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CLASS B
NARCOTIC TREATMENT
PROGRAM PHARMACY

INSPECTION

Opening Random

INFORMATION

Pharmacy Name: _____ Date: _____

License Number: _____ Exp Date: _____

C.S. License Number: _____ Exp Date: _____

DEA Registration: _____ Exp Date: _____

Pharmacy FEIN # (Tax ID): _____

Pharmacy Email: _____

Pharmacy Phone # _____ Fax: _____

Toll Free Number: _____

Affiliated Websites: _____

Pharmacy Hours: Monday-Friday: _____ Saturday: _____ Sunday: _____

Pharmacy Address: _____

City: _____ State: _____ Zip: _____

Supervising Pharmacist: _____

License #: _____ Expiration Date: _____

Personnel

List ALL current licensed pharmacy employees (attach a separate sheet, if necessary):

Name:	License #	Title:	Exp:
Name:	License #	Title:	Exp:
Name:	License #	Title:	Exp:
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INSPECTION

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|--|------------|-----------|--|
| | YES | NO | |
|--|------------|-----------|--|
- 1 ☐ ☐ Class B pharmacy means a pharmacy located in Utah that is authorized to provide pharmaceutical care for patients in an institutional setting; and whose primary purpose is to provide a physical environment for patients to obtain health care services; and includes closed-door, hospital, clinic, nuclear, and branch pharmacies; and pharmaceutical administration and sterile product preparation facilities. [UCA 58-17b-102 (11)(a)(i-ii)(b)(i-ii)]

 - 2 ☐ ☐ The facility shall maintain a current list of licensed employees involved in the practice of pharmacy at the facility. The list shall include individual licensee names, license classifications, license numbers, and license expiration dates. The list shall be readily retrievable. The list may be maintained in paper or electronic form. [UAC R156-17b-614a (5)(a)(i-iv)(b)]

 - 3 ☐ ☐ Notification has been provided to the Division in regards to the unique email address used in self audits or alerts for the pharmacy. The pharmacy will use a single email address and notify the Division of any change in the email address within seven days of the change. [UAC R156-17b-603(3)(t) (i-ii)]

 - 4 ☐ ☐ Notification has been provided to the Division in regards to the assignment of the PIC at the above stated pharmacy. The Division is notified of a change in PIC within 30 days of the change. [UAC R156-17b-603 (3) (s)]

 - 5 ☐ ☐ All individuals employed in a pharmacy facility having any contact with the public or patients receiving services from that pharmacy facility does wear on their person a clearly visible and readable identification showing the individual's name and position. [UCA 58-17b-603 (1)]

 - 6 ☐ ☐ The facility conducts a pharmacy self-audit on a form provided by the Division, in accordance with the the following time frames: within 30 days of a change of consulting pharmacist, PIC, DMPIC, or RDPIC; within 30 days of the opening of a new facility; and at least 90 days before the end of each license renewal cycle. The facility maintains each pharmacy self-audit form for two years from the date of the self-audit. [UCA R156-17b-603 (3)(u)(i-iv)]
 Date of last self inspection: _____

 - 7 ☐ ☐ The facility does have current and retrievable editions of the following reference publications in print or electronic format and readily available and retrievable to facility personnel:

UCA 58-1 (DOPL Licensing Act)	UAC R156-1 (General Rules of DOPL)
UCA 58-17b (Pharmacy Practice Act)	UAC R156-17b (Pharmacy Practice Act Rules)
UCA 58-37 (Controlled Substance Act)	UAC R156-37 (Controlled Substance Act Rules)
UCA 58-37f (Controlled Substance Database Act)	UAC R156-37f (Controlled Substance Database Act Rule)
Code of Federal Regulations Title 21 parts 1300 to end	FDA Approved Drug Product(Orange Book)
General Drug References	

 - 8 ☐ ☐ The facility is well lighted, ventilated, clean and sanitary. [UAC R156-17b-614a (1) (a)]

 - 9 ☐ ☐ If transferring a drug from a manufacturer's or distributor's original container to another container, the dispensing area, shall have a sink with hot and cold culinary water separate and apart from restroom facilities. All required equipment shall be clean and in good operating condition. [UAC R156-17b-614a (1)(b)(c)]

- 10 ☐ ☐ The facility is equipped to permit the orderly storage of prescription drugs and durable medical equipment in a manner to permit clear identification, separation and easy retrieval of products and an environment necessary to maintain the integrity of the product inventory. [UAC R156-17b-614a (1) (d)(i)(ii)]
- 11 ☐ ☐ The facility is equipped to permit practice within the standards and ethics of the profession as dictated by the usual and ordinary scope of practice to be conducted within that facility. [UAC R156-17b-614a (1) (e)]
- 12 ☐ ☐ All out of date legend drugs and controlled substances shall be removed from the inventory at regular intervals and in correlation to the beyond use date imprinted on the label. [UAC R156-17b-605 (1)]
- 13 ☐ ☐ The facility is stocked with the quality and quantity of product necessary for the facility to meet its scope of practice in a manner consistent with the public safety. [UAC R156-17b-614a (1) (e)]
- 14 ☐ ☐ If dispensing controlled substances, the facility is equipped with a security system to permit detection of entry at all times when the facility is closed, and provide notice of unauthorized entry to an individual, and be equipped with a lock where drugs are stored and locked when the pharmacy department is closed. [UAC R156-17b-614a (1)(g)(i-ii)(h)(i-ii)]
- 15 ☐ ☐ If the pharmacy does not store drugs in a locked cabinet and has a drop/false ceiling, the pharmacy's perimeter walls shall extend to the hard deck, or other measures shall be taken to prevent unauthorized entry into the pharmacy. [UAC R156-17b-614a (15)]
N/A
- 16 ☐ ☐ Only a licensed Utah pharmacist or authorized pharmacy personnel does have access to the pharmacy when the pharmacy is closed. [UAC R156-17b-614a (7)]
- 17 ☐ ☐ The temperature of the pharmacy is maintained within a range compatible with the proper storage of the drugs. [UAC R156-17b-614a (3)]
- 18 ☐ ☐ The temperature of the refrigerator and freezer is maintained within a range compatible with the proper storage of drugs requiring refrigeration or freezing. The pharmacy shall keep a daily written or electronic log of the temperature of the refrigerator or freezer on days of operation. The pharmacy shall retain the log entry for three years. [UAC R156-17b-614a (3)]
- 19 ☐ ☐ Patient counseling shall not be required for inpatients of a hospital or institution where other licensed health care professionals are authorized to administer the patient's drugs. [UAC R156-17b-610 (7)]
- 20 ☐ ☐ Every pharmacy shall verbally offer to counsel a patient or a patient's agent in a personal face-to-face discussion regarding each prescription drug dispensed. If the patient's agent delivers the prescription in person to the pharmacist or pharmacy intern; or receives the drug in person at the time it is dispensed at the facility. [UCA 58-17b-613 (1)]
- 21 ☐ ☐ Counseling shall be offered orally in person unless the patient or patient's agent is not at the pharmacy or a specific communication barrier prohibits oral communication [UAC R156-17b-610(1)]
- 22 ☐ ☐ A pharmacy facility shall orally offer to counsel, but is not be required to counsel a patient or patient's agent when the patient or patient's agent refuses counseling. [UAC R156-17b-610(2)]
- 23 ☐ ☐ The offer to counsel is documented and said documentation shall be available to the Division. These records must be maintained for a period of five years and be available for inspection within 7-10 business days. [UAC R156-17b-610 (4)]
- 24 ☐ ☐ Unless otherwise requested, child-resistant containers will be used for dispensing medications to patients. [16 CFR 1700.15]

- 25 ☐ ☐ Each drug dispensed from the pharmacy does have a label securely affixed to the container indicating the required minimum information, including: [UCA 58-17b-602 (5) (a) (i-viii)]
- | | |
|--|---|
| name address, & phone number of pharmacy | serial number of prescription |
| filling date or last dispensing date | name of the patient or animal owner/species |
| name of the prescriber | directions for use & cautionary statement |
| <input type="checkbox"/> trade, generic or chemical name | amount dispensed & strength of dosage form |
| (Unless Otherwise Indicated by Prescriber) | beyond use date |
- 26 ☐ ☐ Controlled substances are not accepted back for destruction unless allowed for by state and federal law. [UAC R156-37-606 (1-2) & 21 CFR 1307.22]
- 27 ☐ ☐ The registered pharmacy does only process electronically signed prescriptions for controlled substances under the following conditions: the pharmacy uses a pharmacy application that meets all the applicable requirements; the prescription is otherwise in conformity with the requirements of the Code of Federal Regulations; and Certification Authority (CA) has been obtained. The electronic prescription must be transmitted from the practitioner to the pharmacy in its electronic form and at no time may the prescription be converted to another form (i.e. facsimile) for transmission. [UAC R156-17b-613(1) & 21 CFR 1311]
- 28 ☐ ☐ Prescription files, including refill information, are maintained for a minimum of five years and should be immediately retrievable in written or electronic format. [UAC R156-17b-612 (4)]
- 29 ☐ ☐ Prescription records may be maintained electronically so long as the original of each prescription, including telephone prescriptions, is maintained in a physical file and contains all of the information required by federal and state law; and an automated data processing system is used for the storage and immediate retrieval of refill information for prescription orders. [UAC R156-37-602 (4) (a-b)]
- 30 ☐ ☐ All records relating to Schedule II controlled substances received, purchased, administered or dispensed by the practitioner shall be maintained separately from all other records of the pharmacy or practice. Records shall be maintained by the licensee for a period of five years. [UAC R156-37-602(3, 5)]
- 31 ☐ ☐ All records relating to Schedule III, IV, V controlled substances received, purchased, administered or dispensed by the practitioner shall be maintained separately from all other records of the pharmacy or practice. Records shall be maintained by the licensee for a period of five years. [UAC R156-37-602(3, 6)]
- 32 ☐ ☐ Requirement for taking the initial controlled substance inventory shall include the following: pharmacies having stock of controlled substances shall take an inventory, including out-of-date drugs and drugs in automated pharmacy systems, on the opening day of business; if a pharmacy commences business with no Schedule I or II controlled substances, the pharmacy shall record this fact as the initial inventory and shall document Schedule I and II controlled substance inventory separately from an inventory reporting no Schedule III, IV, and V controlled substances; the initial inventory shall serve as the pharmacy's inventory until the next completed inventory as specified in Subsection (4) of this section. [UAC R156-17b-605(3)(a-c)] ☐ **N/A**
- 33 ☐ ☐ Requirement for annual controlled substances inventory shall be within 12 months following the inventory date of each year and may be taken within four days of the specified inventory date and shall include all stocks including out-of-date drugs and drugs in automated pharmacy systems. [UAC R156-17b-605 (4)]
- 34 ☐ ☐ General Requirements for inventory of a pharmacy shall include: [UAC R156-17b-605 (2)(a)(b)(c)(f)(g)(h)(k)(l)]

the PIC shall be responsible for taking all required inventories, but may delegate the performance of the inventory to another person or persons;

- ☐ the inventory records shall be maintained for a period of five years and be readily available for inspection
- ☐ the inventory shall be filed separately from all records
- ☐ the inventory may be taken either as the opening of the business or the close of business on the inventory date;
- ☐ the person taking the inventory and the PIC shall indicate the time the inventory was taken and shall sign and date the inventory with the date the inventory was taken. The signature of the PIC and the date of the inventory shall be documented within 72 hours or three working days of the completed initial, annual, change of ownership and closing inventory.
- ☐ the inventory of Schedule I and II controlled substances shall be listed separately from the inventory of Schedule III, IV and V controlled substances.
- ☐ if the pharmacy maintains a perpetual inventory of any of the drugs required to be inventories, the perpetual inventory shall be reconciled on the date of the inventory.

- 35 ☐ ☐ All pharmacy shall maintain a perpetual inventory of Schedule II controlled substances that shall be reconciled according to facility policy. [UAC R156-17b-605(6)]
- 36 ☐ ☐ The pharmacy does reconcile its controlled substance inventory to account for shortages of controlled substances. [UAC R156-17b-603 (3) (j) & R156-37-502(5)]
- 37 ☐ ☐ Any facility who experiences a shortage or theft of controlled substances does immediately notify law enforcement and file the appropriate forms with the Drug Enforcement Administration, with a copy to the Division directed to the attention of the Investigation Bureau. [UAC R156-37-602 (2)]
- 38 ☐ ☐ Pharmacists or other responsible individuals do verify that the suppliers' invoices of controlled substances, listed on the invoices were actually received by clearly recording their initials and the actual date of receipt of the controlled substances. [UAC R156-17b-614a (11)]
- 39 ☐ ☐ The facility does maintain a record of suppliers' credit memos for controlled substances. [UAC R156-17b-614a (12)]
- 40 ☐ ☐ The facility does maintain a copy 3 of DEA order form (form 222) which has been properly dated, initialed, and filed and all copies of each unaccepted or defective order form and any attached statements or other documents. [UAC R156-17b614a(9)(a-c)]

COMMENTS

☐ By checking this box it is indicated that the undersigned Division Investigator has reviewed the above inspection report and comments made with the undersigned "Responsible Party."

Signature of Responsible Party: _____

Date: _____

Name of Responsible Party (Print): _____

Signature of Division Investigator: _____

Date: _____

Name of Division Investigator (Print): _____

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