication system and review of discrepancies and transaction reports. [64B16-28.605(6)] | |
| Pharmacist participating in remote medication order processing are licensed in Florida [64B16-28.606(2)(a) F.A.C.] | |
| If pharmacist performing remote order entry is not an employee of the institution there is a compliant written agreement or contract with the pharmacist or entity employing the pharmacist. [64B16-28.606(2)(d) F.A.C.] | |
| Policy and Procedure for remote medication order processing compliant and available for review. [64B16-28.606(3) F.A.C] | |
| Pharmacy has established institutional formulary if necessary for the substitution of medicinal drugs. [465.025 (9), F.S] | |

Facility Performing Immediate Use Compounding Only

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| Immediate Use sterile compounds are prepared in compliance with USP <797> and administration begins not later than 1 hour from start of preparation. [64B16-27.797 FAC] | |
| CSP is properly labeled if preparer does not administer or witness the administration of the Immediate Use CSP [64B16-27.797 FAC] | |

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

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| 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. | |

Class III Institutional Pharmacy

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| Current Class III permit. [465.019(2)(d), F.S.] [64B16-28.750 F.A.C] | |
| Pharmacy is a hospital providing services to affiliated institutional pharmacies under common control. [465.019(2)(d)(1) F.S.] | |
| All Prepacking, compounding, dispensing, distribution and provision of pharmaceutical services is among permitted entities under common control. [465.019(2)(d) F.S.] | |
| Policy and Procedure for maintenance of drug records to monitor the movement, dispensing, distribution and transportation of drugs [465.019 F.S.]; [64B16-28.750(5)(a)(3) F.A.C.] | |
| Policy and Procedure for safe practices for the preparation, dispensing, prepackaging, distribution, and transportation of all medicinal drugs. [465.019, F.S.] [64B16-28.750(5)(a)(2) F.A.C.] | |
| Provisions for maintaining records of pharmacy staff responsible for each step in the preparation, dispensing, prepacking, transportation, and distribution of drugs. [465.019(2)(d)(2)(d), F.S.]; [64B16-28.750(5)(a)(4) F.A.C.] | |
| Pharmacy has procedure for Identification of drugs products that may not be safely distributed among Class III Institutional Pharmacies and health care establishment permittees. [64B16-28.750(5)(a)(5) F.A.C.] | |
| Documentation is available for inspection: of the hospital with which the permittee is affiliated, all other Class III Institutional Pharmacy permits under common control with the permittee, all healthcare clinic establishments under common control with the permittee, and the manner in which the permittee and other entities are under common control. [64B16-28.750(5)(a)(13)(c) 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: