board meeting attendance

Info Pinnacle [info@pinnaclecompounds.com]
Sent: Tuesday, January 24, 2017 3:21 PM
To: Pharmacy Board
Attachments: Pinnacle Compounding Inspe~1.pdf (2 MB)

Hello,

Pinnacle Compounding, NV license # PH03149, is going to start sterile compounding and may be shipping into your state. Attached is our state inspection. We need to get setup to attend the March 1-2 Board Meeting in Reno please.

Thanks,

Amy Frost

Pinnacle Compounding
P.O. Box 1615
Missoula, MT 59806
info@pinnaclecompounds.com
P. (855) 466-1076
F. (406) 541-6267

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State of Montana Department of Labor and Industry
Business Standards Division
301 South Park 4th Floor Helena, MT 59620

Montana State Board of Pharmacy

Inspection Report

Record ID PHA-PHR-LIC-35266

Licensee Name:	Pinnacle Compounding Pharmacy	Inspection Date:	2016-12-12
Licensee Address	1120 KENSINGTON STE E MISSOULA, MT 59801	Inspector Name:	John Douglas
		Inspector Phone:	(406) 431-1952
Licensee Phone	406-541-6121	Inspector Email:	jdouglas@mt.gov
Inspection Type:	Annual Inspection		
Inspection Status:	Passed		

Checklist Name: PHA Community

Check List Item	Status	Comments
Is the pharmacy orderly and clean? 24.174.819(1)	Yes	Pharmacy Facility
Are required current licesnses posted in a conspicuous place? 37-3-321(1)	Yes	Pharmacy Facility
Is there adequate space and suitable equipment? 24.174.819 (2)	Yes	Pharmacy Facility
Are proper containers available and used? 24.174.819(3)	Yes	Pharmacy Facility
Is the pharmacy secure? 24.174.814	Yes	Pharmacy Facility
Does the electronic data system meet all requirements? 24.174.817	Yes	Pharmacy Facility
Is the system log of prescriptions or log book signed? 24.174.817(1b)	Yes	Daily log printed
Does the system maintain the confidentiality and accuracy of patient and prescription information? 24.174.818	Yes	Pharmacy Facility
Can the system produce a drug audit? 24.174.818(1b)	Yes	Pharmacy Facility
Are the pharmacists identified?	Yes	Pharmacy Facility
Telepharmacy Site? 24.174.1302	No	Pharmacy Facility

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Is the pharmacy registered with the Montana Prescription Drug Registry? 24.174.1702(1)	Yes	Pharmacy Facility
Is the pharmacy reporting required information to the Registry at least weekly? 24.174.1704(1)	No	Per Donna Peterson, MPDR Director: Pinnacle Compounding in Missoula, license# PHA-PHR-LIC-35266. This pharmacy has significant gaps in reporting and many reporting errors that have not been corrected.
Are patient profiles maintained as required? 24.174.901	Yes	Delivery to Patient
Does the pharmacist perform prospective drug review? 24.174.902	Yes	Delivery to Patient
Does the pharmacist counsel patients as required? 24.174.903 (1)	Yes	Contact information provided when mailing
Is there an appropriate counseling area? 24.174.903(2)	Yes	Delivery to Patient
Are generics substituted only with patient permission? 37-7-506 (1)	Yes	Delivery to Patient
Are generic selections properly documented? 37-7-505	Yes	Delivery to Patient
Are prescription refills properly documented? 24.174.515	Yes	Delivery to Patient
Are outdated pharmaceuticals removed from stock? 24.174.23019(1b)	Yes	Delivery to Patient
Are records of dispensing maintained for two years? 24.174.512	Yes	Delivery to Patient
Do the prescriptions contain the required information? 24.174.510	Yes	Prescription Requirements
Are prescriptions properly labeled? 24.174.511	Yes	Prescription Requirements
Are dispensing records maintained for two years? 24.174.512	Yes	Prescription Requirements
Are prescription transfers properly documented? 24.174.514	Yes	Prescription Requirements
Does pharmacy access a common eletronic file? 24.174.514(3)	No	Prescription Requirements

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If pharmacy accesses a common electronic file, are the required notices in place? 24.174.514(3)	N/A	Prescription Requirements
Does the pharmacy accept transmission of prescriptions by electronic means? 24.174.523	Yes	Prescription Requirements
If pharmacy accepts transmission or prescription by electronic means, are all requirements being met? 24.174.523(4)	Yes	Prescription Requirements
Telepharmacy prescription requirements met? 24.174.1302(4)	N/A	Prescription Requirements
Is the pharmacy registered with the D.E.A.? 21CFR1301	Yes	Record Keeping
Is the pharmacy Montana D.D. registration current? 24.174.1401(2)	Yes	Record Keeping
Is the D.E.A. Biennial Inventory current and available? 21CFR1304.11	Yes	Record Keeping
Is D.E.A. form 222 properly executed? 21CFR1305.06	Yes	Record Keeping
Are all Power of Attorney forms in place? 21CFR1305.07	Yes	Record Keeping
Are Schedule II records filed separately? 21CFR1304.04	Yes	Record Keeping
Are controlled substance invoices filed properly? 21CFR1303.04	Yes	Record Keeping
Are controlled substance prescriptions filed properly? 21CFR1304.04	Yes	Record Keeping
Are all controlled substance records maintained for two years? 21CFR1304.04	Yes	Record Keeping
Does pharmacy maintain perpetual inventory on C-II drugs? 24.174.814(1a)	Yes	Record Keeping
Is the perpetual inventory reconciled on a regular schedule? 24.174.814(1a)	Yes	Record Keeping
Have there been shortages or losses of CS in the past year? 21CFR1301.74	No	Record Keeping
If so, was the loss reported to the DEA and Board of Pharmacy? CSAsection 301	N/A	Record Keeping
DEA Registration/Requirements for Telepharmacy met? 24.174.1302(4)	N/A	Record Keeping
Is Certification of Pharmacist in Charge in place?	Yes	Record Keeping

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Is the Pharmacist in Charge Agreement in Place (Non-Pharmacist owner) 24.174.801	Yes	Record Keeping
Are support personnel properly registered? 24.174.701	Yes	Pharmacy Technicians
Are technicians and auxiliary personnel properly identified? 24.174.703(4)	Yes	Pharmacy Technicians
Is there a current "Technician Utilization Certificate" posted? 24.174.712	Yes	Pharmacy Technicians
Is the utilization plan accessible and being used? 24.174.712	Yes	Pharmacy Technicians
Do the contents of the training documents meet requirments? 24.174.713	Yes	Pharmacy Technicians
Are the training documents available for inspections? 24.174.714	Yes	Pharmacy Technicians
Do the Technicians and support personnel understand their responsibilities and limitations?24.174.705	Yes	Pharmacy Technicians
Technician requirements for Telepharmacy met? 24.174.1302(4)	N/A	Pharmacy Technicians
Is the standard ratio being observed? 24.174.711	Yes	Pharmacy Technicians
Has an application for increased ratio be requested? 24.174.711 (4)	No	Pharmacy Technicians
If an application for increased ratio has be requested, are the required documents in place? 24.174.711(4)	N/A	Pharmacy Technicians
Is the intern registered with the Board? 24.174.602	N/A	Pharmacy Interns
Are all the requirments of Intership being met? 24.174.602	N/A	Pharmacy Interns
Are the preceptor requirements being met? 24.174.604	N/A	Pharmacy Interns
Are the required forms and reports in place? 24.174.612	N/A	Pharmacy Interns
Has the RPh completed and accredited training course? 24.174.503	N/A	Administration of Vaccines
Does the RPh have a current C.P.R. certificate? 24.174.503	N/A	Administration of Vaccines
Are vaccines administered with established protocol? 24.174.503	N/A	Administration of Vaccines

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Is there a current copy of the C.D.C reference? 24.174.503	N/A	Administration of Vaccines
Are the required policies and procedures in place? 24.174.503	N/A	Administration of Vaccines
Are required records maintained? 24.174.503	N/A	Administration of Vaccines
Is there a proper endorsement on the pharmacy license? 24.174.503	N/A	Administration of Vaccines
Has the RPh provided an executed copy of the agreement? 24.174.524(1)	N/A	Collaborative Practice
Does the agreeement include all requirements? 24.174.524(2)	N/A	Collaborative Practice
Additional Comments		USP <797> Compliance: Per discussion with Amy Frost, Pinnacle Compounding Pharmacy is expanding into the sterile compounding realm. At the time of this inspection, sterile compounding practice has not commenced. Extensive evaluation of this facility's SOPs has occurred and the SOPs have been updated per recommendations. The facility's PEC at the time of this inspection is a CAI located in a documented ISO 7 environment. The SEC is an open architectural design.

Additional Comments:

VLS Pharmacy, Inc.
4402 – 5TH AVENUE BROOKLYN, NEW YORK 11220
PH: 718.854.1384

January 22, 2017

RECEIVED
JAN 25 2017

Nevada State Board of Pharmacy
431 W Plumb Lane
Reno, Nevada 89509

To Whom It May Concern:

VLS Pharmacy is currently licensed as a Non Resident State Pharmacy in the State of Nevada. The license # is PH03179. We are seeking to dispense Sterile and Non Sterile Compounds to the state of Nevada. VLS Pharmacy is currently accredited through the Pharmacy Compounding Accreditation Board. In addition our facility has been inspected by the National Association Boards of Pharmacy, Verified Pharmacy Program. It has been determined that VLS Pharmacy is in full compliance with all regulatory agencies. Please review documents at your convenience and reach out to us if additional information is required.

Thank you

William Rodriguez
VLS Pharmacy, Inc.
4402 5th Avenue
Brooklyn, New York 11220
Email: gopeshvls@yahoo.com

PH03179

December 29, 2016

ACHC | PCAB PHARMACY COMPOUNDING ACCREDITATION BOARD

VLS Pharmacy Inc
Gopesh Patel
4402 5th Ave
Brooklyn, NY 11220

Dear VLS Pharmacy Inc:

Thank you for submission of your recent Plan of Correction (POC) addressing to the deficiencies found during your on-site survey. The Accreditation Commission for Health Care, Inc. (ACHC) conducted an extensive evaluation of your POC, and has concluded that the plan meets the intent of compliance with the PCAB Accreditation Standards for Accreditation. PCAB is a service of ACHC.

On behalf of the Accreditation Commission for Health Care, Inc., it is my pleasure to inform you that VLS Pharmacy Inc has been ***approved for accreditation*** for the Certification Program for patient specific prescriptions of sterile and non-sterile compounds. Your accreditation is effective December 20, 2016 through July 15, 2018. Of course, maintaining accreditation is contingent upon continued compliance with PCAB Accreditation standards during this period. In granting accreditation, ACHC finds that your company has demonstrated that it operates at a level of quality, integrity and effectiveness consistent with its standards.

Should you have any questions about your organization's findings, please contact your organization's Account Advisor, Aimee Pope.

Again, congratulations on being awarded accreditation. It is an achievement of which your organization can be proud and one which demonstrates your commitment to quality in the provision of care.

Sincerely,

Jon Pritchett, Pharm.D., RPh.
Associate Director of Pharmacy

CERTIFICATE *of* ACCREDITATION

ACCREDITATION COMMISSION FOR HEALTH CARE CERTIFIES THAT:

VLS Pharmacy Inc

BROOKLYN, NEW YORK

HAS DEMONSTRATED A COMMITMENT TO PROVIDING QUALITY CARE AND SERVICES TO CONSUMERS THROUGH COMPLIANCE WITH ACHC'S NATIONALLY-RECOGNIZED STANDARDS FOR ACCREDITATION AND IS THEREFORE GRANTED ACCREDITATION FOR THE FOLLOWING:

PHARMACY

PCAB ACCREDITATION

For patient specific prescription compounding of

Non-Sterile Compounding, Ref. USP <795>

Sterile Compounding, Ref. USP <797>

FROM *December 20, 2016* THROUGH *July 15, 2018*

CHIEF EXECUTIVE OFFICER

CHAIRMAN OF THE BOARD OF COMMISSIONERS

ACHC ACCREDITED • ACHC ACCREDITED • ACHC ACCREDITED • ACHC

ACCREDITATION COMMISSION *for* HEALTH CARE

United Compounding Management (UCM) Supplement

	Non-Sterile Compounding	Y	N	?	NA	Notes
1.00	Does the pharmacy ever weigh any bulk powders outside of a powder hood?		X			
2.00	Does the pharmacy mix topical cream compounds using an unguator? *If not, please specify what is used (ie. Manual mixing, Resodyn mixer, Hobart mixer, etc)*	X				As well as Resodyn Mixer
3.00	Does the pharmacy utilize an ointment mill for topical cream compounds?	X				
4.00	Do compounding personnel don shoe covers or designated shoes while in the non-sterile compounding lab?	X				
5.00	Do compounding personnel don gowns or designated scrubs while in the non-sterile compounding lab?	X				
6.00	Do compounding personnel don hair bonnets while in the non-sterile compounding lab?	X				
	Quality Assurance	**Y**	**N**	**?**	**NA**	**Notes**
7.00	Does the pharmacy utilize lab software that has the capability to barcode chemicals and track inventory as well as capture ingredient weights?	X				
8.00	Does the pharmacy have policies and procedures in place describing the chemical intake process?	X				
8.01	Does the process include verification by a pharmacist or trained technician upon entry into system?	X				
8.02	Does the process include review of Certificate of Analysis documentation by a pharmacist or trained technician?	X				
9.00	Does the pharmacy send samples of compounded preparations to an analytical lab for process validation testing including, at a minimum, potency/purity? *Indicate in the notes if additional testing is perfomed (ie. Mixing studies).*		X			PIC stated that the pharmacy is in the process of sending random samples to an outside lab to perform potency testing; Triturated products like T3 and T4 get potency tests at ARL for every batch. PIC stated that so far, one has been tested and the other batch is in process.
9.01	If yes, are random compounded preparation samples submitted at least on a quarterly basis?				X	

10.00	Does the pharmacy have a policies and procedures in place to validate temperature control of shipped prescriptions that includes either data from the shipping container manufacturer or in-house testing that includes extremes in time and temperature (hottest day, coldest day, time in transit, etc).		X			Pharmacy uses FedEx to deliver to other NYC Boroughs
11.00	Does the pharmacy have designated individuals responsible for the creation of new Master Formulation Records?	X				
11.01	Are these individuals trained on how to calculate packing statistics on compounded capsules?	X				
11.02	Are these individuals trained on how to adjust ingredients for assay, loss on drying, and/or salt as needed?	X				
12.00	Does the pharmacy have designated individuals responsible for the creation of compound records (logs)?	X				
12.01	Are these individuals trained on how to calculate packing statistics on compounded capsules?	X				
12.02	Are these individuals trained on how to adjust ingredients for assay, loss on drying, and/or salt as needed?	X				
13.00	Does the pharmacy have a hands-on compounding training program in place for new hire pharmacists involved in the compounding process, supervision of compounding technicians, and/or creation of Master Formulation Records?	X				
14.00	Does the pharmacy have a training program in place for new hire pharmacy technicians involved in the compounding process that includes product validation testing of end-product potency/purity?	X				
15.00	Does the pharmacy have a process in place to verify and document capsule weights for accuracy?	X				
15.01	If yes, does the pharmacy weigh a minimum of 10% of the total quantity of capsules compounded in a given batch?	X				
16.00	Does the pharmacy use manufactured tablets in topical cream preparations?		X			
16.01	If yes, has the pharmacy submitted any samples to a lab for product validation testing involving end-product potency/purity?				X	

	Sales and Marketing Practices	Y	N	?	NA	Notes
17.00	Does the pharmacy promote quantities for Scar Topical compounds exceeding 60 Grams for a 30 Day supply? *Ask for copies of pre-printed prescription forms and pull hard copies to review.*		X			Pharmacy does not compound scar creams. Two month compounding records appeared to reflect this statement from the PIC.
18.00	Does the pharmacy promote quantities for Pain Topical compounds exceeding 240 Grams for a 30 Day supply? *Ask for copies of pre-printed prescription forms and pull hard copies to review.*		X			Pharmacy does not compound pain creams. Two month compounding records appeared to reflect this statement from the PIC.
19.00	Does the pharmacy utilize a sales force?	X				
19.01	If yes, does the pharmacy contract with any 1099 sales and marketing representatives? *Indicate how many and compensation structure.*		X			sales person is an employee
20.00	Does the pharmacy allow prescribers to invest in the company?		X			
20.01	If yes, do prescriber investors refer prescriptions to the pharmacy? *Please indicate any compensation structure in place for referrals.*				X	
21.00	Does the pharmacy contract with any telemedicine, telemarketing, or lead generation companies?		X			
21.01	If yes, does the pharmacy issue payments to the company for prescription referrals?				X	

	Regulatory and Contract Compliance	Y	N	?	NA	Notes
22.00	If the pharmacy is compounding stock batches of a formulation in anticipation of prescriptions, does the pharmacy have policies and procedures in place to ensure that a stock batch falls within USP beyond use dating upon dispensing? *Note largest batch size compounded, the compound type (topical cream, etc), and how quickly the pharmacy goes through that batch size.*				X	No stock batches
23.00	If the pharmacy compounds with blood products or biological materials, do they comply with OSHA requirements of offering Hepatitis B vaccinations and blood-bourne pathogen training?				X	
24.00	Does the pharmacy have a policy and procedure for copayment collection?	X				
24.01	Are copayments primarily collected prior to dispensing the prescription to the patient? *Indicate percentage collected prior to dispensing.*	X				100%
24.02	Are patients ever sent a bill for copayment amounts that are not collected prior to dispensing the prescription? *Indicate percentage.*		X			
24.03	If yes, are the amounts tracked and is there follow up, including but not limited to refusal to fill until a payment is made? *Note pharmacy tracking process.*				X	
25.00	Does the pharmacy utilize a copayment assistance program?		X			
25.01	If yes, is there established criteria based on financial need with a patient waiver?				X	
26.00	Does the pharmacy frequently offer free trial fills of a prescription for patients?		X			

General Pharmacy Scorecard			
Category	Points	Out Of	Minimum
Types of Practice Additional Questions	0	0	-1
General Operations and Licensure	3	3	2
Personnel	3	3	3
Facility and Security	15	16	13
Product Receipt and Inventory	17	17	16
Prescription Processing	17	18	15
Patient Counseling and Communication	10	10	9
Quality Assurance/Quality Improvement Program	16	20	18
Totals	81	87	75
Non-Sterile Compounding Scorecard			
Category	Points	Out Of	Minimum
General Operations and Information	15	16	15
Component Selection and Use	13	13	11
Beyond Use Dating (BUD)	6	6	6
Environment	25	25	22
Training	5	6	5
Compounding Equipment	5	5	5
Documentation	5	5	4
Compounding Procedures	12	12	11
Finished Preparation Release Checks and Tests	12	12	11
Patient Counseling and Communication	2	4	3
Totals	100	104	93
Sterile Compounding Scorecard			
Category	Points	Out Of	Minimum
General Operations and Information	17	19	17
Component Selection and Use	27	27	25
Environment	49	51	49
Cleaning and Disinfection	15	15	15
Training	6	18	16
Garbing	13	13	13
Environmental Monitoring	44	44	43
Compounding Equipment	7	7	7
Compounding Procedures	18	24	24
Finished Preparation Release Checks and Tests	11	17	17
Patient Counseling and Communication	4	4	4
Totals	211	239	230
UCM Supplement Scorecard			
Category	Points	Out Of	Minimum
General Information	4	4	2
Quality Assurance	15	17	14
Sales and Marketing Practices	4	4	2
Regulatory and Contract Compliance	5	5	4
Totals	28	30	22

Overall Pharmacy Scorecard			
Inspection	Total Points	% Total Min	Determination
General Pharmacy	81	108.0%	Approved With or Without Action Plan
Non-Sterile Compounding	100	107.5%	Approved With or Without Action Plan
Sterile Compounding	211	91.7%	Approved Pending Action Plan
UCM Supplement	28	127.3%	Approved With or Without Action Plan

Pharmacy Type	Overall Points	% Total Min Overall	Determination
Non-Sterile Compounding Pharmacy	209	110.0%	Approved With or Without Action Plan
Sterile Compounding Pharmacy	320	97.9%	Approved Pending Action Plan
Non-Sterile and Sterile Compounding Pharmacy	420	100.0%	Approved With or Without Action Plan

***Any determinations indicating "fail" results in an overall failure to meet accreditation standards - less than 80% of total minimum points. Pharmacies requiring a corrective action plan (CAP) will be sent a separate CAP under UCM letterhead.**

Scorecard Key	
<80% of Total Minimum Score	Fail - Does not meet accreditation standards
80% - 99.9% of Total Minimum Score	Approved Pending Action Plan
>99.9% of Total Minimum Score	Approved With or Without Action Plan