

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

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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
Licensee Phone:	406-541-6121	Inspector Phone:	(406) 431-1952
Inspection Type:	Annual Inspection	Inspector Email:	jdouglas@mt.gov
Inspection Status:	Passed		

Checklist Name: PHA Community

Criteria - Use Item	Status	Comments
Is the pharmacy orderly and clean? 24.174.819(1)	Yes	Pharmacy Facility
Are required current licenses 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 electronic 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 requirements? 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 requirements 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 agreement 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: