

IDAHO STATE BOARD OF PHARMACY
1199 SHORELINE LN, SUITE 303
BOISE, ID 83702
PHONE: 208-334-2356
FAX: 208-334-3536

FACILITY

_test Facility
 123 MAIN
 BOISE, ID 83709
 2083333333
 Owner: Bob

LICENSE

License No: M51422
 License Type: Manufacturer

Inspection Type:	Annual	Inspection Date:	8/20/2019 12:00:00 AM
Result:	Completed		

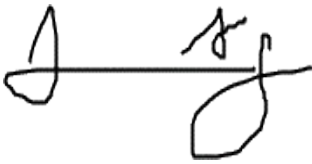
Notes:
Remarks:

Checklist Results

27.01.01.103. BOARD INSPECTIONS AND INVESTIGATIONS	
Question	Answer
27.01.01.103.01. Records Subject to Board Inspection. Records created, maintained, or retained by Board licensees or registrants in compliance with statutes or rules enforced by the Board must be made available for inspection upon request by Board inspectors or authorized agents. It is unlawful to refuse to permit or to obstruct a Board inspection. (7-1-18)	True
27.01.01.103.02. Inspections. Prior to the commencement of business, as applicable, and thereafter at regular intervals, registrants and licensees must permit the Board or its compliance officers to enter and inspect the premises and to audit the records of each drug outlet for compliance with laws enforced by or under the Board's jurisdiction. (7-1-18)	True
27.01.01.300. DRUG OUTLETS: MINIMUM FACILITY STAND	
Question	Answer
27.01.01.300.01. Security and Privacy. A drug outlet must be constructed and equipped with adequate security to protect its equipment, records and supply of drugs, devices and other restricted sale items from unauthorized access, acquisition or use. All protected health information must be stored and maintained in accordance with HIPAA. (7-1-18)	Compliant
27.01.01.300.02. Controlled Substance Storage. Drug outlets that dispense prescription drugs must store controlled substances in accordance with federal law. (7-1-18)	Compliant
27.01.01.300.03. Authorized Access to the Restricted Drug Storage Area. Access to the restricted drug storage area must be limited to authorized personnel. (7-1-18)	Compliant
27.01.01.300.05. Electronic Recordkeeping System. A drug outlet that dispenses more than twenty (20) prescriptions per day must use an electronic recordkeeping system to establish and store patient medication records and prescription drug order, refill, transfer information, and other information necessary to provide safe and appropriate patient care. The electronic recordkeeping system must have audit trail functionality that documents for each prescription drug order the identity of each individual involved at each step of its processing, filling, and dispensing or, alternatively, the identity of the pharmacist or prescriber responsible for the accuracy of these processes. (7-1-18)	Compliant
27.01.01.104.10. Substandard, Misbranded, Adulterated, or Expired Products. Manufacturing, compounding, delivering, distributing, dispensing, or permitting to be manufactured, compounded, delivered, distributed or dispensed substandard, misbranded, or adulterated drugs or preparations or those made using secret formulas. Failing to remove expired drugs from stock.	Compliant
27.01.01.500. RECORDKEEPING: MAINTENANCE AND INVEN	
Question	Answer
27.01.01.500.01. Records Maintenance and Retention Requirement. Unless an alternative standard is stated for a specified record type, form, or format, records required to evidence compliance with statutes or rules enforced by the Board must be maintained and retained in a readily retrievable form and location for at least three (3) years from the date of the transaction. (7-1-18)	Compliant
27.01.01.500.03. Inventory Records. Each drug outlet must maintain a current, complete and accurate record of each controlled substance manufactured, imported, received, ordered, sold, delivered, exported, dispensed or otherwise disposed of by the registrant. Drug outlets must maintain inventories and records in accordance with federal law. An annual inventory must be conducted at each registered location no later than seven (7) days after the date of the most recent inventory in a form and manner that satisfies the inventory requirements of federal law. Drugs stored outside a drug outlet in accordance with these rules must be regularly inventoried and inspected to ensure that they are properly stored, secured, and accounted for. Additional inventories are necessary when required by federal law. (7-1-18)	Compliant
27.01.01.500.05. Drug Distributor Records. Wholesalers and other entities engaged in wholesale drug distribution must maintain inventories and records or transactions pertaining to the receipt and distribution or other disposition of drugs in accordance with federal law. The records must include at least: (4-11-19)	True
27.01.01.500.05 a. The source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped; (4-11-19)	Compliant

27.01.01.500.05.b. The identity and quantity of the drugs received and distributed or disposed of; (4-11-19)	Compliant
27.01.01.500.05.c. The dates of receipt and distribution or other disposition of the drugs; and (4-11-19)	Compliant
27.01.01.500.05.d. Controlled substance distribution invoices, in the form and including the requirements of federal law. (4-11-19)	Compliant
27.01.01.500.07. Electronic Records Storage. Records may be electronically stored and maintained if they remain legible and are in a readily retrievable format, and if federal law does not require them to be kept in a hard copy format. (7-1-18)	Compliant
27.01.01.103.03. Inspection Deficiencies.	
Question	Answer
27.01.01.103.03. Inspection Deficiencies. Deficiencies noted must be promptly remedied, and if requested, the Board office notified of corrective measures. One (1) follow-up inspection may be performed by the Board at no cost. For additional follow-up inspections, the drug outlet will be charged actual travel and personnel costs incurred in the inspection to be paid within ninety (90) days of inspection. (7-1-18) [Deficiencies must be corrected within-]	DAYS
27.01.01.103.04. Inspection Reports. Inspection reports must be reviewed with the Board inspector and signed by an agent of the drug outlet upon completion of the exit interview. (7-1-18) [Discussed with]	NAME
Deficiencies- Education of Code and Rule provided?	Yes
Deficiencies- Issued Warning to Pharmacy -Possible Discipline?	True
Disclaimer - Any items not discussed specifically by compliance officer on this inspection does not constitute compliance nor approval.	True

THE UNDERSIGNED LICENSEE OR REPRESENTATIVE AT THE TIME OF INSPECTION ACKNOWLEDGES RECEIPT OF THIS INSPECTION REPORT.



Berk Fraser

8/20/2019 12:00:00 AM

Date/Time



Signature of Owner/Representative