

Proposed Checklist of Pharmacist-in-Charge Responsibilities

Approved for Division website: BOP meeting October 2023

This checklist is created to highlight the responsibilities of a pharmacist-in-charge (PIC) according to Utah Code 58-17b and Utah Admin. Code R156-17b. This form can be used as a tool to aid the pharmacy in preparation for a Division inspection as well as maintain standard operating procedures for a Class A and B pharmacy in accordance with the state and federal regulations. Below is the summary of duties and responsibilities of a PIC.

****This summary only contains a subset of the responsibilities and is subject to change. Please refer to the current Utah Code 58-17b and Utah Admin. Code R156-17b to ensure compliance.**

Daily

- Oversee the operation of the pharmacy and remote dispensing pharmacy in conformance with all laws and rules pertinent to the practice of pharmacy and the distribution of drugs, durable medical equipment, and medical supplies including: 58-17b-602 and R156-17b-603.
 - Ensuring drugs are packaged, prepared, compounded, labeled, and dispensed safely and accurately as prescribed.
 - Assure that pharmacy personnel deliver drugs to the patient or patient's agent safely and accurately as prescribed.
 - Assure that pharmacy personnel communicates to the patient or the patient's agent information concerning any prescription dispensed to the patient.
 - Assure that a reasonable effort is made to obtain, record, and maintain patient medication records.
 - Establish policies for procurement of prescription drugs, devices, and other products dispensed from the pharmacy.
 - Disposal of expired drugs or reverse distribution of drugs from the pharmacy.
 - Proper storage of all materials, including drugs, chemicals, and biologicals.
 - Maintain records of all transactions of the pharmacy.
 - Establish and maintain effective controls against theft or diversion of prescription drugs and records.
 - Implement ongoing quality assurance to monitor performance of automated pharmacy system.
 - Assure appropriate licensure of all pharmacy personnel.

Report Control Substance dispensing data (either in real time or batch file reporting) to the database. 58-37f-203(1).

Pharmacy shall submit a zero report if no controlled substances have been dispensed. 58-37f-203(6).

Ensure reporting of administered vaccines to Utah State Immunization Information System (USIIS) electronic registry within 1 week of administration.

Annually:

Annual controlled substance inventory of all stocks including out-of-date drugs and drugs in automated pharmacy systems. Use cover sheet to ensure compliance.
<https://dopl.utah.gov/wp-content/uploads/2022/09/controlled-substances-inventory-log.pdf>

Renewal of waiver of controlled substance license even if not dispensing controlled substances and does not anticipate doing so in the immediate future.

Obtain renewal of Vaccine Administration Protocol from licensed provider.

Inventories:

All out of date legend drugs and controlled substances shall be removed from the inventory and availability to dispense at regular intervals.

Ensure pharmacy maintains a perpetual inventory on all schedule II controlled substances.

Oversee maintenance of all Scheduled II-V controlled substances inventory.

Staffing:

Notify the Division within 30 days of any change in PIC.

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 for inspection by the Division and may be maintained in paper or electronic form.

Obtain proper licenses for the pharmacy and pharmacy personnel in the facility.

Ensure technician-in-training programs meet the requirements established by the Division.

Ensure all technician-in-training have an active Pharmacy Technician Trainee License.

Ensure that pharmacist to non-pharmacist personnel ratio in the pharmacy is appropriate.

Ensure all individuals with public or patient contact are wearing identification that clearly states name and position and individuals clearly state name and position when communicating via any means.

Ensure pharmacists, pharmacy interns, and pharmacy technicians employed by the pharmacy have received required training in accordance with Utah Admin Code R156-17b-309 and R156-17b-621 of the Pharmacy Practice Act Rules are authorized to administer vaccines.

Miscellaneous:

The PIC must provide a secure email address to be used for self-audits or pharmacy alerts initiated by the Division. Notify DOPL within seven days of any change to email address.

Ensure facilities utilizing Automated Pharmacy Systems are compliant with R156-17b-620.

Ensure facilities engaging in sterile or non-sterile compounding are compliant with compounding laws/rules R156-17b-614.

Ensure the pharmacy uses United States Postal Service, common carrier, or supportive personnel to deliver prescriptions by shipping. Ship all prescriptions according to manufacturers recommendations or USP Chapter 1079, and all applicable rules outlined in R156-17b-608.

Ensure each drug dispensed from the pharmacy has a label securely affixed to the container indicating the required minimum information.

Ensure electronic prescriptions meet applicable requirements and is maintained in electronic form and at no time converted to another form for transmission (i.e facsimile).

Conduct a pharmacy self-audit within 90 days before the end of each renewal cycle.

Facility:

Readily available and current editions of reference publications:

- DOPL Licensing Act
- General Rules of DOPL
- Pharmacy Practice Act and Act Rules
- Controlled Substance Act and Act Rules
- Controlled Substance Database Act Rule
- Code of Federal Regulations
- Orange Book
- General Drug References

The facility is well lighted, ventilated, clean and sanitary.

The facility is equipped with a security system or some measure 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.

Only a licensed Utah pharmacist or authorized pharmacy personnel have access to the pharmacy when the pharmacy is closed.

The temperature of the pharmacy is maintained within a range compatible with the proper storage of the drugs.

The temperature of the refrigerators and freezers are maintained within a range compatible with the proper storage of drugs requiring refrigeration or freezing. A log of temperatures must be recorded daily and retained for three years.

Ensure facility has a counseling area to allow for confidential patient counseling.

Records:

Maintain records of disposal of controlled substances and be made available on request to the Division or its agents for inspection for a period of 5 years. R156-37-606.

Maintain a record of unique initials or identification codes of every dispensing pharmacist for no less than 5 years.

Maintain records and are readily available for the following according to The Code of Federal Regulations (CFR) and Division of Professional Licensing (DOPL). R156-37-602.
Disposal of controlled substances.
Purchase, distribution, dispensing, prescribing, and administration of controlled substances (separated by CII, CIII-CV, and non-controlled).
Perpetual records of all vaccines administered.

Ensure facility maintains a copy of DEA form 222.

Offer to counsel on prescriptions, document that counseling was offered, and make said documentation available to the Division for a period of five years.

Prescription files, including refill information, is maintained for a minimum of five years and should be immediately retrievable in written or electronic format.

Controlled Substance Records:

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 for a period of five years.

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 for a period of five years.

Ensures the facility maintains a supplier invoices and credit memos for controlled substances.

Maintain records of disposal of controlled substances and be made available on request to the Division or its agents for inspection for a period of 5 years. R156-37-606.

Ensures shortages or theft of controlled substances are reported to law enforcement, DOPL, and the DEA with the proper forms.

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