STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES

COMMUNITY PHARMACY

Florida HEALTH
WWW.DOH.STATE.FL.US

File # 18019
Insp # 116738

ROUTINE [X] CHANGE LOC [ ] NEW [ ] CURRENTLY NOT OPERATING [ ] CHANGE OWNER [ ]

INSPECTION AUTHORITY - CHAPTER 465.017, CHAPTER 893.09 AND CHAPTER 456, FLORIDA STATUTES

NAME OF ESTABLISHMENT		PERMIT NUMBER		DATE OF INSPECTION
ONCOLOGY PLUS INCORPORATED		25216		11/26/2013
DOING BUSINESS AS		DEA NUMBER		PRESCRIPTION DEPARTMENT MANAGER
		BO7398464		
STREET ADDRESS		TELEPHONE #	EXT.	ZACHARY T SCHOLL
1070 E. BRANDON BLVD		877-410-0779		
CITY	COUNTY	STATE/ZIP		PRESCRIPTION DEPARTMENT MANAGER LICENSE #
BRANDON	39	33511		25614

PRESCRIPTION DEPARTMENT HOURS								REGISTERED PHARMACIST/INTERN/TECHNICIAN	LICENSE #
	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday		
Open	9	9	9	9	9	X	9	1. See attached	
Close	7	7	7	7	7		7	2.	
								3.	

		SATISFACTORY	N/A	YES	NO
1	Rx department hours open 5 days for 40 hours per week. [64B16-28.1081, F.A.C.]			X	
2	Pharmacy technicians properly identified and supervised. [64B16-27.420, F.A.C.]			X	
3	Pharmacist on duty when Rx department open. [64B16-28.109, F.A.C.]			X	
4	Proper signs displayed. [465.025(7), F.S.] [64B16-28.109(1), F.A.C.] [64B16-28.1081, F.A.C.] [64B16-28.1035, F.A.C.] [64B16-27.1001, F.A.C.]			X	
5	A verbal and printed offer to counsel is made to the patient or the patient's agent. [64B16-27.820(1), F.A.C.]			X	
6	Prescription department is clean and safe, has sink/running water convenient to prescription department and adequate equipment as is necessary to the professional practice of pharmacy. [64B16-28.102, F.A.C.]			X	
7	Medication properly labeled. [465.0255, F.S.] [64B16-28.108, F.A.C.]			X	
8	Expired medications removed from the shelves. [64B16-28.110, F.A.C.]			X	
9	CQI Policy and Procedures and quarterly meetings. [766.101, F.S.] [64B16-27.300, F.A.C.]			X	
10	Board-approved Policy and Procedure implemented to prevent the fraudulent dispensing of controlled substances. [465.022(4), F.S.]			X	
11	Prescriptions have the date dispensed and dispensing pharmacists. [893.04(1)(c) 6, F.S.] [64B16-28.140(3)(b), F.A.C.]			X	
12	Pharmacy maintains patient profile records. [64B16-27.800, F.A.C.]			X	
13	All controlled substance prescriptions contain information required. [893.04, F.S.]			X	
14	Prescriptions for controlled substances are on counterfeit-proof prescription pads or blanks purchased from a Department-approved vendor and the quantity and date meet the requirements of [456.42(2), F.S.].			X	
15	Prescriptions may not be filled in excess of one year or six months for controls from the date written. [893.04(1)(g), F.S.] [64B16-27.211, F.A.C.]			X	
16	Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a), F.S.]			X	
17	DEA 222 order forms properly completed. [893.07, F.S.]		X		
18	Controlled substance records and Rx information in computer system is retrievable. [21CFR 1306.22] [64B16-28.140, F.A.C.]			X	
19	Controlled substance records maintained for 4 years. [465.022(12)(b), F.S.]			X	
20	Certified daily log OR printout maintained. [21CFR 1306.22(b)(3)] [64B16-28.140(3)(b), F.A.C.]			X	
21	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.]		X		
22	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.] [465.015, F.S.]		X		
23	Pharmacy is reporting to the PDMP within 7 days of dispensing controlled substance. [893.055(4), F.S.]			X	
24	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.]		X		
25	Compounding records properly maintained. [64B16-28.140(4), F.A.C.]*			X	
26	Unit dose records properly maintained. [465.016(1)(l), F.S.] [64B16-28.118, F.A.C.]		X		
27	Pedigree records retrievable. [64F-12.012(3)(a)2., (d), F.A.C.]			X	
28	Preparation time does not exceed 1 hour when preparing, and administration begins not later than 1 hour following start of immediate use CSPs. [64B16-27.797(1)(j), F.A.C.]		X		
29	Preparation is properly labeled if preparer does not administer or witness administration when preparing immediate-use CSPs. [64B16-27.797(1) (j), F.A.C.]		X		
30	Compliant office use compounding agreement between practitioner and pharmacy available for review. [64B16-27.700 (3)(d)]		X		
31	Complete office use compounding records available for review. [64B16-27.700 (3)(e)]		X		

* Note: If establishment is engaged in sterile compounding, a separate inspection form should be completed.

Remarks: Biennial inventory Jan 2013. No walk in patients. PDM will write the Board to see if they need this Community Pharmacy Permit in addition to the Special P&E Extended Scope.

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.

PRINT NAME OF RECIPIENT James Shepherd

Institutional Representative

11-26-2013
Date

Investigator/Sr. Pharmacist Signature

ID oi129

INV 359 Revised 6/13,12/12, 5/12, 12/11, 10/11, 9/11, 10/10, 10/09, 5/06, 12/02, 12/00

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Standards of Practice for Compounding Sterile Preparations (CSPs)

ROUTINE [X] CHANGE LOC [ ] NEW [ ] CURRENTLY NOT OPERATING [ ] CHANGE OWNER [ ]

File # 10117
Insp #

INSPECTION AUTHORITY - CHAPTER 465.017, CHAPTER 893.09 AND CHAPTER 456, FLORIDA STATUTES

NAME OF ESTABLISHMENT		PERMIT NUMBER		DATE OF INSPECTION
ONCOLOGY PLUS, INCORPORATED		18045		11/26/2013
DOING BUSINESS AS		DEA NUMBER		PRESCRIPTION DEPARTMENT MANAGER
ONCOLOGY PLUS		BO7398464		
STREET ADDRESS		TELEPHONE #	EXT.	
1070 E BRANDON BLVDE		813-340-9381		
CITY	COUNTY	STATE/ZIP		PRESCRIPTION DEPARTMENT MANAGER LICENSE #
BRANDON	39	33511		

COMPOUNDING PERSONNEL	MEDIA FILLED TEST DATE	COMPOUNDING PERSONNEL	MEDIA FILLED TEST DATE
See attached			

		SATISFACTORY	N/A	YES	NO
High-Risk Level CSPs					
1	Sterilized high-risk preparations pass sterility test OR preparations are properly stored, prior to administration, not exceeding time periods specified in rule. [64B16-27.797(1)(l)4.]		X		
2	Personnel authorized to compound high-risk-level CSPs completed a media-filled test with high-risk test kit within the past 6 months (semiannually). [64B16-27.797(1)(l),F.A.C.]		X		
3	High risk sterile compounded preparations greater than 25 units have antimicrobial testing prior to dispensing [64B16-27.797(7)(a)3., F.A.C.]		X		
Medium and Low-Risk Level CSPs					
4	Medium-risk and low-risk preparations must pass sterility testing OR preparations are properly stored and do not exceed time periods specified in rule. [64B16-27.797(1)(n)4.; (o)4.]			X	
5	Personnel authorized to compound medium or low-risk level CSPs completed a media-filled test with medium-risk test kit within the past 12 months. [64B16-27.797(1)(n), F.A.C.]			X	
Barrier Isolator or Compounding Environment					
6	All sterile compounds prepared in barrier isolator which has been certified as ISO 5 by independent contractor. [64B16-27.797(5)(e), F.A.C.]		X		
7	Compounding environment appropriate for Risk Level (certification by independent qualified organization). Semi-annually for high risk, annual for medium and low-risk.			X	
	a) Anteroom/Ante area maintained within ISO class 8 [64B16-27.797(1)(a), F.A.C.]			X	
	b) Buffer area (clean room) maintained within ISO class 7 (separate room required for high-risk) [64B16-27.797(1)(f); (5)(a), F.A.C.]			X	
	c) Laminar Air Flow Hood(s) or class100 ISO room maintained within ISO class 5 [64B16-27.797(1)(k), F.A.C.]			X	
8	Buffer area does not contain sinks and drains. [64B16-27.797(1)(f), F.A.C.]			X	
Antineoplastic Drugs (Cytotoxins)					
9	Spill kits for antineoplastic agent spills. [64B16-27.797(5), F.A.C.]			X	
10	All cytotoxic preparations are compounded in a vertical flow, Class II, biological safety cabinet in a negative pressure room. [64B16-27.797(6), F.A.C.]			X	
11	Disposal of antineoplastic waste meets all applicable requirements. [64B16-27.797(6), F.A.C.]			X	
General Requirements					
12	P & P includes use of single/multidose containers not to exceed 797 guidelines. [64B16.27-797(4), F.A.C.]			X	
13	P & P includes verification of compounding accuracy and sterility. [64B16-27.797(4), F.A.C.]			X	
14	P & P includes personnel training and evaluation in aseptic manipulation skills. [64B16-27.797(4), F.A.C.]			X	
15	P & P includes environmental quality and control. [64B16-27.797(4), F.A.C.]			X	
16	Current reference material, hard copy or readily available online, are maintained. [64B16-27.797(5)(d), F.A.C.]			X	
17	Appropriate disposal containers. [64B16-27.797(5), F.A.C.]			X	
18	Appropriate temperature and transport devices. [64B16-27.797(5), F.A.C.]			X	
19	Adequate supplies (gloves, mask, etc.) to preserve a suitable environment for aseptic preparation and protective apparel for cytotoxins. [64B16-27.797(5)(6), F.A.C.]			X	
20	Documented on-going quality assurance program with audits at regular planned intervals. [64B16-27.797(7), F.A.C.]			X	
21	Compounding personnel skilled and trained based on observation. [64B16-27.797(7), F.A.C]			X	
22	Compounding records properly maintained [64B16-28.140(4), F.A.C.]			X	
23	Quantity of compounded drug is reasonable considering the intended use and nature of the practitioner's practice [64B16-27.700(3)(b), F.A.C.]			X	

Remarks: EOC Certified anteroom, buffer rooms and hoods 8/27/2013. Air and surface sampling done by EOC. Cleaning logs, pressures and other QA well documented. Pharmacists are due for media fill.

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.

PRINT NAME OF RECIPIENT James Shepherd

Institutional Representative

11-26-2013
Date

Investigator/Sr. Pharmacist Signature

ID oi129

INV 797 Revised 12/12, 12/11 Created 8/11