UTAH DEPARTMENT OF COMMERCE
Division of Professional Licensing

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CLASS B
HOSPITAL CLINIC

# 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: _____

Pharmacist In Charge (PIC): _____

PIC License # _____ Expiration Date: _____

## Personnel

**List ALL pharmacists, interns, pharmacy technicians and techs-in-training (attach a separate sheet, if necessary):**

Name: _____ License # _____ Exp: _____

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## 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 | ☐ | ☐ | 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 | ☐ | ☐ | If the facility has a pharmacy technician training program, the program and curriculum of education and training, meets standards established by Division rule made in collaboration with the Board. [UAC R156-17b-303a (3)] ☐ **N/A** |
| 6 | ☐ | ☐ | A pharmacy technician trainee shall practice only under the direct supervision of a pharmacist, and in a ratio not to exceed one pharmacy technician trainee to one pharmacist. [UAC R156-17b-601(4)(a)] |
| 7 | ☐ | ☐ | Pharmacy technicians shall have general supervision by a pharmacist. [UCA 58-17b-102 (56)] |
| 8 | ☐ | ☐ | The operating standards for a Pharmacist acting as a preceptor includes meeting the following criteria by providing direct, on-site supervision to no more than two pharmacy interns during a working shift. [UAC R156-17b-606(1)(d)(i)] |
| 9 | ☐ | ☐ | In accordance with Subsecton 58-17b-102(71)(b) all supportive personnel shall be under the supervision of a licensed pharmacist or DMP. The licensed pharmacist or DMP shall be present in the area where the person being supervised is performing services and shall be immediately available to assist the person being supervised in the serivces being performed except for the delivery of pre-filled prescriptions as provided in Subsection (1)(g) above. [UAC R156-17b-607 (3)] |
| 10 | ☐ | ☐ | In accordance with Subsection 58-17b-102(71)(a), supportive personnel may assist in any tasks not related to drug preparation or processing including: stock ordering and restocking; cashiering; billing; filing; receiving a written prescription and delivering it to the pharmacist, pharmacy intern, pharmacy technician, pharmacy technician trainee, DMP, or DMP desigenee; housekeeping; and delivering a pre-filled prescription to a patient. [UAC R156-17b-607 (1)(a-g)] |

**11** ☐ ☐ The pharmacist-in-charge (PIC) is responsible for assuring that no pharmacy or pharmacist operates the pharmacy or allows operation of the pharmacy with a ratio of pharmacist to pharmacy personnel which, under the circumstances of the particular practice setting, results in, or reasonably would be expected to result in, an unreasonable risk of harm to public health, safety, and welfare. [UAC R156-17b-603 (3) (r)]

**12** ☐ ☐ 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)]

**13** ☐ ☐ When communicating by any means, written, verbal, or electronic, pharmacy personnel do identify themselves as to licensure classification. [UCA 58-17b-603 (2)]

**14** ☐ ☐ The facility or parent company does maintain a record for not less than five years of the initials or identification codes that identify each dispensing pharmacist by name. The initials or identification codes shall be unique to ensure that each pharmacist can be identified; therefore identical initials or identification codes shall not be used. [UAC R156-17b-614a (8)]

**15** ☐ ☐ 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

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

**17** ☐ ☐ 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)]

**18** ☐ ☐ 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)]

**19** ☐ ☐ 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) (d)]

**20** ☐ ☐ 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)]

**21** ☐ ☐ 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) (e)]

**22** ☐ ☐ 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) (f)(i-ii)(g)]

**23** ☐ ☐ 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**

**24** ☐ ☐ 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)]

**25** ☐ ☐ A pharmacy shall not dispense a prescription drug or device to a patient unless a pharmacist is physically present and immediately available in the facility. [UAC R156-17b-614a(6)]

**26** ☐ ☐ The temperature of the pharmacy is maintained within a range compatible with the proper storage of the drugs. [UAC R156-17b-614a (2)]

**27** ☐ ☐ 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 (2)]

**28** ☐ ☐ For the purpose of promoting therapeutic appropriateness, a pharmacist shall at the time of dispensing a prescription, or a prescription drug order, review the patient's medication record. Such review shall at a minimum identify clinically significant conditions, situations or items, such as: [UAC R156-17b-611 (2) (a-g)]

- ☐ Inappropriate drug utilization
- ☐ Therapeutic duplications
- ☐ Drug-disease contraindications
- ☐ Drug-drug interactions
- ☐ Incorrect drug dosage
- ☐ Incorrect duration of drug treatment
- ☐ Drug-allergy interactions
- ☐ Clinical abuse or misuse

**29** ☐ ☐ 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)]

**30** ☐ ☐ 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) (vii,viii)]

- ☐ trade, generic or chemical name *(Unless Otherwise Indicated by Prescriber)*
- ☐ beyond use date

**31** ☐ ☐ In accordance with Section 58-17b-610.6, the guidelines for a hospital pharmacy to dispense to an individual who is no longer a patient, on the day discharged from the hospital setting, are established in this section. The prescription drug shall be dispensed during regular hours, by a pharmacist; or outside of regular inpatient hospital hours, by the prescribing practitioner using an appropriately labeled pre-packaged drug. [UAC R156-17b-610.6 (1) (a,b)]

**32** ☐ ☐ Labeling for a prescription under Section 58-17b-610.6 shall at a minimum include: [UAC R156-17b-610.6 (2) (a-f)]

- ☐ prescribing practitioner's name, facility name and telephone number;
- ☐ patient's name;
- ☐ name and strength of medication;
- ☐ date given;
- ☐ instructions for use;
- ☐ beyond use date.

**33** ☐ ☐ Unless otherwise requested, child-resistant containers will be used for dispensing medications to patients. [UAC 58-1-502(6)& 16 CFR 1700.14]

**34** ☐ ☐ 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]

**35** ☐ ☐ The registered pharmacy does only processes 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) & CFR, Title 21, Chapter 11, Section 1311]

**36** ☐ ☐ 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)]

**37** ☐ ☐ 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)]

**38** ☐ ☐ 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)]

**39** ☐ ☐ 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)]

**40** ☐ ☐ 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)]

**41** ☐ ☐ 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-c)] ☐ **N/A**

**42** ☐ ☐ General Requirements for inventory of a pharmacy shall include: [UAC R156-17b-605 (2)(a)(b)(c)(e)(f)(i)(j)]

- ☐ 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.

**43** ☐ ☐ All pharmacies shall maintain a perpetual inventory of all Schedule II controlled substances. [UAC R156-17b-605(7)]

**44** ☐ ☐ 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)]

**45** ☐ ☐ Any facility who experiences any theft, including diversion, or significant loss of controlled substances shall immediately file the appropriate forms 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)]

**46** ☐ ☐ 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)]

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

**48** ☐ ☐ 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)]

**49** ☐ ☐ Applicable data of controlled substances dispensed under 58-17b-610.6 shall be reported to the Utah Controlled Substance Database. [UAC R156-17b-610.6 (3)]

**50** ☐ ☐ The Division shall implement on a statewide basis, including non-resident pharmacies as defined in Section 58-17b-102, the following two options for a pharmacist to submit information: real-time submission of the information required to be submitted under this part of the controlled substance database; and 24-hour dail or next business day, whichever is later, batch submission of the information required to be submitted under this part to the controlled substance database. [UCA 58-37f-203(1)(a)(i,ii)]

**51** ☐ ☐ In accordance with 58-37f-203(6), the pharmacist-in-charge and the pharmacist identified in Subsections 58-37f-203(2) and (3) shall provide the following data fields to the Division: the state that issued identification, type of identification used, and identification number used by individual picking up dispensed drug. [UCA R156-37f-203 (4) (aa-cc)]

**52** ☐ ☐ Performing checks of certain medications prepared for distribution fill or prepared by another technician with a Class B hospital pharmacy, such as medications prepared for distribution to an automated dispensing cabinet, cart fill, crash cart medication tray, or unit dosing from a prepared stock bottle, in accordance with the following operating standards: [UCA R156-17b-601 (1) (l) (i-v)]

☐ technicians authorized by a hospital to check medications shall have at least one year of experience working as a pharmacy technician and at least six months experience at the hospital where the technician is authorized to check medications;

☐ technicians shall only check steps in the medication distribution process that do not require the professional judgement of a pharmacist and that are supported by sufficient automation or technology to ensure accuracy (e.g. barcode scanning, drug identification automatiion, checklists, visual aids);

☐ hospitals that authorize technicians to check medications shall have a training program and ongoing competency assessment that is documented and retrievable for the duration of each technician's employment and shall maintain a list of technicians on staff that are allowed to check medications;

☐ hosptials that authorize technicians to check medications shall have a medication error reporting system in place and shall be able to produce documentation of its use;

☐ a supervising pharmacist shall be immediately available during all times that a pharmacy technician is checking medications;

**53** ☐ ☐ Hospitals that authorize technicians to check medications shall have comprehensive policies and procedures that guide technician checking that includes the following: [UCA R156-17b-601 (1) (l) (vi) (A-F)]

☐ process for technician training and ongoing competency assessment and documentation;
☐ process for supervising technicians who check medications;
☐ list of medications, or types of medications that may or may not be checked by a technician;

☐ description of the automation or technology to be utilized by the institution to augment the technician check;
☐ process for maintaining a permanent log of the unique initials or identification codes that identify each technician responsible for checked medications by name; and
☐ description of processes used to track and respond to medication errors.

**54** ☐ ☐ The pharmacy maintains emergency kits in nursing homes, long-term care facilities, or other entities (such as hospice, EMT's, ambulances)? If the answer is "yes", note name(s) of facilities or entities.

**55** ☐ ☐ The pharmacy maintains automated prescription dispensing devices outside the pharmacy such as Pyxis in a nursing home? If the answer is "yes", note type and location.

**56** ☐ ☐ 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]

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

**58** ☐ ☐ The facility is engaged in compounding with hazardous drugs as defined by USP-NF Chapter 800. If you answer "yes" to this question, a compounding questionnaire must be completed.

**59** ☐ ☐ The facility is engaged in simple, 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 (3)]

**60** ☐ ☐ 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 (3)]

**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 8/2022