UTAH DEPARTMENT OF COMMERCE
Division of Professional Licensing

160 E 300 S
P.O. Box 16741
Salt Lake City, UT 84114-6741

Phone: (801) 530-6628
Toll Free: (866) 275-3675
Online: DOPL.utah.gov
Email: DOPLInvestigations@utah.gov

CLASS B
PHARMACEUTICAL
ADMINISTRATION FACILITY

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: _____

Consulting Pharmacist: _____

License # _____ Expiration Date: _____

Personnel

List ALL licensed personnel that have access to the pharmacy and administer medication

(attach a separate sheet, if necessary)

Name: _____ License # _____ Exp: _____

Name: _____ License # _____ Exp: _____

Name: _____ License # _____ Exp: _____

Name: _____ License # _____ Exp: _____

Name: _____ License # _____ Exp: _____

Name: _____ License # _____ Exp: _____

Name: _____ License # _____ Exp: _____

Name: _____ License # _____ Exp: _____

Name: _____ License # _____ Exp: _____

Name: _____ License # _____ Exp: _____

Name: _____ License # _____ Exp: _____

Name: _____ License # _____ Exp: _____

INSPECTION

	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)]
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 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	☐	☐	The licensed pharmacist shall provide consultation on all aspects of pharmacy services in the facility; establish a system of records of receipt and disposition of all controlled substances in sufficient detail to enable an accurate reconciliation; and determine that drug records are in order and that an account of all controlled substances is maintained and periodically reconciled. [UAC R156-17b-614c (1)]
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	☐	☐	When communicating by any means, written, verbal, or electronic, pharmacy personnel do identify themselves as to licensure classification. [UCA 58-17b-603 (2)]
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: [UAC R156-17b-614a (4) (a-k)]

- ☐ 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)]
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) (c)]
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 health, safety and welfare. [UAC R156-17b-614a (1) (f)]

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 on any entrances to the facility where drugs are stored. [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. [R156-17b-610 (7)]

20 ☐ ☐ Controlled substances are not accepted back for destruction unless allowed for by state and federal law. [UAC R156-37-606 (1-2) & 21 CFR 1307.21]

21 ☐ ☐ Authorized destruction of all prescription drugs shall be witnessed by the medical or nursing director or a designated physician, registered nurse or other licensed person employed in the facility and the consulting pharmacist or licensed pharmacy technician and must be in compliance with DEA regulations. [UAC R156-17-614c (2)]

22 ☐ ☐ Prescriptions for patients in the facility can be verbally requested by a licensed prescribing practitioner and may be entered as the prescribing practitioner's order; but the practitioner must personally sign the order in the facility record within 72 hours if a Schedule II controlled substance and within 30 days if any other prescription drug. The prescribing practitioner's verbal order may be copied and forwarded to a pharmacy for dispensing and may serve as the pharmacy's record of the prescription order. [UAC R156-17b-614c (3)]

23 ☐ ☐ Prescriptions for controlled substances for patients in Class B pharmaceutical administration facilities shall be dispensed according to Title 58, Chapter 37, Utah Controlled Substances Act, and R156-37, Utah Controlled Substances Act Rules. [UAC R156-17b-614c (4)]

24 ☐ ☐ 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)]

25 ☐ ☐ 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)]

26 ☐ ☐ 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)]

27 ☐ ☐ Requirements for taking the initial controlled substances inventory shall include the following: all pharmacies shall take an inventory on the opening day of business. Such inventory shall include all controlled substances including any out-of-date drugs and drugs in automated pharmacy systems. In the event a pharmacy commences business with no controlled substances on hand, the pharmacy shall record this fact as the initial inventory. An inventory reporting no Schedule I and II controlled substances shall be listed 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)(b)(c)]
☐ **N/A**

28 ☐ ☐ 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.

29 ☐ ☐ All pharmacies shall maintain a perpetual inventory of all Schedule II controlled substances. [UAC R156-17b-605(6)]

30 ☐ ☐ The pharmacy does reconcile its controlled substance inventory to account for shortages of controlled substances. [UAC R156-17b-603 (3) (k) & R156-37-502(4)]

31 ☐ ☐ Any facility who experiences any theft, including diversion, or significant loss of controlled substances shall immediately file the appropriate froms with the Drug Enforcement Administration, with a copy to the Division directed to the attention of the Investigation Bureau Division; and report the incident to the local law enforcement agency. [UAC R156-37-602 (2)]

32 ☐ ☐ 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)]

33 ☐ ☐ The facility does maintain a record of suppliers' credit memos for controlled substances. [UAC R156-17b-614a (12)]

34 ☐ ☐ 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)]

35 ☐ ☐ Requirements for emergency drug kits shall include: [UAC R156-17b-614c (5) (a-g)]

☐ an emergency drug kit may be used by pharmaceutical administration facilities. The emergency drug kit shall be considered to be a physical extension of the pharmacy supplying the emergency drug kit and shall at all times remain under the ownership of that pharmacy;

☐ the contents and quantity of drugs and supplies in the emergecy drug kit shall be determined by the Medical Director or Director of Nursing of the pharmaceutical administration facility and the consulting pharmacist of the supplying phrmacy;

☐ a copy of the approved list of contents shall be conspicuously posted on or near the kit;

☐ the emergency kit shall be used only for bona fide emergencies and only when medications cannot be obtained from a pharmacy in a timely manner;

☐ records documenting the receipt and removal of drugs in the emergency kit shall be maintained by the facility and the pharmacy;

☐ the pharmacy shall be repsonsible for ensuring proper storage, security and accountability of the emergency kit and shall insure that the emergency kit is stored in a locked area and is locked itself; and emergency kit drugs are accessible only to licensed physicians, physician assistants and nurses employed by the facility;

☐ the contents of the emergency kit, the approved list of contents and all related records shall be made freely available and open for inspection to appropriate representatives of the Division and the Utah Department of Health.

36 ☐ ☐ The pharmacy utilizes an Automated Pharmacy System? If the answer is "yes" to this question, a automation questionnaire must be completed. [UAC R156-17b-620]

37 ☐ ☐ Does the pharmacy purchase any compound products from other entities for dispensing to patients? [UAC 58-17b-102(18)(b)(i)]

38 ☐ ☐ The facility is engaged in medium or complex compounding activities as defined by USP 35 Chapter 795. If you answer “yes” to this question, a compounding questionnaire must be completed. [(UAC R156-17b-614a (2)]

39 ☐ ☐ The facility is engaged in low, medium, or high risk *sterile* compounding as defined by USP 35 Chapter 797. If you answer “yes” to this question, a compounding questionnaire must be completed. [UAC R156-17b-614a (2)]

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):

Revised 8/2023