[Your Pharmacy Name Here]



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| Prepared by/Date: | Approved by/Date: |

# 1.0 Policies

## 1.01 “Example” of a Mission Statement Policy

1. **Purpose:** This policy describes the Pharmacy Mission Statement.
2. **Scope:** This policy applies to all Pharmacy personnel who must understand, be aware of, and always comply with the Pharmacy Mission. All personnel require training to this policy.
3. **Definitions:** N/A
4. **Policy:**

Mission Statement: "This pharmacy is committed to providing the best services and products that meet or exceed our customer's expectations to improve their health and wellness. We will constantly strive for continuous improvements in our processes, product quality, and on-time delivery."

* **NOTE:** To the Policy Maker only. Delete prior to publication.Above is an example of how the statement could read. It is the responsibility of Pharmacy management to draft the mission for the Pharmacy based on its goals, objectives, and customer service ideals. The statement should be no longer than the example above and may be shorter. It is intended to be an "easy to remember” statement by all personnel, and it sometimes is printed on the back of personnel ID cards or banners within the work environment; also, auditors may ask personnel what the company "mission" is to see if they are fully aware of this policy.

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## 1.02 Whistleblower Policy

1. **Purpose:** This policy describes the process under which complaints regarding unethical behavior, accounting controls and practices, and Code of Conduct matters will be addressed.
2. **Scope:** This policy applies to all Pharmacy personnel.
3. **Definitions:** N/A
4. **Policy:** Any person may submit a good faith complaint under this policy regarding suspected dishonest or unethical behavior. All personnel may do so without fear of dismissal or retaliation of any kind for any lawful action taken in making the complaint. This Pharmacy is committed to achieving compliance with all applicable securities laws and regulations, accounting standards and controls, audit practices, and business ethics practices.

Receipt of Complaints: All personnel with concerns regarding questionable conduct or a violation of the company Code of Conduct may report their concerns to the Director of Pharmacy via email, phone call, or in person.

Upon receipt of complaint, the Director of Pharmacy shall determine whether the complaint pertains to the matters within the scope of this policy and, when applicable, acknowledge receipt of the complaint to the individual who made the claim.

* Confidentiality will be maintained to the fullest extent possible consistent with the need to conduct an adequate review or investigation.
* Warranted investigations will be prompt and appropriate corrective action will be taken as warranted in the judgment of Pharmacy personnel.
* As per the **Pharmacy Code of Conduct** and this policy, the Pharmacy shall not discharge, demote, suspend, threaten, harass, or in any manner discriminate against any employee in the terms for any lawful actions taken in making a good faith complaint.
* A log of submitted complaints will be maintained by Pharmacy management to track receipt, investigation, and resolution, and Pharmacy management shall prepare a periodic summary report. These reports will be maintained in a confidential manner and in compliance with Pharmacy document retention procedures.

**References:**  [Policy 3.18 - Code of Conduct](#page80)

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## 1.03 Safety Program

1. **Purpose:** This policy outlines the Pharmacy Safety Program.
2. **Scope:** This policy applies to all Pharmacy personnel.
3. **Definitions:**

**OSHA:** Occupational Safety and Health Administration; an agency of the United States Department of Labor that regulates workplace safety and health.

1. **Policy:**
2. The Pharmacy is committed to providing a safe workplace for all personnel.
3. The Pharmacy shall comply with state and federal laws and regulations concerning occupational safety and health (OSHA). The Pharmacy strongly maintains, however, that the best source of protection for the health and safety of the work force is in the individual employee.
4. The Pharmacist-in-Charge (PIC) should oversee program administration and development. The PIC shall determine if an accident is “[OSHA reportable](https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=9638).” For reportable events, the appropriate [OSHA forms](https://www.osha.gov/recordkeeping/new-osha300form1-1-04.pdf) should be filled out and a copy maintained on file.
5. Personnel are responsible for following all health and safety rules described in this program, OSHA safety standards, and the training they receive.
6. Safety Training is an essential part of the Safety Program. To ensure all personnel are trained before they start a task, a basic Safety Training Orientation shall be completed for all new personnel. Basic training shall include:

* Basic Safety Rules
* Emergency Planning – What to do in the event of an emergency
* Reporting an Accident or Unsafe Condition
* Hazard Prevention and Control
* Safety Inspections, Safety Meetings, and Safety Suggestions

1. It is the responsibility of the PIC to outline the safety training requirements for the job description and ensure that the proper safety training is completed and documented.

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## 1.04 Training Program

1. **Purpose:** This procedure describes the Pharmacy Training Program and outlines the training requirements for personnel employed within the Pharmacy.
2. **Scope:** This policy applies to all Pharmacy personnel.
3. **Definitions:**

**Additional Training (AT):**  Any training that is above and beyond what is normally required by an employee. This training can result from: a test score below a minimum required; not meeting pre-defined performance levels; refresher training for those that may have been away for a long period of time; an investigated complaint; or revision of training materials.

**Annual Training:**  Mandatory training that is conducted annually by law, such as HIPAA training.

**Computer-Based Training (CBT**)**:**  Accomplished via computer-based modules created by vendors or proprietary training created for personnel education and training.

**Continuing Education (CE):**  Education that is achieved on an annual basis by pharmacy technicians and pharmacists as part of their mandatory continuing education needs for licensure and/or required specialized credentialing. This training may be accomplished via external means, e.g. not through the Pharmacy. The Training Department provides pharmacists and pharmacy technicians with resources that offer continuing education. Documentation of this type of training must be delivered to the Training Department as soon as possible after education is completed. These can be in the form of certificates or other documentation to prove completion.

**External Training:** Training that is accomplished outside of the Pharmacy sponsored training for example: Microsoft Office training, seminars, workshops, etc.

**Learning Management System (LMS):**  A system where training, as it pertains to personnel needs, will be made electronically accessible for personnel to complete and pertains to Pharmacy operations.

**On-the-Job Training (OJT):**  Accomplished while performing the job under the direction and supervision of a trainer. The trainer is responsible for documenting all training accomplished via an OJT record, which can be electronic or in hard copy.

**Self**-**Paced** **Training:**  Training that does not have a definitive due date.

**Specialty Training:** Training that is specific to working in a specific work area of the Pharmacy.

**Subject Matter Expert (SME):**  Individuals with expertise in specific specialties who: 1) are primary trainers for their respective specialties; and/or 2) are responsible for documenting, revising, and reviewing procedures in their specialty.

1. **Policy:** It is the policy of the Pharmacy to ensure an effective Training Program is in place and all personnel are provided relevant up-to-date training as it becomes available to meet each employee's specific needs.

**Responsibility**

The Training Department has overall responsibility for training coordination, scheduling, tracking, and training documentation management.

Personnel are responsible for the completion of assigned training and completing training documentation within defined timelines. The manager will be informed of an employee’s failure to meet these requirements.

The manager’s responsibility is to ensure the training is accomplished.

**New Hire Training**

All new personnel must attend a New Hire Orientation training within the first 30 days of hire. This initial training will cover HR material/ benefits, Pharmacy policies, procedures, and/ or programs such as safety and annual mandatory training requirements.

All new personnel will be assigned training upon hire based on the job description. Training will be scheduled by the Training Department.

**Training Documentation**

The Training Department will maintain personnel Training Files. The file may be electronic or hard copy.

All completed training shall be documented on a Training Record. This shall be a hard copy document that contains: title of training, name of trainer, the printed name of the employee(s) who attended with their written signature and date. The Training Record is submitted to the Training Department for recording on the employee's training file.

At any time, a Supervisor or Manager may request to view the personnel training file for their direct personnel.

As authorized by senior management, the Training Department will cooperate with any auditor or agency who is on official business and requests to view training documentation.

1. **References:** Policy 3.36 Medicare Training

Policy 3.37 Medicaid Training

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## 1.05 Compliance Program

1. **Purpose:** It is the policy of the Pharmacy to comply with all applicable laws and regulations while providing optimum and quality health care.
2. **Scope:** This policy applies to all Pharmacy personnel.
3. **Definitions:** N/A
4. **Policy:** It is the policy of the Pharmacy to have an effective compliance program as defined in our Code of Conduct and policies and procedures.

**Responsibility:**

* 1. All Personnel: It is the responsibility of all personnel to comply with the Code of Conduct and to understand all policies and procedures that apply to them. Personnel should:
* Ask their manager for clarification of the policies and procedures when needed.
* Raise any concerns about potential compliance issues immediately, but not more than 30 days from discovery.
* Cooperate with Pharmacy investigations into compliance concerns.
  1. Managers: In addition to the above responsibilities, managers are responsible for:
* Creating a culture that fosters ethics and compliance.
* Encouraging personnel to raise concerns.
* Ensuring personnel take all required compliance training in a timely fashion.
* Promptly addressing or reporting employee concerns that are reported to them.
* Taking prompt corrective action to fix any substantiated compliance-related issues.
  1. Management Team: The Pharmacist-in-Charge (PIC) shall assign a management teamfor the Pharmacy that is responsible for:
* Tracking applicable laws and regulations.
* Assisting with and conducting risk assessments in the Pharmacy.
* Leading investigations (either internally or externally) of all compliance-related concerns.
* Recommending corrective actions as appropriate.

The management team shall stay current with all laws and regulations affecting the Pharmacy (including federal and state pharmacy law, state-controlled substance law, state Medicaid law, Medicare law, Fraud/ Waste/ Abuse law, and HIPAA). The management team shall communicate changes in governing laws and regulations as well as recommended corrective actions to Pharmacy personnel.

* 1. Personnel who have questions or concerns about the Compliance program or any compliance-related issue should contact the management team.
  2. The Pharmacy has a zero-tolerance policy for retaliation against anyone who raises a compliance concern.

1. **References:** Policy 1.02 Whistleblower Policy

Policy 3.18 Code of Conduct

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## 1.06 Family and Medical Leave Act

1. **Purpose:** To describe the Pharmacy’s policy of providing leave in accordance with the Family and Medical Leave Act (FMLA).
2. **Scope:** This policy applies to all personnel who are eligible for FMLA leave, as defined by federal law.
3. **Definitions:** N/A
4. **Policy:** The Pharmacy realizes that personnel occasionally need to take time away from work to care for important family and medical needs. This policy is designed to meet those needs in a manner that is beneficial to personnel, their families, and the Pharmacy. It also represents the intent of the Pharmacy to comply with the requirements and purposes of the Family and Medical Leave Act of 1993 (FMLA), when the Pharmacy employs fifty (50) or more employees within a 75-mile radius. Please note that the Pharmacy utilizes the most current guidance and forms available from the United States Department of Labor. Accordingly, the following summary merely outlines the requirement of the FMLA and its complex applications to your possible circumstance.
   1. Reason for Leave

The FMLA entitles eligible personnel of covered employers to take unpaid, job-protected leave for specified family and medical reasons with continuation of group health insurance coverage under the same terms and conditions as if the employee had not taken leave. Eligible personnel are entitled to:

* Twelve workweeks of leave in a 12-month period for:
  + The birth of a child and to care for the newborn child within one year of birth.
  + The placement with the employee of a child for adoption or foster care and to care for the newly placed child within one year of placement.
  + To care for the employee’s spouse, child, or parent who has a serious health condition.
  + A serious health condition that makes the employee unable to perform the essential functions of his or her job.
  + Any qualifying exigency arising out of the fact that the employee’s spouse, son, daughter, or parent is a covered military member on “covered active duty.”
* Twenty-six workweeks of leave during a single 12-month period to care for a covered service member with a serious injury or illness if the eligible employee is the service member’s spouse, son, daughter, parent, or next of kin (military caregiver leave).

Requests for leaves of absence in situations other than those governed by the FMLA, such as military, educational, personal, and so forth, are not addressed in this policy.

* 1. Eligibility

To be eligible for a leave of absence under this policy, you must have:

* Been employed by the Pharmacy for at least 12 months;
* Worked at least 1,250 hours during the previous 12 months; and
* Be qualified to receive a FMLA leave as provided in 1.0 above.
  1. Amounts of Leave

If you are an eligible employee, you may take up to twelve (12) weeks of leave during a 12-month period for qualifying situations. A request for a leave of absence generally will not be approved if you have already used 12 weeks of leave under this policy during the 12 months preceding the date you requested to begin your leave (rolling 12 months). Different rules may apply when both spouses work for the same Pharmacy. Please consult the Pharmacist-in-Charge (PIC) if this applies to your situation.

New Child Leave must be taken within twelve months of the child’s birth or placement. It must be taken at one time unless you have made special arrangements with the Pharmacy to take the leave in a different manner, which must be verified in writing and signed by a Pharmacy Director or PIC. If both husband and wife work for the Pharmacy, they will be entitled to a total of 12 weeks combined rather than 12 weeks each.

* 1. Compensation during Leave

Leaves of absence under this policy are generally without pay. If you take a leave under this policy, you must use all your available accrued paid time off (PTO) as part of that leave. Regardless of whether you receive PTO during the leave, the full amount of leave time will be counted toward the 12-week maximum FMLA leave available in a 12-month period.

During any leave under this policy, you will continue to be covered by the Pharmacy’s group health insurance plan if you satisfy the requirements of this policy and the insurance plan.

* 1. You Pay Your Portion

During leave, you are responsible to pay your portion of the insurance premium as though you continued in active employment. All premiums should be submitted to the Payroll Department. You may pay for your share of the premium before you take the leave, and you are required to pay it no later than 30 days after it would be due if you were actively employed.

* 1. Not Returning to Employment

Coverage may stop if the Pharmacy learns and verifies that you do not intend to return to your employment or if you do not return to your employment. In these cases, the Pharmacy may request you to reimburse it for any premiums it has paid on your behalf during the leave unless the reason you did not return was because of a continued serious health condition or for other reasons beyond your control as identified in the FMLA.

* 1. Failure to Comply

If you fail to comply with these requirements, including paying your portion of the insurance premium, your insurance coverage may end.

* 1. Notifying the Pharmacy

You are responsible for notifying the Pharmacy if you need leave under this policy. The following information provides the required notification that you must provide depending on the circumstances of the situation causing you to need leave.

* Foreseeable Events: The Pharmacy requests you to complete and submit the [FMLA Request Form](#FM09) at least 30 days in advance of foreseeable leave, such as leave for planned medical treatment or for your child’s birth.
* Unforeseeable Events: For unforeseeable events, such as accidental injury causing a serious health condition, premature birth, or a sudden change in your health, the Pharmacy requests you notify it of your need for leave as soon as it is possible and practical to do so (preferably by submitting the [FMLA Request Form](#FM09), but at least orally). You can generally notify the Pharmacy of unforeseen leave within one or two business days of when you find out you will need the leave. For unforeseeable leave, the Pharmacy requests that you submit the form as soon as practicable even if you have provided oral notification.
* Failure to Comply: Failure to follow these practices may result in delay or denial of your leave. In the case of foreseeable leave, the Pharmacy may delay your leave for up to 30 days from the date you notify the Pharmacy of your need to take a leave of absence.
  1. Certification of Serious Health Condition

If you are requesting medical leave to care for a family member or medical leave due to your own serious health condition, you must provide a Certification of Physician or Practitioner to verify the serious health condition causing the need for a leave of absence (see References for links). The Certification must be completed by a qualified health care provider. If you have a question about who is qualified as a health care provider, please ask the Pharmacy Director or PIC.

* 1. Definition of Serious Health Condition

FMLA leave will not be granted for a health condition unless it is for an illness, injury, impairment, or physical or mental condition that involves one or more of the following:

* + In-patient care.
  + A period of incapacity requiring more than three calendar days of absence from work or similar daily activities, and the individual receives continuing treatment by a health care provider.
  + A chronic or long-term condition that is so serious that if it were not treated it would result in more than three calendar days of absence and you receive continuing treatment by a health care provider.
  + Prenatal care.
  1. Timing of Certification

The Pharmacy requests that you submit the Certification with your Application Form for a leave of absence. In no event should the Certification be submitted later than 15 days following your request for a leave. After you turn in the Certification from your health care provider, the Pharmacy may still request you to see another health care provider at its expense (and possibly a third one, if the first two medical opinions are inconsistent). The Pharmacy reserves the right to request periodical additional Certification during the term of a leave of absence.

* 1. Requirement to Minimize Disruption for Planned Medical Treatments

For all leaves involving planned medical treatments, including intermittent and reduced schedule leaves, you are obligated to plan for treatments so that they will cause the least disruption to the Pharmacy’s operations. Your earliest possible notice to the Pharmacy and your flexibility in scheduling will assist in making certain that minimal disruption occurs.

* 1. Inability to Perform the Job

Inability to perform the job is a requirement for employee medical leave. You may qualify for medical leave due to your own serious health condition only if the Medical Certification states that you are not able to perform the essential functions of your employment position.

* 1. Medical Necessity for Family Medical Leave

You may qualify for medical leave to care for a covered family member only if the Certification states that you are needed to care for your family member and your family member is covered by the FMLA.

* 1. Failure to Comply

If you fail to follow these guidelines or if you falsify any information related to the Medical Certification, your leave may be delayed or denied, and discipline, up to and including discharge, may result.

* 1. Returning to Work after Employee Medical Leave

When you return from leave due to your own serious health condition you must provide certification that you are able to resume working. Prior to returning to work, you should contact Payroll to submit your medical clearance to return to work and to determine when you should report for duty. Failure to follow these procedures may result in delay when you are ready to come back to work or discipline, up to and including termination.

* 1. Intermittent or Reduced Schedule Leave

If and only if it is medically necessary, leave under this policy may be taken on an intermittent or reduced schedule basis. Intermittent or reduced schedule leave will be counted on an hour-by-hour basis to apply toward the 12-week maximum per 12 months.

Additional Requirements:

You must explain the medical reason for an intermittent or reduced schedule leave, and you must support your reason with the appropriate medical Certification. Furthermore, you must inform the Pharmacy about your anticipated treatment schedule and the reasons for your proposed schedule.

Alternative Position or Schedule:

The Pharmacy may require you to work in a different position or on a different schedule during the period of an intermittent or reduced schedule leave that will better accommodate the necessities of your schedule. The alternative position will have the same pay and benefits as the position you held prior to the commencement of the leave.

* 1. Restoration of Same or Equivalent Position

When you return from FMLA leave under this policy, you will be returned to the same or an equivalent position unless you have been notified prior to your leave request that you are a “key employee.” You will not lose any seniority or benefits because of your leave, although you will not accrue any additional PTO or other benefits during the period of the leave.

If your FMLA leave exceeds 12 weeks within a 12-month period, you will not be guaranteed a job upon return from the leave, unless otherwise required by law. Use of an FMLA leave shall not insulate you from: (1) disciplinary actions based on conduct that occurred prior to going on leave; or (2) transfer among positions if such transfer was planned prior to your requesting FMLA leave and is not based on the fact that a leave was planned. If you fail to return to work at the end of FMLA leave, you will be considered to have voluntarily terminated your employment.

1. **References:**

* [FM-9 FMLA Request Form](#_FM-09_Family_and)
* [WH-380-E: Certification of Health Care Provider for Employee’s Serious Health Condition (FMLA)](http://www.dol.gov/whd/forms/WH-380-E.pdf)
* [WH-380-F: Certification of Health Care Provider for Family Member’s Serious Health Condition (FMLA)](http://www.dol.gov/whd/forms/WH-380-F.pdf)

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## 1.07 Substance Abuse

1. **Purpose:** The purpose of this policy is to describe the Pharmacy’s policy on substance abuse.
2. **Scope:** This policy applies to all personnel.
3. **Definitions:** N/A
4. **Policy:** The Pharmacy is aware that a disproportionately high number of pharmacists and pharmacy personnel experience issues with addiction and substance abuse. Personnel who experience problems with substance abuse are encouraged to get professional help. There are many professional organizations available that will provide counseling and assistance to pharmacists and pharmacy personnel who have problems with substance abuse. If you have a substance abuse problem, you are encouraged to seek help from the Pharmacy’s Personnel Assistance Program (if one exists) or to contact the confidential substance abuse treatment program identified by the state Board of Pharmacy. Personnel who self-report and who seek help for treatment will not be disciplined for seeking help, and the Pharmacy will attempt to work with each individual in obtaining any necessary treatment.

It is unsafe for patients and other personnel to have personnel working who are under the influence of alcohol, prescription drugs, marijuana (if legal in the state), or an illegal substance. Accordingly, consistent with its Code of Conduct, the Pharmacy will discipline personnel who report to work under the influence of alcohol or other substances.

If state law requires pharmacies, pharmacy technicians, pharmacists, or pharmacists-in-charge to report suspected substance abuse problems, and someone on the Pharmacy’s staff has knowledge that a licensed colleague has a substance abuse problem, the employee is encouraged to communicate his/ her suspicions to the Pharmacy before reporting the suspected behavior to the state Board of Pharmacy. Depending upon the requirements of state law, management may be required to report the suspected substance abuse to either the Board or the state’s confidential substance abuse treatment program. In the alternative, if state law permits, management may request that an employee self-report and seek treatment. If the employee does not seek treatment, management may report the employee to the Board or substance abuse treatment program. Be advised that the Pharmacy will comply, and expects its personnel to comply, with all laws.

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## 1.08 Patient Bill of Rights

1. **Purpose:** The purpose of this policy is to describe a Patient’s Bill of Rights that shall be followed for the services provided to Pharmacy customers.
2. **Scope:** This policy applies to all Pharmacy personnel.
3. **Definitions:** N/A
4. **Policy:** The Pharmacy is committed to protecting the health and welfare of patients through the Pharmacy’s delivery of quality, patient-focused care and education. We encourage our pharmacists and Pharmacy personnel to adopt this 8-point Patient Bill of Rights and apply it to their patients and customers so that patients and their families understand their rights and responsibilities. The Patient Bill of Rights shall be posted within the Pharmacy in an easily viewable location and/ or a copy shall be provided to customers upon request.

**Patient Bill of Rights**

1. The patient has the right to considerate and respectful care.
2. The patient has the right to and is encouraged to obtain from pharmacists and other direct caregivers relevant, current, and understandable information concerning his or her medication therapy and treatment.
3. The patient is entitled to the opportunity to discuss and request information related to his or her specific drug therapy, the possible adverse side effects, and drug interactions.
4. The patient has the right to make decisions about the plan of care prior to and during treatment, and to refuse a recommended treatment or plan of care.
5. The patient has the right to expect that all communication, discussion, and patient counseling will be conducted to protect each patient's privacy.
6. The patient has the right to expect that all records and discussion pertaining to his or her drug therapy will be treated as confidential by the pharmacist, and the patient has the right to expect that the pharmacist will emphasize the confidentiality of patient information to any other parties entitled to review the patient's information and records.
7. Patients have a right to competent counseling from the pharmacist to help them understand their medications and use them correctly.
8. Patients have the right to file a complaint with the state Board of Pharmacy concerning any pharmacist or pharmacy if they believe that a violation was committed concerning safety, health, privacy, or the confidentiality of their personal information.

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## 1.09 Mandatory Reporting Policy

1. **Purpose:** To provide guidance to personnel as to when changes in job duties, licensing, and misconduct could result in a report to the Board of Pharmacy or other applicable licensing or regulatory authority.
2. **Scope:** This policy applies to all personnel with professional licenses.
3. **Definitions:**  N/A
4. **Policy:** Applicable state laws and pharmacy regulations may require the Pharmacy to report employment-related issues to the Board of Pharmacy. The types of situations that often result in mandatory reporting may include:
   * + A change in pharmacist
     + A change in P.I.C.
     + A change in intern/ extern employment
     + A change in preceptor
     + A change in technician
     + Charges, arrests, and convictions
     + Unprofessional conduct as defined by state regulations
     + Drug or alcohol impairment
     + Lawsuits, claims, or settlements if required by state regulations

Be advised that the Pharmacy will comply with federal, state, and local reporting requirements, and the Pharmacy expects its licensed personnel to comply with any applicable self-reporting requirements.

**NOTE:** To the Policy Maker only. Delete prior to publication. Mandatory reporting requirements are state-specific. This list is not intended to be comprehensive and is intended to be a suggestion of what types of events might trigger mandatory reporting. You should consult with a local attorney or with your local Board of Pharmacy to determine what events are subject to mandatory reporting and modify your policy and practices accordingly.

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## 1.10 HIPAA Privacy & Patient Confidentiality

1. **Purpose:** This procedure describes how Pharmacy personnel will comply with the HIPAA Privacy and Patient Confidentiality Rule, as well as applicable state laws.
2. **Scope:** This procedure applies to all Pharmacy personnel.
3. **Definitions:** N/A
4. **Safety Requirements:** N/A
5. **Procedure:** We will provide a copy of our HIPAA Notice of Privacy Practices (Notice) to our patients and to anyone else who requests a copy, and we will revise the Notice as appropriate. Our personnel will not use or disclose patient information in a manner that is inconsistent with our Notice, HIPAA, or state law.

Pharmacy personnel are responsible for the following:

1. Provide our Notice to each new patient and have the patient sign the Acknowledgement of Receipt form. If the patient refuses to sign the acknowledgment, note on the form that the patient refused and the reason for the refusal. If the patient has a personal representative, such as a parent/ or guardian, provide the Notice to that individual, asking the person to sign the Acknowledgment form.
2. Retain each completed acknowledgment form for six (6) years from the date it was created or the date that it was last in effect, whichever is later.
3. Do not access patient information that you are not authorized to access or is not necessary to perform your job. Always limit uses, disclosures, and requests for patient information to the minimum amount necessary.
4. When a patient picks up a prescription, and you do not know the person, ask for a photo ID, date of birth, address, or some other information to verify identity.
5. When someone other than a patient requests to pick up a prescription or asks for another patient’s information, that individual may not do so until the patient has first signed an authorization form.
6. In all other cases, if you are not sure that an individual has the authority to access the information requested, direct the request to the Privacy Officer who will verify the person’s identity and authority to make a determination regarding the patient information requested.
7. **References:** [FM-06 HIPAA Notice of Privacy Practices](#TM02)

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## 1.11 Patient Confidentiality

1. **Purpose:** This policy is to describe the Pharmacy policies regarding the confidentiality of patient information.
2. **Scope:** This policy applies to all personnel.
3. **Definitions:**

**Protected Health Information (PHI):** Individually identifiable health information that: (a) is transmitted by or maintained in electronic media; or (b) that is transmitted or maintained in any other forum or medium. PHI does not include individually identifiable health information that is: (a) kept in records governed by FERPA (Family Educational Right to Privacy Act); (b) records described in [20 U.S.C. 1232g(a)(4)(B)(iv](http://uscode.house.gov/view.xhtml?req=(title:20%20section:1232g%20edition:prelim)%20OR%20(granuleid:USC-prelim-title20-section1232g)&f=treesort&edition=prelim&num=0&jumpTo=true)); and (c) employment records held by a covered entity (such as a pharmacy) in its role as employer.

1. **Policy:**  The law and our professional ethics require that personnel maintain the confidentiality of PHI when handling patient matters. To maintain this professional confidence, no personnel shall disclose patient information to outsiders, including other patients, third parties, or members of one's own family. Pharmacy personnel should take care to use only patient first names when addressing patients and that discussions and advice regarding patient health matters and medications be done quietly and at such a distance from other patrons as to minimize the risk of a third party overhearing the discussion. Patients trust personnel to maintain their confidentiality and care.

**Care of Patient Records**

Pharmacy policy and federal and state laws require that the Pharmacy maintain accurate and current patient records. These records are important because they help prevent medication errors and enable the Pharmacy to monitor and track usage, as well as bill for services provided. Patient records may not be removed from the premises for any reason.

Patient records should be handled with care. Falsification of patient records is strictly prohibited.

Occasionally, patients or other physicians will request copies of Pharmacy records. Under no circumstances will requests for patient records be fulfilled unless an authorization that complies with HIPAA regulations is completed.

Any disclosure of PHI or other confidential information relating to patients will result in disciplinary action, up to and including discharge. The Pharmacy has policies and procedures regarding HIPAA compliance, and you are expected to follow them. Failure to follow our policies and procedures may result in disciplinary action up to and including discharge.

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## 1.12 Security of Health Information

1. **Purpose:** This policy is to describe safeguards that the Pharmacy has adopted to protect the security of health information.
2. **Scope:** This policy applies to all personnel.
3. **Definitions:**

**Protected Health Information (PHI):**  Individually identifiable health information that: (a) is transmitted by or maintained in electronic media; or (b) that is transmitted or maintained in any other forum or medium. PHI does not include individually identifiable health information that is: (a) kept in records governed by FERPA (Family Educational Right to Privacy Act); (b) records described at [20 U.S.C. 1232g(a)(4)(B)(iv)](http://uscode.house.gov/view.xhtml?req=(title:20%20section:1232g%20edition:prelim)%20OR%20(granuleid:USC-prelim-title20-section1232g)&f=treesort&edition=prelim&num=0&jumpTo=true); and (c) employment records held by a covered entity (such as a pharmacy) in its role as employer.

1. **Policy:**  The law and professional ethics require that personnel maintain the confidentiality of PHI when handling patient matters. These laws apply whether the patient information is contained in hard copy or electronic format. To ensure that the health information of Pharmacy patients is as secure as possible, the Pharmacy has adopted the following rules:
   * + Building alarms must be set when the premises are unoccupied.
     + The building must be locked during non-business hours.
     + Access to the area behind the Pharmacy counter must be restricted.
     + No visitors are permitted behind the Pharmacy counter.
     + Computer screens must be blocked from secondary viewers whenever possible.
     + Personnel are prohibited from sharing their computer access passwords.
     + The Pharmacy will conduct periodic reviews of user activity and access.
     + Personnel are prohibited from downloading software from the Internet or using any unauthorized software on company computers.
     + Backup systems to ensure periodic backup of data and patient health information to prevent loss of data in case of an emergency.
     + Fire extinguishers should be made readily accessible in areas where patient health information is stored.
     + Computer server rooms must be kept locked.
     + Access to computer programs containing PHI is granted on a need to know basis.
     + Whenever possible, use encryption software and programs when transmitting PHI.
     + Remember that HIPAA protocols apply to online and email communications with patients and other providers.
     + Personnel must not make or retain copies of records containing PHI.
     + Personnel may never take PHI off Pharmacy premises.

Failure to follow Pharmacy policies and procedures may result in disciplinary action, up to and including discharge.

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## 1.13 Anti-Harassment

1. **Purpose:** A fundamental policy of the Pharmacy is that the workplace is for work. This policy is to ensure that personnel are able to focus on their jobs without experiencing illegal harassment.
2. **Scope:** This policy applies to all personnel.
3. **Definitions:**

**Prohibited Harassment:** Includes but is not limited to: verbal harassment (derogatory statements, slurs, teasing, jokes, epithets, innuendo); physical harassment (sexual and personal touching, assault, physical interference with normal work or involvement); visual harassment (posters, cartoons, drawings, computer materials, sexual gestures); and any use of technology such as texting that mimics any or all these examples.

1. **Policy:** The Pharmacy is committed to maintaining a work environment free from tension created by non-work-related conduct, including, but not limited to, harassment and discrimination based on protected characteristics including race, color, gender, religion, national origin, age, disability, sexual orientation, veteran status or any other basis protected by state and federal law. The Pharmacy expects all personnel to conduct themselves in a professional manner with respect and concern for coworkers. Any harassment or discrimination based on the protected characteristics listed above will not be tolerated, whether it is by Pharmacy personnel, vendors, or customers.

**Sexual Harassment**

Harassment or discrimination because of gender or sex deserves special attention and is strictly prohibited. Sexual harassment includes unwelcome sexual advances, requests for sexual favors, sexually motivated physical contact, and other verbal or physical conduct or visual forms of harassment of a sexual nature. Examples of harassment can include, but are not limited to, the following:

* Making a sexual or suggestive remark or gesture about any person’s clothing, physical appearance, or body (including whistling or “cat calls” and gestures using hand or body movements).
* Referring to a person using a slang term or nickname that has a sexual connotation (such as “babe,” “honey,” “hunk,” “stud,” etc.).
* Asking another employee for a date or making a sexual proposition when such an invitation is unwelcoming to the other person.
* Commenting about or asking unsolicited personal questions about another employee’s sexual activities or social life.
* Using vulgar or profane language, joking, telling a story, teasing, insulting, or making an innuendo about a sexual subject.
* Touching or brushing against another person in an unauthorized, personal or offensive manner (contact that is not accidental or incidental).
* Staring or looking at another person in an offensive or improper way (including “elevator eyes” - looking up and down at an employee).
* Bringing any sexually provocative or suggestive magazines, pictures, drawings, cartoons, calendars, or objects into the workplace or viewing or retrieving such materials on any office computer, Pharmacy technology, or anything such as sending an unwanted text or email message with similarly undesirable content.
* Communicating that an employee will receive a job benefit or threatening to take unfavorable action against an employee based upon whether the employee submits to sexual conduct.

The Pharmacy discourages inter-office relationships. Personnel are cautioned that such relationships may be deemed sexual harassment for which disciplinary action, including termination, may be rendered. Supervisors are not permitted to have a dating or sexual relationship with a subordinate employee. If a supervisor and a subordinate employee intend to have a dating or sexual relationship, they are required to consult with Human Resources to determine an alternate reporting and/or supervisory structure. Failure to do so may result in termination from employment of one or both parties.

1. **References:** Policy 3.18 Code of Conduct

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## 1.14 Reporting Discrimination and Harassment

1. **Purpose:** To inform personnel of the policy for reporting discrimination and harassment.
2. **Scope:** This policy applies to all personnel.
3. **Definitions:** N/A
4. **Policy:** If you believe you have been subjected to discrimination or harassment in violation of these policies or if you witness any behavior that you believe may be inappropriate, you must report it immediately! Failure to do so may lead to disciplinary action, including termination.

Reports should be made to your supervisor. If your supervisor is involved, or if you are uncomfortable speaking with him/ her, reports should be made to any manager or Human Resources representative. If you are not satisfied that your supervisor has corrected the problem, you must report the conduct to the Pharmacy's President or Human Resource Manager immediately.

All complaints of harassment will be investigated promptly and in as impartial and confidential a manner as possible. Personnel are required to cooperate in any investigation. Any employee, supervisor, or manager who is found to have violated the harassment policy will be subject to appropriate disciplinary action, up to and including immediate termination.

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## 1.15 Policy Against Retaliation

1. **Purpose:** To inform Pharmacy personnel of their rights to be free of retaliation for engaging in protected activity.
2. **Scope:** This policy applies to all personnel.
3. **Definitions:** N/A
4. **Policy:** Personnel who engage in protected activity shall not suffer retaliatory actions from any employee or agent of the Pharmacy. Protected activity includes, but is not limited to:

* Reporting harassment or discrimination to the Pharmacy through a supervisor, manager, executive, or Human Resources manager.
* Reporting harassment or discrimination to a state or federal agency.
* Participating in a Pharmacy or other investigation of harassment or discrimination.
* Reporting any other activity which the employee believes to be illegal or against public policy.

Pharmacy personnel who are found to have engaged in retaliation are subject to disciplinary action, including immediate discharge. Adverse employment actions taken in violation of this policy will be reversed.

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## 1.16 Quality Program

1. **Purpose:** The purpose of this policy is to describe the quality program that assures the quality of the products and services the Pharmacy provides to our customers.
2. **Scope:**  This policy applies to all Pharmacy personnel.
3. **Definitions:**

**External Customers:** The people outside the Pharmacy who buy our products or pay for our services. Our external customers may or may not be the “actual users” of the product or service.

**Internal Customers:** Every work activity consists of an order, work performed, verifications, fulfillment/ shipment/ delivery, and payment. Persons playing a role in this process must at each step ensure “high quality” and accurate work is passed on to the next person or department in the process chain. These persons are the “internal customers.”

**Quality Job:** Work tasks completed accurately by trained personnel following procedures that include quality control or verification of critical process steps and are accurately documented.

**Quality Product:** Productthat is fulfilled using commercially available medications or compounded medications (if applicable) made by trained personnel following approved formulations.

1. **Policy:** It is the policy of the Pharmacy to ensure an effective quality program is in place to achieve the Pharmacy’s quality objectives, strategic goals, and expectations, meet the needs of our customers, participate in review of quality decisions and metrics, and demonstrate strong support for the quality program.

**The Quality System**

* The Pharmacy Quality Program or systems are designed to comply with pharmacy industry best practice principles, state and federal regulations, and applicable accreditation requirements.
* Responsibility: The Pharmacist-in-Charge (PIC) has the ultimate responsibility to ensure an effective quality program is in place.
* Authority: The Quality Assurance team is required to be compliant with internal policies and procedures, federal or state regulations, and accreditation requirements.

**Elements of the Quality System**

* 1. Training Program

There shall be a training program that assures personnel understand job tasks to perform high quality work.

* 1. Document Control, Policies and Procedures, Change Management

There shall be defined systems to assure that written documents are current, reflect the Pharmacy policies or work tasks, and are made available to Pharmacy personnel.

There shall be approved Pharmacy Policies and Standard Operating Procedures that are readily available to all personnel and annually reviewed for acceptability.

There shall be a Change Control/ Management system in place to assure that when new procedures or procedure revisions occur, a formal review takes place by subject matter experts for impact to quality, cost, reliability or other critical areas for compliance. Training of impacted personnel must occur for new or revised procedures as part of the Change Control/ Management process.

* 1. Process Controls

Independent Testingby contracted laboratories ensures compounded pharmaceutical products meet potency, sterility, or other specifications. Final Test results are reviewed by lab managers prior to product release.

Environmental Controls shall be in place for maintenance of Pharmacy equipment and/ or cleanroom standards. An external contracted environmental pharmacy shall perform periodic testing to meet federal, state, and USP compliance standards. Certification and testing documentation shall be maintained on file.

Personnel Validation: Periodic competency testing shall be provided to all Laboratory personnel by the Pharmacy management team to meet federal, state, and USP compliance standards. Testing or training documentation shall be maintained in the personnel files.

Aseptic Training is provided to all Sterile Laboratory Technicians prior to working in the aseptic laboratory. This internal training shall be performed by qualified personnel. External training by qualified agencies may be utilized. Training is documented and maintained in the personnel files.

Equipment: Preventive maintenance procedures for equipment (cleaning, calibration, count verification, certification) shall be in place, and performed on a routine basis by trained Pharmacy personnel, and documentation of these activities shall be maintained where used.

* 1. Purchasing Controls

The Pharmacy may only purchase approved drug products from licensed and/ or accredited vendors to assure drug traceability where products can be identified and traced for chain of custody verification.

* 1. Customer Complaints or Quality Events, Corrective Action

All customer complaints or internal quality-related events shall be reported to the PIC. Customer complaints or quality-related events shall be investigated for the root cause and corrective actions shall be implemented, documented, and filed.

* 1. Drug Recalls and/or Adverse Drug Events

Upon notification of Drug Recall, personnel will immediately check inventory to remove recalled products from use and follow the Drug Recall notice requirements.

* 1. Adverse Drug Events (ADE)

ADE reported to the pharmacist or Pharmacy personnel shall be investigated and noted on the patient’s profile. The pharmacist may contact the patient’s physician for ADE evaluation.

* 1. Quality Audits

Periodic Internal Quality Audits shall be conducted by trained personnel on a quarterly basis. The audit is intended to monitor Pharmacy compliance to policies and procedures, including state and federal regulations and accreditation requirements. The purpose of the audits is to identify areas for maintaining or improving quality. An Audit Report will be created that contains an overall score. The PIC will regularly review the audit reports with pharmacy personnel. Non-compliance observations will be noted and followed up for Corrective and Preventative Action (CAPA) until closure by the PIC. The PIC shall provide a trend report to Pharmacy personnel. This is required for accreditations.

* 1. Quality Performance Indicators

The Pharmacy uses the following metric systems:

* Complaint Trend Reports: Customer complaint trend reports are created and presented to Pharmacy personnel.
* Operational Review Meetings: Quality information is shared with Pharmacy personnel for review of data, plans for high-risk situations, non-compliance, or other quality- or operations-related information. The meeting minutes are maintained by the PIC.
* Audit Reports or audit trend analysis are provided on an ongoing basis to Pharmacy personnel for awareness, support, and approval.
* Annual Review: The PIC reviews the overall status of the Quality System with Pharmacy personnel. This review includes an “evaluation of resources” to support the quality system, internal personnel issues, equipment or supply issues, evaluation of new projects or Pharmacy program changes, or other areas that impact product quality.

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## 1.17 Federal Anti-Kickback Policy

1. **Purpose:** This policy provides guidance to ensure that pharmacy complies with the Federal Anti-Kickback Statute (“Stark Law”).
2. **Scope:** This policy applies to all pharmacy employees and contractors.
3. **Definitions:**

**Code of Conduct:** Document setting forth appropriate legal and ethical behavior which Employees and Contractors, when acting in that capacity, must follow.

**Contractor:** Any person who is not considered an Employee of the Company, who provides services to the Company pursuant to an independent contractor or consulting agreement.

**Employee:** Any full-time, part-time, temporary or casual employee of the Company.

**Remuneration:** Any benefit provided to an individual to induce the recipient to refer, recommend, arrange for purchase, lease or order goods or services. Remuneration includes cash, credits, gifts, free goods or services, forgiveness of debt, sale or purchase of items that is below the market value of such items.

1. **Policy:**

The Federal Anti-Kickback Statute prohibits the payment or receipt of any “Remuneration” that is intended to induce referrals or the purchase, lease or order of goods or services that may be reimbursed, in whole or in part, under a Federal Health Care Program, such as Medicare or Medicaid. It also prohibits payment or receipt of any Remuneration intended to induce the recommendation of the purchase lease or order of any such item or service.

The Company provides goods or services that may be reimbursed in whole or in part by Medicare, Medicaid and other government programs, such as outpatient prescription drugs and specialty pharmacy services. Payment or other Remuneration offered by the Company to induce referrals or the purchase of such goods or services could violate the Federal Anti- Kickback Statute. For example, payments made to clients or other payers to induce the award of business, payments or financial assistance provided to physicians to induce referrals, and free goods provided to patients to induce them to select a specific health care provider could violate the Federal Anti-Kickback Statute.

The Federal Anti-Kickback Statute also prohibits the receipt of Remuneration that is intended to induce purchases and/or recommendations of the purchase of goods or services. For example, payments received by the Company from pharmaceutical companies that are intended to induce the Company’s purchase of drugs or the Company’s recommendation of drugs to health plans could violate the Federal Anti-Kickback Statute.

The federal government has created several "safe harbors" under the Federal Anti- Kickback Statute. If a transaction, relationship, or payment is structured in a manner that meets the requirements of a safe harbor, it can be protected from civil or criminal penalty under the Federal Anti-Kickback Statute. The Company will, in all instances, seek to structure its relationships in a manner to meet the requirements of available safe harbors. The following are examples of safe harbors applicable to the business practices of the Company:

* Discount safe harbor - Protects payments between parties that take the form of appropriately disclosed rebates or discounts. This safe harbor provides protection for discounts and rebates paid by pharmaceutical companies to the Company, as well as discounts and rebates paid by the Company to clients.
* Group Purchasing Organizations (GPO) safe harbor - Provides protection for administrative fees paid to the Company by pharmaceutical companies when the Company is acting in the capacity of a Group Purchasing Organization for its health plan clients.
* Personal services safe harbor - Offers protection for “fair market value” payments made for legitimate, commercially reasonable and necessary services, subject to the satisfaction of certain additional safe harbor requirements. This safe harbor is relevant to the Company’s service agreements, including service contracts with pharmaceutical manufacturers, physician consultants, clients, and pharmacy service agreements.
* Other safe harbors may also be available for a particular business arrangement. Contact the Company’s Legal Department for guidance on the appropriate structure of such relationships.
* Because the Federal Anti-Kickback Statute is an “intent-based statute,” failure to satisfy a safe harbor does not mean the conduct is illegal. Rather, the analysis of each arrangement should begin with the question of whether anything of value is being offered or exchanged to induce referrals, recommendations or the purchase of goods or services.

**Responsibility:**

The Company has developed controls for protection against legal risk to the company through this policy and this policy will be strictly enforced.

All Employees and Contractors are expected to report to the Compliance Officer or other appropriate individual if they see any suspected violations of the Federal Anti-Kickback Statute or the Company’s Policies and Procedures.

Failure by any Employee or Contractor to comply with this policy could lead to disciplinary action, up to and including termination of employment or assignment, as well as legal action. In addition, a violation of the Federal Anti-Kickback Statute can result in criminal and civil penalties. A violation is a felony punishable by a fine of up to $25,000 per violation and imprisonment for up to 5 years. Also, civil monetary penalties may be imposed of up to $50,000 for each violation plus damages of up to three times the total amount of the unlawful Remuneration.

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# 2.0 Standard Operating Procedures

## 2.01 Policy and Procedures

1. **Purpose:** This procedure describes the Pharmacy’s policy and Standard Operating Procedure (SOP) requirements.
2. **Scope:** This procedure is to be followed by all Pharmacy personnel who author, review or revise a policy or procedure and who are subject matter experts, or who manage the document database.
3. **Definitions:**

**Policy:** Core Pharmacy principles or objectives, approved by the Pharmacy owner, that govern the Pharmacy and are implemented. All personnel must be made aware of and must comply with the Pharmacy’s policies.

**Standard Operating Procedure (SOP**)**:** Sets of written steps that describe the work or tasks performed daily and are critical to establish a consistent process and maintain quality, such as Pharmacy work instructions.

**Subject Matter Experts (SME):** Personnel who are identified as experts of specific subject matter regarding work areas, processes, or departments. SMEs may be requested to author or review written procedures.

**Master Policy and Procedure Index:** A current index that lists all policies and procedures with Number, Document Title, Current Revision Number, and Effective Date.

1. **Safety Requirements:** N/A
2. **Procedure**

**Policies:**

* 1. The Pharmacy owner is responsible for authoring and approving all policies. 
     + All policies must be written using the approved Policy Template. The Pharmacy owner will maintain the Policy Template, Policy Number, and the Revision Number that begins at zero (0) for a new policy. The Revision Number increases numerically as the document is revised. The Policy Template contains Purpose, Scope, Definitions, and Policy sections. Where applicable, the policy may contain References, Attachments, or other sections.
     + All policies must be acknowledged as being necessary to be drafted or updated by the Pharmacy owner before starting the drafting/ updating process.
  2. Upon obtaining approval, request a Policy Number from the Pharmacy owner.
  3. All written policies must undergo a formal “review and approval” process. Feedback must be provided to the author until the document is finalized, approved, and signed.
  4. The Pharmacy owner is responsible for working with the author to develop training material and a training schedule, to complete Pharmacy-wide training, and to maintain all training documentation.
  5. The Pharmacy owner will upload the approved policy to the Policy and Procedure Database, maintain a current Master Policy and Procedure Index, and file the signed Policy.
  6. Approved policies and procedures must be accessible by all Pharmacy personnel in a “read only” format. The format may be an electronic or a hard copy.

**SOPs:**

* 1. Drafting an SOP:
     + All SOPs must:
       - Be written using the approved SOP Template. The electronic template is maintained by Pharmacy owner.
       - Be written in the same format, with the SOP Template, containing a Title, Document Number, Revision Number that begins at zero (0) for a new SOP, and increases numerically as the document is revised. The SOP template must also contain Purpose, Scope, Definitions, Safety Requirements, Procedure, References, and Attachments sections. If a section does not apply, enter N/A.
       - Be verified by the Pharmacy owner to determine if an existing procedure could be revised instead of creating a new one. Once this verification is complete, the author will obtain approval from the Pharmacy owner.
       - Have a SOP number, which is provided by the Pharmacy owner once the approval is granted.
       - Be written in an easy-to-read format and should be understood in "general terms" to reflect a process or task.
       - Be written in a language that will be fully understood by the intended audience.
     + The Pharmacy owner will follow the Change Control process (SOP 2.02) and provide instructions for the review and approval process, the required signatures, the creation of a training plan/ timeline, the identification of SMEs, and other required information.
     + All reviewer feedback will be sent to the author of the SOP until the document is finalized, approved, and signed.
     + The author is responsible for tracking the document during the review and approval process and for submitting final documents to Document Control. The document can either be in electronic or hard copy format.

**NOTE:** To the Policy Maker only. Delete prior to publication. The person who writes or revises a procedure cannot be the same person who approves it.

* + - The Pharmacy owner is responsible for working with the author on the development of training material, the creation of a training schedule, documentation of all complete training, and maintaining the company-wide training file.
    - The Pharmacy owner is responsible for uploading approved procedures into the Pharmacy Policy and Procedure Database, maintaining a current Master Policy and Procedure Index, and filing the approved signed document.
  1. Revising an SOP:
     + If an approved SOP requires revision, contact Document Control, who will follow the Change Control and Revision Process.
     + All control documents must follow the Change Control process.
     + Only the Pharmacy owner is “authorized” to access approved documents from the secure Pharmacy policy and procedure database in an “editable” form.
     + Approved procedures must be accessible by all company personnel in a “read only” format. The format may be an electronic or a hard copy.

**Annual Policy and Procedure Review:**

* + - Annually, the Pharmacy owner must perform a review of all procedures applicable to the work area and verify if they still apply "as is" or if revisions are required. If a procedure no longer applies, it will be made obsolete; if changes are required, follow the Change Control process.
    - The Pharmacy owner will track and document the SOP Annual Review date on the Master Policy and Procedure Index.

1. **References:**

* [SOP 2.02 - Document Change Control Procedure](#page38)

1. **Attachments:** N/A

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## 2.02 Document Control and Change Control

1. **Purpose:** This procedure describes the requirements for Document Control and Change Control for the document approval process.
2. **Scope:** This procedure must be followed by all personnel who author, review, reference or use, revise or archive approved Pharmacy documents or records. This procedure must also be followed by personnel who are Subject Matter Experts (SMEs), or who manage the Document Control and Change Control process. This procedure applies to approved Pharmacy Policies, Standard Operating Procedures (SOPs), Pharmacy forms, document review, approval, and revision, training, and Document Control.
3. **Definitions:**

**Control Record:** A document that has a title, a Policy Number, and a Revision Number and has been formally reviewed and approved by SMEs. Examples of a Control Record include Pharmacy policies and SOPs or Pharmacy forms. Other Control Record typesare those that must be retained as part of the regulatory compliance process, for example, prescription records, controlled substance records, test records, audit records, HIPAA records, training records, drug formula records, or other Pharmacy-related documents.

**Document Control (DC):** The act of maintaining control of the most current approved Pharmacy documents (electronic or hard copy). The procedure is established to assist Pharmacy personnel with the Change Control Process, assign Policy or Revision Numbers, maintain approved Pharmacy Policy and Procedure document templates, and maintain the current Pharmacy Policy and Procedure Index.

**Change Control:** The formal review and approval process that ensures that a new policy or SOP has been reviewed by the appropriate SMEs. The Change Control and Review Process is followed for new documents, revised documents, Pharmacy forms, or operational process changes. The change review process includes evaluating the impact on quality, safety, operation efficiency, cost, regulatory compliance, or other critical criteria to establish Pharmacy operations or best practices.

1. **Safety Requirements:** N/A
2. **Procedure:**

**Change Control – Document Review and Approval Process:**

1. Initiator: When a new or revised policy or SOP is needed, review the request with the Pharmacy owner for approval and assistance with the Change Control Process.
   * + A Change Form ([FM-02](#FM02)) is required for all Control Documents.
     + The initiator is responsible for filling out the Change Form (FM-02) correctly and completely.
2. The Change review process requires:
   * + The Pharmacy owner and/ or SMEs to review the document for accuracy of the Policy or SOP, impact to quality, safety, operation efficiency, cost, regulatory compliance, or other critical criteria to establish Pharmacy operations or best practices.
     + All reviewer changes/ comments/ corrections or other communication to be returned to the author, who will address all concerns. This process will be repeated until all reviewers have agreed on a final version that meets compliance requirements. Following the completion of all reviews, Senior Management must sign the Change Form.
     + Urgent Procedures to be flagged as URGENT and to include a "need by date” to expedite the review.
     + A standard review process of 7 business days to be maintained when at all possible. This allows for the implementation of procedures in a “timely” manner.
     + For the final approved document to contain an “Approved by Signature and Date;” this will be the Master Copy.
     + For the signed Master (hard) Copy Change Form and an electronic copy of the document to be submitted to Senior Management.

**Approved Document Implementation**:

* 1. The Pharmacy owner will create a training course on the revised document. All impacted personnel must be trained within 30 days (or sooner) from the date the document was approved.
  2. For revised documents, the Pharmacy owner will remove previous revisions and replace them with the current version in the database. For new documents, the Pharmacy owner will upload an electronic copy of the document to the database.
  3. The Pharmacy owner will update the Pharmacy Master Index.
  4. The Pharmacy owner will file the Change Form and Master Copy (hard or electronic format).

**Master Policy and Procedure Index:**

1. All Policies and SOPs must be maintained and updated to incorporate any new changes.
2. The Master Policy and Procedure Index must list the Policy and Procedure Numbers, Document Title, Revision Number, Revision Date, and Approved Date.
3. An Annual Review Date may also be listed as needed for tracking purposes.

**Annual Policy and Procedure Review:**

1. All Policies and Procedures must be reviewed annually by the Pharmacy owner or SMEs.
2. The Pharmacy owner must track this review process with the SMEs and document the review date on the Master Policy and Procedure Index.
3. For document revisions, follow the Change Control Process; procedures that no longer apply will be made obsolete.

**Customer Complaints or Quality Events:**

1. Policies and Procedures may be reviewed as part of corrective actions resulting from a customer complaint or quality related event investigation.
2. Documents that need revision will follow the Change Control Process.

**Internal Forms:**

1. Forms used within Pharmacy operations are Control Documents and must contain a Form Number and Revision Number. The Pharmacy owner must maintain copies of all the forms. When new forms are needed, contact Senior Management to request a Form Number and follow the Change Control Process. When forms require a revision, contact Senior Management and follow the Change Control Process.

**Control Records and Document Retention:**

1. Pharmacy documents identified as Control Records must be filed and archived in an easily retrievable manner to prevent loss or damage.
2. Where applicable, Control Records are maintained on site for three years. After the three-year period, records are stored in a secure and easily retrievable offsite location. Control Records must be archived for a minimum of 10 years (or more as required for the specific type of record).
3. Follow SOP 2.03 - Records Management, which outlines the Pharmacy program and requirements.
4. **References:**

* [SOP 2.03 - Records Management](#page41)
* [FM-02 – Pharmacy Change Form](#FM02)

1. **Attachments:** N/A

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## 2.03 Records Management

1. **Purpose:** This procedure describes how Pharmacy Records must be managed and protected to comply with all applicable laws and regulations and Pharmacy Policies.
2. **Scope:** This procedure applies to all Pharmacy personnel, independent contractors, individuals and organizations while conducting Pharmacy business (collectively called personnel), unless superseded by a contractual agreement.
3. **Definitions:**

**Document Record:** Any recorded information that supports the activity of the Pharmacy, however created, received, modified, maintained, archived, retrieved, or transmitted. Records may be in either hard copy or electronic format.

**Retention Period:** The duration for which records are retained.

**Personal Health Information (PHI):** Individually identifiable health information that: (a) is transmitted by or maintained in electronic media; or (b) that is transmitted or maintained in any other forum or medium. PHI does not include individually identifiable health information that is: (a) kept in records governed by FERPA (Family Educational Right to Privacy Act); (b) records described at [20 U.S.C. 1232g(a)(4)(B)(iv)](http://uscode.house.gov/view.xhtml?req=(title:20%20section:1232g%20edition:prelim)%20OR%20(granuleid:USC-prelim-title20-section1232g)&f=treesort&edition=prelim&num=0&jumpTo=true); and (c) employment records held by a covered entity (such as a pharmacy) in its role as employer.

**Proprietary Information:** Information not available to the general public that the Pharmacy desires to protect. Examples of Pharmacy Proprietary Information include financial information, annual operating plans, personnel records, formula sheets, training presentations, Pharmacy policies and SOPs, and contract terms and conditions.

**Legal or Tax Audit Holds:** In connection with anticipated litigation, ongoing litigation, investigations, or subpoenas, the Pharmacy is required to suspend the disposal of and preserve records regardless of the format or manner in which the records are stored (e.g., electronic, paper, online/ websites, etc.). This mandate and any actions to fulfill this mandate are communicated through a Legal or Tax Audit Hold Notice.

**Shred Bin:** Locked, secured bins provided by a contracted document destruction service vendor intended to store proprietary documents or documents containing PHI that need to be destroyed.

1. **Safety Requirements:** N/A
2. **Procedure:**

**General**

1. All personnel while conducting Pharmacy business, must:
   * + Create and maintain complete, accurate, and reliable Document Records that meet the Pharmacy’s legal and regulatory requirements.
     + Manage all Document Records according to this procedure.
     + Store Document Records in approved locations.
     + Accurately label Document Records with enough information so appropriate retention rules may be applied (both electronic and hard copy).
     + Ensure inactive hard copy records are moved to an approved offsite storage location.
     + Retain Document Records for the legally required time period.
     + Fully comply with the requirements of all Legal and Tax Audit Hold notices.
2. **Records Storage Requirements:** 
   * + Document Records must be stored securely, based on its format type. Whenever possible, electronic records should be retained in place of hard copy records, unless law, regulation or Pharmacy policy requires the retention of hard copy records.
     + Personnel must take the following steps to make sure all Document Records are stored securely:
       - When one’s desk or work area is unattended, it is that individual’s responsibility to ensure that all Document Records are properly secured. This means that all Document Records containing proprietary information or PHI must not be left unattended on desks, fax machines, printers or photocopiers. When one’s desk/work area is left unattended, the individual must secure all hard copy records in a locked drawer, filing cabinet, or office to prevent inadvertent disclosure of information.
       - Electronic records are stored in a secure database with limited or authorized access or permissions.
       - All personnel who discover unsecured or inappropriately filed proprietary information or PHI, must immediately secure the Document Records and then notify the Pharmacy owner.

**Legal and Tax Audit Holds:**

* + - All personnel must fully comply with the requirements of a Legal and Tax Audit Hold Notice, including but not limited to the following:
      * Keep and avoid discarding any relevant documents, including originals, copies, faxes, emails, calendar entries, electronic files, desk or personal files, regardless of storage media (hard copy or electronic), until further notice from a Legal department.
      * Never alter any relevant document.
      * If revisions need to be made to existing documents for legitimate reasons, new versions of those documents must be created.

1. **Records Destruction:** 
   * + No Document Records under a Legal and Tax Audit Hold Notice may be destroyed.
     + Electronic records must be destroyed in accordance with approved IT Policies or Procedures.
     + Hard copy records that do not contain proprietary information or PHI should be disposed of in recycling cans.
     + Hard copy records that contain proprietary Information or PHI should be disposed of in locked shred bins located throughout the Pharmacy.
     + If the Pharmacy contracts with an outside shredding vendor, the outside shredding vendor must:
       - Ensure their shredding personnel are bonded.
       - Provide locked, secure shred bins throughout the premises, based on the estimated volume of records generated by the location.
       - Physically collect records from the shred bins located throughout the pharmacy on a regularly scheduled, mutually-agreed-upon basis.
       - Ensure that Pharmacy personnel will escort them while on the premises, collecting the records from the shred bins.
       - Shred all records from the shred bins, using a mechanical shredding device, on premises.
       - At the conclusion of shredding process, immediately provide the Pharmacy with a Certificate of Destruction.
     + Records stored at an offsite storage vendor and which require destruction must be shredded in accordance with the requirements above. The Pharmacy is responsible for checking with the Board of Pharmacy to ensure offsite storage is permissible.
     + The Pharmacy owner must maintain the Certificates of Destruction in an accessible location, and they must be made available for inspection upon request.
2. **References:**

* [SOP 2.02 - Document Control and Change Control](#page38)

1. **Attachments:** N/A

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# 3.0 Human Resources

## 3.01 Disabilities and Reasonable Accommodation

1. **Purpose:** This policy describes the process by which personnel and applicants with disabilities can request reasonable accommodations for their disabilities.
2. **Scope:** This policy applies to Pharmacies with personnel of 15 or more.
3. **Definitions:** This policy adopts the definitions set forth in the Americans with Disabilities Act (ADA) and any applicable state law.
4. **Policy:** Qualified individuals with disabilities, as defined under applicable federal and state law, may request reasonable accommodations that will assist them in performing the essential functions of their positions. Requests for accommodation must be directed to the Pharmacy owner. The Pharmacy owner will work with individuals on a case-by-case basis to determine what reasonable accommodation, if any, is appropriate.

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## 3.02 ADA Access

1. **Purpose:** This policy describes the Pharmacy’s compliance with federal and state laws requiring places of public accommodation to provide equal access and opportunities to disabled individuals.
2. **Scope:** This policy applies to applicants, personnel, contractors, and customers.
3. **Definitions:** This policy adopts the definitions set forth in the Americans with Disabilities Act (ADA) and any applicable state law.
4. **Policy:** It is the policy of the Pharmacy to comply with federal and state laws requiring equal access for disabled individuals. Guide dogs and other animals that assist disabled individuals must be permitted on the premises, and the Pharmacy will take measures to ensure that individuals who are disabled have equal access to Pharmacy personnel and premises as set forth in the ADA.

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## 3.03 At Will Employment

1. **Purpose:** This policy describes the Pharmacy’s practice of hiring personnel whose employment may be terminated at-will.
2. **Scope:** This policy applies to all personnel.
3. **Definitions:**

**At-Will Employment:** Refers to employment that may be terminated at the will of either the Pharmacy owner or the employee at any time, for any reason.

1. **Policy:** Pharmacy personnel are at-will personnel. The Pharmacy does not guarantee employment to any employee for any length of time. Personnel are free to resign from the Pharmacy at any time for any reason, just as the Pharmacy is free to terminate anyone’s employment at any time, for any legal reason.

Exceptions to this policy may be created only in writing. Any contract guaranteeing employment for a specific length of time is not enforceable, unless it is signed by the Pharmacy owner or an authorized designee.

**NOTE:** To the Policy Maker only. Delete prior to publication.Some states will presume an “at-will” employment status while others will not. All personnel should be informed at the start of their employment of their at-will status. Laws and legal interpretations vary from state-to-state, we recommend consulting a local attorney to ensure that the policy includes any required state-specific language.

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## 3.04 Equal Employment Opportunity

1. **Purpose:** To describe the Pharmacy’s practice of providing equal employment opportunities without regard to an individual’s protected class.
2. **Scope:** This policy applies to all personnel and applicants for employment.
3. **Definitions:** N/A
4. **Policy:** The Pharmacy strives to provide equal employment opportunities to all qualified individuals without regard to that person’s membership in a protected class. The Pharmacy will not discriminate against any applicant for employment or its personnel on the basis of their race, religion, national origin, sexual orientation, disability, age, sex, pregnancy, color, military or veteran status, or genetic testing results.

**NOTE:** To the Policy Maker only. Delete prior to publication. Sexual orientation is not a protected category under federal employment laws, although it is in many states and localities. This category has been included in the policy because, given recent court decisions favoring protecting same-sex relationships, it appears that the federal trend is toward recognizing sexual orientation as a protected class. Any Pharmacy may choose to remove this protected class designation. However, it is strongly recommended to consult with a local employment attorney regarding all local employment laws to ensure that all of the protected categories under the state law are included in this policy.

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## 3.05 Job Classifications

1. **Purpose:** This policy describes the mechanism for verifying that all personnel understand the various classifications of personnel hired by the Pharmacy.
2. **Scope:** This policy applies to all personnel.
3. **Definitions:** N/A
4. **Policy:** For purposes of compensation and benefits, all personnel are placed in the following classifications:

* “Regular Full-time” personnel are those who are scheduled to work thirty-five (35) to forty (40) hours per week.
* “Part-time” personnel are those who are scheduled to work less than thirty-five (35) to forty (40) hours per week.
* “Temporary” personnel are those who are hired for a particular project or for a pre-established time period. Temporary personnel may work full-time or part-time and are not eligible for benefits.
* “Non-exempt” personnel are those who are covered by the requirements for payment of overtime pay at one-and-one-half times their regular hourly rate of pay for all hours worked in excess of forty (40) per work week. Non-exempt personnel must receive written authorization (email accepted) from their supervisors prior to working overtime. Non-exempt personnel who fail to obtain advance approval before working overtime hours are subject to discipline.
* “Exempt” personnel are those who are not covered by laws governing the payment of overtime. Exempt personnel will not be paid extra for hours worked in excess of forty (40) per week and are expected to work the hours necessary to perform their job duties

**NOTE:** To the Policy Maker only. Delete prior to publication.The federal government (DOL) does not offer a specific definition for what constitutes full-time and part-time classification. It is left to the employer to determine. However, generally 35-40 hours are considered full-time and are eligible for any benefits offered to full-time employees. Employees whose standard weekly schedule is less than 35 hours are considered part-time.Some states have overtime laws that differ from federal law. We recommend consulting with a local employment law attorney for state-specific guidance.

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## 3.06 Reviewing Licensed Personnel Credentials

1. **Purpose:** This policy describes the process the Pharmacy uses to examine and review the licensing, educational, or occupational criteria for its licensed personnel.
2. **Scope:** This policy applies to all applicants and personnel with professional licenses, including but not limited to:
   * 1. Pharmacists
     2. Preceptors
     3. Pharmacy Interns
     4. Pharmacy Externs
     5. Pharmacy Technicians
3. **Definitions:** N/A
4. **Policy:** Upon successful completion of a preliminary interview, prior to offering employment to an applicant for a licensed position, the Pharmacy will conduct a thorough background check and review all credentials.

An applicant’s background check will include, but will not be limited to:

* + - Review and verification of the applicant’s educational background
    - Review and verification of the applicant’s employment background
    - Licensure
    - Criminal history
    - Past disciplinary actions

The Pharmacy will also check the Office of Inspector General (OIG) Exclusion database to ensure that the applicant is not listed on the OIG’s List of Excluded Individuals/ Entities (LEIE).

Upon renewing their licenses, all personnel should provide the Pharmacy with verification that their license has been renewed.

The Pharmacy will conduct reviews of its licensed personnel’s credentials on at least an annual basis. Any personnel who receive a notice of complaint from the state Board of Pharmacy or other applicable licensing authority is required to notify the Pharmacy of the complaint within two (2) business days. Failure to do so will result in disciplinary action, which could include termination of employment.

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## 3.07 Maintenance of Personal Licenses/OIG Compliance

1. **Purpose:** This procedure describes the process the Pharmacy uses to ensure that its licensed personnel maintain their current professional licenses and that the Pharmacy is compliant with the Office of Inspector General (“OIG”) regulations prohibiting individuals and entities who are on the OIG’s List of Excluded Individuals/ Entities (LEIE) from participating in federally funded programs.
2. **Scope:** This procedure applies to all Pharmacy personnel with professional licenses, including but not limited to:
   * 1. Pharmacists
     2. Preceptors
     3. Pharmacy Interns
     4. Pharmacy Externs
     5. Pharmacy Technicians
3. **Definitions:** N/A
4. **Safety Requirements:** N/A
5. **Procedure:** For all licensed personnel, the Pharmacy must, upon each employee’s date of hire and thereafter on a monthly basis, run each name through the OIG and/or the Department of Health and Human Services (HHS) database(s) to ensure that no one has been placed on the List of Excluded Individuals/ Entities (LEIE). Any personnel who have been placed on that list will be subject to termination of their employment.

An applicant who is on HHS’s or the OIG’s LEIE is not eligible for employment with the Pharmacy.

The Pharmacy may subcontract the search requirement to an outside entity that is qualified to perform the task.

The Pharmacy must maintain a schedule of the date(s) of expiration for each licensed employee’s professional license. The Pharmacy must, at least annually, conduct a review with the Board of Pharmacy to ensure that all personnel’s licenses are current and in good standing.

All personnel with expired professional licenses or professional licenses that are not in good standing are subject to termination from employment.

1. **References:** N/A
2. **Attachments:** N/A

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## 3.08 Director of Pharmacy Job Description

1. **Purpose:** This policy describes the job description and qualifications of the Director of Pharmacy.
2. **Scope:** This policy applies to all personnel and potential applicants applying for the position of Director of Pharmacy.
3. **Definitions:**

**Director of Pharmacy:** Oversees and manages Pharmacy personnel, operations, compliance, and customer relations. The Director of Pharmacy reports to the owner of the Pharmacy.

1. **Policy:**  The Director of Pharmacy is expected to meet the following requirements:
   1. **Duties and Responsibilities:** Specific duties include, but are not limited to:

* Developing, implementing, and maintaining Pharmacy policies in compliance with government rules and regulations
* Recruiting and training new personnel
* Fostering good professional relationships with customers and within the community
* Determining personnel workloads and delegating assignments as necessary
* Developing and implementing long-term goals to ensure the Pharmacy’s efficiency and productivity
* Ensuring the Pharmacy is properly staffed
* Ensuring personnel have the proper licenses and training to perform their job duties
* Evaluating, mentoring, disciplining, and terminating personnel
* Working with the executive leadership to achieve stated Pharmacy goals
* Evaluating costs and assisting executive leadership with budgeting and strategic planning
* Ensuring the Pharmacy is stocked with necessary medications and supplies and that medications are stored in compliance with all laws and regulations
* Being aware of applicable laws and regulations, including changes to laws and regulations, and providing training to personnel to ensure compliance with all applicable laws and regulations
* Ensure compliance with CLIA, OSHA, HIPAA
* Administering immunizations
* Updating vaccination schedules from CDC
* Properly securing and maintaining controlled substances
* Operating the state prescription drug monitoring program
* Properly disposing of hazardous waste drugs
* Following recall protocol
* Complying with the legal requirements for pseudoephedrine sales
* Complying with Medicare DME guidelines
* Overseeing return to stock processing
* Properly disposing of personal health information
* Complying with Continuing Medical Education (CME) Fraud, Waste, and Abuse
* Properly documenting requirements for Medicare (Durable Medical Equipment) DME
* Maintaining a safe and clean work environment
* Maintaining a positive and respectful work environment
* Promoting teamwork
* Providing professional services
  1. **Skills and Specifications:**
* Excellent leadership qualities
* Ability to act as a team player
* Effective training skills
* Excellent oral and written communication skills
* Ability to work independently
* Excellent customer service skills
* Ability to build relationships and network
* Computer skills as necessary to operate Pharmacy management software and other necessary programs
* Punctuality
* An example for other Pharmacy personnel
  1. **Education and Qualifications:**
* Bachelor’s or advanced degree in Pharmacy from an accredited institution

**NOTE:** This is optional – the Pharmacy may substitute for experience.

* Three or more years of clinical pharmacy care experience
* Must be licensed as a registered pharmacist with an unrestricted license in the state of employment and be eligible for pharmacy licensure elsewhere

**NOTE:** This is optional if the Pharmacy has a separate Pharmacist-in-Charge.

* Three or more years of recent contracting, quality assurance, and management experience in a health care environment
* Knowledge of good pharmacy practices
* Management experience
* Ability to communicate effectively with customers and personnel
* Ability to work scheduled hours
* The ability to sit and stand for long periods of time
* The ability to bend, reach, and type
* The ability to speak on the telephone
* The ability to lift, push, or pull a minimum of 10 lbs.

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## 3.09 Pharmacist-in-Charge (PIC) Job Description

1. **Purpose:** This policy describes the job description and qualifications of the Pharmacist-in-Charge (PIC).
2. **Scope:** This policy applies to all personnel and potential applicants applying for the position of Pharmacist-in-Charge.
3. **Definitions:**

**Pharmacist-in-Charge (PIC):**  Responsible for the legal operation of the Pharmacy, including all state and federal regulations governing the Pharmacy. The PIC reports to the owner of the Pharmacy.

1. **Policy:**  The PIC is expected to meet the following requirements:
   1. **Duties and Responsibilities:** The PIC will direct professional pharmacists, technicians, and support personnel in completing a variety of assignments, such as prescription entry, interpretation and review of prescriptions, drug utilization review, prescriber calls, issue resolution, and filling prescriptions. Specific duties will include, but not be limited to:

* Compounding and dispensing prescribed medications
* Supervising professional, paraprofessional, and support personnel
* Ensuring compliance with all applicable laws and regulations
* Filling prescriptions for pharmaceutical preparations and devices
* Submitting appropriate claims for third-party reimbursement
* Consulting with physicians and nurses regarding pharmaceutical questions
* Answering pharmaceutical questions from patients and personnel
* Monitoring storage, distribution, and use of pharmaceuticals
* Providing training and assigning duties to Pharmacy personnel
* Ensuring patients/ clients are evaluated for appropriateness of therapy provided by the Pharmacy
* Providing input on performance evaluations for Pharmacy personnel
* Documenting and reporting medication errors to the Pharmacy Owner or Director of Pharmacy
* Maintaining records of all transactions of the Pharmacy as necessary to ensure accurate control over and accountability for all drugs as required by applicable state and federal laws, rules, and regulations
* Ensuring legal operation of the Pharmacy
* Overseeing prescription processing activities to ensure that quality and standard of practice is maintained
* Participating in regular personnel meetings as necessary
* Ensuring policies and procedures are in compliance with state Board of Pharmacy requirements
* Providing regulatory direction and education to personnel
* Assisting in production when necessary
* Maintaining applicable continuing education records and licensure
* Assisting with preparation of Pharmacy budget
* Reviewing monthly financial statistics and helping to maintain expenditures within budget guidelines
* Complying with Pharmacy policies
* Understanding confidentiality with respect to patient/ client care; complying with all federal and state laws applicable to the confidentiality of protected health information (PHI) and electronic protected health information (EPHI); and following HIPAA guidelines regarding readily identifiable protected health information
* Promoting teamwork
* Providing professional services
* Administering immunizations
* Updating vaccination schedules from Center for Disease Control (CDC)
* Properly securing and maintaining controlled substances
* Operating the state prescription drug monitoring program
* Properly disposing of hazardous waste drugs
* Following recall protocol
* Complying with the legal requirements for pseudoephedrine sales
* Complying with Medicare Durable Medical Equipment (DME) guidelines
* Overseeing return to stock processing
* Properly disposing of personal health information
* Complying with Continuing Medical Education (CME) Fraud, Waste, and Abuse
* Properly documenting requirements for Medicare Durable Medical Equipment (DME)
* Maintaining a safe and clean work environment
* Maintaining a positive and respectful work environment
  1. **Skills and Specifications:**
* Ability to act as a team player
* Organizational and time management skills
* Ability to work in a fast-paced environment
* Effective training skills
* Excellent oral and written communication skills
* Ability to work independently
* Excellent customer service skills
* Ability to build relationships and network
* Computer skills as necessary to operate Pharmacy management software and other necessary programs
* Punctuality
* Set an example for other Pharmacy personnel
* Knowledge of inventory control, pharmaceutical chemistry and manufacturing methods
* Knowledge of federal and state regulations regarding pharmacy
* Ability to read, analyze, and interpret complex topics
  1. **Education and Qualifications:**
* Bachelor’s or advanced degree in pharmacy from an accredited institution
* Three (3) or more years of clinical pharmacy care experience
* Must be licensed as a registered pharmacist with an unrestricted license in the state of employment and be eligible for pharmacy licensure elsewhere
* At least one year of related pharmacy management experience
* Ability to communicate effectively with customers and personnel
* Ability to work scheduled hours, including weekends and evenings as required
* Ability to sit and stand intermittently for long periods of time
* Ability to bend, reach, and type
* Ability to speak on the telephone
* Ability to lift, push, or pull a minimum of 25 lbs.
* Ability to read, write, speak, and understand English

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## 3.10 Store Manager Job Description

1. **Purpose:** This policy describes the job description and qualifications of the Store Manager.
2. **Scope:** This policy applies to all personnel and potential applicants applying for the position of Store Manager.
3. **Definitions:**

**Store Manager:** Oversees all issues related to the operation of the Pharmacy, including implementation of policies and procedures, billing, and the operation of the Pharmacy management software. The Store Manager reports to \_\_\_\_\_\_\_.

1. **Policy:** The Store Manager is expected to meet the following requirements:
2. **Duties and Responsibilities:** Specific duties will include, but not be limited to:

* Overseeing the refill department and billing, including accurate and timely data submission via Pharmacy management software
* Partnering with management to ensure the operations of the Pharmacy are successful on a daily basis and that management goals are met
* Preparing daily, weekly and monthly metric reporting and data reporting for the facility as required for contract maintenance
* Ensuring that all reporting deadlines are met
* Submitting necessary drug reports
* Acting as a human resources liaison
* Leading office operations and implementing policies and procedures
* Managing personnel’s work schedules and time off calendars
* Managing licensure and certificate recordkeeping for all applicable licenses and certifications for individuals and the Pharmacy operation
* Defining and managing procedures for record retention
* Managing and updating distribution lists (e.g. staff rosters, distribution group lists, etc.)
* Managing the process for office supplies, and processing check requests and purchase requisitions
* Providing ad-hoc project support, including but not limited to filing, copying, faxing, and deliveries
* Depositing daily registers and insurance checks into the bank
* Participating in regular personnel meetings as necessary
* Ensuring that policies and procedures are compliant with state Board of Pharmacy requirements
* Maintaining applicable continuing education records and licensure
* Assisting with preparation of Pharmacy budget
* Reviewing monthly financial statistics and helping to maintain expenditures within budget guidelines
* Complying with Pharmacy policies
* Promoting teamwork
* Providing professional services
* Maintaining proper records for Medicare Durable Medical Equipment (DME)
* Other job duties as necessary

1. **Skills and Specifications:**

* Ability to act as a team player
* Organizational and time management skills
* Ability to work in a fast-paced environment
* Effective training skills
* Excellent oral and written communication skills
* Ability to work independently
* Computer skills as necessary to operate Pharmacy management software and other necessary programs
* Excellent customer service skills
* Detail-oriented
* Punctuality
* Demonstrated proficiency with functionality of computers and applications
* Demonstrated proficiency in running and analyzing reports
* Prior experience in the following functional areas: Accounting/ reconciliation, Human Resources and/ or Training
* Understand and abide by all PHI and HIPAA laws and regulations

1. **Education and Qualifications:**

* High school diploma or equivalency
* Bachelor of Science preferred
* Prior experience coaching and mentoring a team of individuals
* Prior experience working in the health care industry preferred
* Ability to see, speak, and communicate effectively with customers and personnel
* Ability to work scheduled hours, including weekends and evenings as required
* Ability to sit and stand intermittently for long periods of time
* Ability to bend, reach, and type
* Ability to speak on the telephone
* Ability to lift, push, or pull a minimum of 25 lbs.
* Ability to read, write, speak, and understand English

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## 3.11 Staff Pharmacist Job Description

1. **Purpose:** This policy describes the job description and qualifications of the Staff Pharmacist.
2. **Scope:** This policy applies to all personnel and potential applicants applying for the position of Staff Pharmacist.
3. **Definitions:**

**Staff Pharmacist:** Prepares, compounds, dispenses, and sells prescriptions and Pharmacy-related products, answers patient questions, participates in patient assistance and other quality assurance programs, under the functional supervision of the Pharmacist-In-Charge (PIC).

1. **Policy:** The Staff Pharmacist is expected to meet the following requirements:
   1. **Duties and Responsibilities:** Specific duties will include, but not be limited to:

* Complying with all applicable laws and regulations
* Assisting with the direction and monitoring of Pharmacy personnel and performance as directed
* Preparing, compounding, dispensing, and selling prescriptions and Pharmacy-related products
* Participating in patient assistance and quality assurance programs as directed
* Following proper Pharmacy and regulatory safety procedures and standards
* Submitting appropriate claims for third-party reimbursement
* Consulting with physicians and nurses regarding pharmaceutical questions
* Providing patient/ clients with counseling and education
* Monitoring storage, distribution, and use of pharmaceuticals
* Ensuring that patients/ clients are evaluated for appropriateness of therapy provided by the Pharmacy
* Documenting and reporting medication errors to the PIC
* Maintaining records of all transactions of the Pharmacy as necessary to ensure accurate control over and accountability for all drugs as required by applicable state and federal laws and regulations
* Overseeing prescription processing activities to ensure that quality and standard of practice is maintained
* Participating in regular personnel meetings as necessary
* Complying with Pharmacy policies
* Providing excellent customer service using best practices
* Maintaining inventory and stock levels consistent with Pharmacy goals and manufacturer protocols
* Communicating in a timely manner with customers, physicians, vendors, and colleagues
* Understanding confidentiality with respect to patient/ client care; complying with all federal and state laws applicable to confidentiality of protected health information (PHI) and electronic protected health information (EPHI); and following HIPAA guidelines regarding readily identifiable protected health information
* Administering immunizations
* Updating vaccination schedules from Center for Disease Control (CDC)
* Properly securing and maintaining controlled substances
* Operating the state prescription drug monitoring program
* Properly disposing of hazardous waste drugs
* Following recall protocol
* Complying with the legal requirements for pseudoephedrine sales
* Complying with Medicare Durable Medical Equipment (DME) guidelines
* Overseeing return to stock processing
* Properly disposing of personal health information
* Complying with Continuing Medical Education (CME) Fraud, Waste, and Abuse
* Properly documenting requirements for Medicare Durable Medical Equipment (DME)
* Maintaining a safe and clean work environment
* Maintaining a positive and respectful work environment
* Promoting teamwork
* Providing professional services
  1. **Skills and Specifications:**
* Excellent leadership qualities
* Ability to act as a team player
* Organizational and time management skills
* Ability to work in a fast-paced environment
* Ability to multitask
* Excellent oral and written communication skills
* Ability to work independently
* Excellent customer service skills
* Ability to build relationships and network
* Computer skills as necessary to operate Pharmacy management software and other necessary programs
* Punctuality
* An example for other Pharmacy personnel
* Knowledge of inventory control, pharmaceutical chemistry and manufacturing methods
* Knowledge of federal and state regulations regarding pharmacy
* Self-motivated
  1. **Education and Qualifications:**
* Bachelor’s or advanced degree in pharmacy from an accredited institution
* Licensed as a registered pharmacist with an unrestricted license in the state of employment and be eligible for pharmacy licensure elsewhere
* Be immunization certified

**NOTE:** This is optional.

* Prior pharmacy experience preferred
* Ability to work a flexible schedule, including evenings and weekends
* Ability to communicate effectively with customers and personnel
* Ability to sit and stand intermittently for long periods of time
* Ability to bend, reach, and type
* Ability to speak on the telephone
* Ability to lift, push, or pull a minimum of 25 lbs.
* Ability to read, write, speak, and understand English

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## 3.12 Pharmacy Technician Job Description

1. **Purpose:** This policy describes the job description and qualifications of the Pharmacy Technician.
2. **Scope:** This policy applies to all personnel and potential applicants applying for the position of Pharmacy Technician.
3. **Definitions:**

**Pharmacy Technician:** Receives and fills prescription requests for patients under the supervision of the Pharmacist-in-Charge (PIC) and maintains patient profiles.

1. **Policy:** The Pharmacy Technician is expected to meet the following requirements:
   1. **Duties and Responsibilities:** Specific duties will include, but not be limited to:

* Retrieving, pouring, counting, labeling, and reconstituting prescription medications
* Accessing, inputting, and retrieving information through the Pharmacy’s computer network to maintain accurate records
* Creating accurate prescription labels
* Obtaining refill authorizations from prescribers
* Processing and preparing third-party insurance claims
* Communicating with physicians, patients, and third-parties, such as insurers
* Maintaining accurate patient/ client profiles
* Maintaining Pharmacy inventory
* Preparing reports related to sales, usage, and inventory
* Complying with established procedures, rules, and regulations
* Providing completed orders to customers
* Answering phones and directing customer calls to the appropriate personnel
* Maintaining and cleaning equipment, work areas, and shelves
* Accepting prescriptions to be filled and ensuring that the PIC has the data necessary to fill the orders
* Greeting and assisting customers
* Recordkeeping related to inventories, receipts, purchases, and deliveries
* Collecting co-payments
* Packaging and labeling products under the supervision of the PIC
* Restocking shelves
* Unpacking and organizing incoming merchandise, including sorting items that require special handling
* Checking for outdated medications and notifying the PIC of low inventories
* Understanding confidentiality with respect to patient/ client care; complying with all federal and state laws applicable to the confidentiality of protected health information (PHI) and electronic protected health information (EPHI); and following HIPAA guidelines regarding readily identifiable protected health information
* Working as a team and communicating clearly
* Helping customers locate over-the-counter products
* Handling customer problems/ concerns in a calm manner and referring them to the pharmacist accordingly
* Notifying the pharmacist of any problems or malfunctions
* Checking refrigerator and freezer temperatures
* Properly processing pseudoephedrine sales
* Properly processing Medicare Durable Medical Equipment (DME) claims
* Promoting teamwork
* Providing professional services
  1. **Skills and Specifications:**
* Ability to read and transcribe pharmaceutical information
* Ability to act as a team player
* Organizational and time management skills
* Ability to work in a fast-paced environment
* Ability to multitask
* Excellent oral and written communication skills
* Excellent customer service skills
* Computer skills as necessary to operate Pharmacy management software and other necessary programs
* Punctuality
* Telephone skills
* Self-motivated
  1. **Education and Qualifications:**
* High school diploma or equivalency
* At least 21 years of age
* Prior experience as a cashier
* Pharmacy technician license from the Board of Pharmacy in the state of employment – if applicable
* Ability to work a flexible schedule, including evenings and weekends
* Ability to communicate effectively with customers and employees
* Ability to stand for long periods of time
* Ability to sit for intermittent periods of time
* Ability to bend, reach, climb, and squat frequently
* Ability to type and operate a computer
* Ability to speak on the telephone
* Ability to lift, push, or pull a minimum of 40 lbs.
* Ability to read, write, speak, and understand English

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## 3.13 Pharmacy Clerk Job Description

1. **Purpose:** This policy describes the job description and qualifications of the Pharmacy Clerk.
2. **Scope:** This policy applies to all personnel and potential applicants applying for the position of Pharmacy Clerk.
3. **Definitions:**

**Pharmacy Clerk:**  Supports the Pharmacist-in-Charge (PIC) by ensuring that the Pharmacy is clean and organized and that customers receive their completed orders in a timely manner. The Pharmacy Clerk reports to \_\_\_\_\_\_\_\_.

1. **Policy:** The Pharmacy Clerk is expected to meet the following requirements:
   1. **Duties and Responsibilities:** Specific duties will include, but not be limited to:

* Providing completed orders to customers
* Ringing up sales
* Answering phones and directing customer calls to the appropriate personnel
* Stocking shelves
* Maintaining and cleaning equipment, work areas, and shelves
* Accepting prescriptions to be filled and ensuring that the pharmacist has the data necessary to fill the orders
* Performing other clerical tasks as needed
* Greeting and assisting customers
* Recordkeeping related to inventories, receipts, purchases, and deliveries
* Preparing prescription labels
* Processing medical insurance claims and collecting co-payments
* Packaging and labeling products under the supervision of a pharmacist
* Restocking shelves
* Unpacking and organizing incoming merchandise, including sorting items that require special handling
* Checking for outdated medications and notifying pharmacist of low inventories
* Working as a team and communicating clearly
* Helping customers locate over-the-counter products
* Handling customer problems/ concerns in a calm manner and referring them to the pharmacist accordingly
* Notifying the pharmacist of any problems or malfunctions
* Checking refrigerator and freezer temperatures
* Properly processing pseudoephedrine sales
* Properly processing Medicare Durable Medical Equipment (DME) claims
* Promoting teamwork
* Providing professional services
  1. **Skills and Specifications:**
* Ability to act as a team player
* Organizational and time management skills
* Ability to work in a fast-paced environment
* Ability to multitask
* Excellent oral and written communication skills
* Excellent customer service skills
* Computer skills as necessary to operate Pharmacy management software and other necessary programs
* Punctuality
* Knowledge of basic math
* Telephone skills
* Self-motivated
  1. **Education and Qualifications:**
* High school diploma or equivalency
* Must be at least 18 years of age
* Ability to work a flexible schedule, including evenings and weekends
* Ability to communicate effectively with customers and employees
* Ability to stand for long periods of time
* Ability to sit for intermittent periods of time
* Ability to bend, reach, climb, and squat frequently
* Ability to type and operate a computer
* Ability to speak on the telephone
* Ability to lift, push, or pull a minimum of 40 lbs.
* Ability to read, write, speak, and understand English

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## 3.14 Delivery Driver Job Description

1. **Purpose:** This policy describes the job description and qualifications of the Pharmacy Delivery Driver.
2. **Scope:** This policy applies to all personnel and potential applicants applying for the position of Pharmacy Delivery Driver.
3. **Definitions:**

**Pharmacy Delivery Driver:**  Responsible for the safe and timely delivery of medications and supplies to customers.

1. **Policy:** The Pharmacy Delivery Driver reports to \_\_\_\_\_\_\_\_\_\_\_ and is expected to meet the following requirements:
   1. **Duties and Responsibilities:** Specific duties will include, but not be limited to:

* Interacting with customers and co-workers professionally and appropriately
* Keeping records of mileage, vehicle maintenance, fuel, and delivery schedules
* Writing receipts
* Ensuring that vehicle is maintained properly, i.e., working brakes, controls, tire pressure, and fuel on a daily basis
* Driving safely
* Obeying traffic laws
* Working in a fast-paced environment
* Driving in differing weather conditions
* Loading and unloading goods
* Taking direction from the Director of Pharmacy or supervisor
* Complying with Pharmacy policies
  1. **Skills and Specifications:**
* Organizational and time management skills
* Ability to work in a fast-paced environment
* Excellent customer service skills
* Punctuality
* Excellent driving and parking skills
* Ability to keep records
  1. **Education and Qualifications:**
* Ability to read, write, speak, and understand English
* At least 18 years old
* Have a valid driver’s license
* Have access to a vehicle

**NOTE:** To the Policy Maker only. Delete prior to publication.This is optional if the Pharmacy has a delivery vehicle.

* Have proof of valid insurance

**NOTE:** To the Policy Maker only. Delete prior to publication.This is optional if the Pharmacy has a delivery vehicle.

* Ability to effectively read and interpret maps
* Ability to sit for long periods of time
* Punctual
* Ability to sit, walk, stand,
* Ability to lift, push, and pull up to 25 lbs.
* Have no moving violations within the past two years
* Have no serious traffic offenses

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## 3.15 Store Maintenance Personnel Job Description

1. **Purpose:** This policy describes the job description and qualifications of the Pharmacy Maintenance Personnel.
2. **Scope:** This policy applies to all personnel and potential applicants applying for the position of Pharmacy Maintenance Personnel.
3. **Definitions:**

**Pharmacy Maintenance Personnel:** Responsible for maintaining the overall appearance, safety, and repair of the facilities.

1. **Policy:** The Pharmacy Maintenance Personnel report to \_\_\_\_\_\_\_ and are expected to meet the following requirements:
   1. **Duties and Responsibilities:** Specific duties will include, but not be limited to:

* Cleaning and polishing lighting fixtures, surfaces, furniture, and trim
* Cleaning building floors by sweeping, mopping, scrubbing, or vacuuming, as appropriate
* Servicing, stocking, and cleaning restrooms
* Following appropriate Pharmacy procedures for the use and storage of cleaning chemicals and power equipment
* Gathering, emptying, and removing trash to the designated collection site
* Recycling trash as required by state or local law
* Maintaining building security by ensuring all doors are locked and alarms are set
* Moving furniture, supplies, and equipment as needed
* Notifying the Pharmacy owner of necessary repairs or potentially hazardous situations
* Requisitioning necessary cleaning products and supplies
* Cleaning windows, glass partitions, and mirrors
* Dusting furniture, machines, and equipment
* Assisting with sterilization procedures as requested
* Removing snow and maintaining sidewalks
* Maintaining the landscaping and outward appearance of store
* Assisting with the placement of advertising, displays, and decorations
* Replacing light bulbs
* Performing minor repairs
  1. **Skills and Specifications:**
* Punctual
* Self-motivated
* Detail-oriented
* Ability to work around chemicals
* Familiar with cleaning equipment and products
  1. **Education and Qualifications:**
* High school diploma or equivalency preferred
* At least 21 years of age
* Prior experience preferred
* Ability to work evenings and weekends
* Ability to stand, walk, carry and move objects weighing up to 40 lbs.
* Ability to bend, reach, kneel, crawl, climb, and squat
* Ability to lift, push, or pull a minimum of 40 lbs.
* Ability to manipulate tools and cleaners
* Ability to operate cleaning equipment, such as floor polishers, vacuums, and dusters
* Ability to read, write, speak, and understand English

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## 3.16 Compensation for Work Related Injuries

1. **Purpose:** This procedure describes the process in which Pharmacy personnel may be compensated for work-related injuries, deaths, and illnesses.
2. **Scope:** This procedure applies to all personnel.
3. **Definitions:** The Pharmacy adopts all applicable definitions from the state workers’ compensation statutes.
4. **Safety Requirements:** N/A
5. **Procedure:** As an employment benefit, at no cost to its personnel, the Pharmacy maintains workers’ compensation insurance for all personnel. This insurance will generally compensate any personnel for work-related illness, injuries, and time away from work.

If an employee is injured at work or while conducting Pharmacy business, the employee should notify the Director of Pharmacy or Pharmacy owner as soon as possible to ensure that the injury is reported in a timely manner to the Pharmacy’s insurance carrier. Under most circumstances, Workers’ Compensation Insurance is an employee’s exclusive method for obtaining compensation for work-related injuries; accordingly, all personnel must follow appropriate reporting procedure for reporting and obtaining treatment for work-related injuries.

All personnel who experience accidents at work or while driving for Pharmacy business may be asked to take a drug or alcohol abuse test. The Pharmacy has a strict policy prohibiting retaliation against for engaging in protected activities such as reporting work-related injuries.

1. **References:**  Policy 1.15 – Policy Against Retaliation
2. **Attachments:** N/A

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## 3.17 Paid Time Off (PTO)

1. **Purpose:** The purpose of this procedure is to describe the process for using Paid Time Off (PTO). PTO is to be used for vacations, sick leave, and personal days off.
2. **Scope:** This procedure applies to all Pharmacy personnel, unless a written alternate arrangement has been reached with the Owner of the Pharmacy. Some states may have specific guidance to PTO and part-time employees and should be applied as appropriate.
3. **Definitions:** N/A
4. **Safety Requirements:** N/A
5. **Procedure:**

Upon here, a full-time employee will receive PTO per schedule below.

The increased PTO for the 1, 2 and 7-year milestones, and the annual receipt of PTO will occur on the employment anniversary date, not the beginning of the calendar year.

The following is the schedule of PTO in relation to an employee’s length of employment:

Length of Service Number of Days of PTO Received on Anniversary

0-90 days

0-365 days Year 1 5 days per year  
 (utilization may begin only after 90 days)

1-year anniversary date 10 days per year

2nd anniversary date through 6th anniversary date 15 days per year

7th anniversary date and beyond 20 days per year

* 1. During the first 90 days of employment, personnel are not eligible for PTO. Personnel who leave the Pharmacy and who have not used all their PTO hours will be paid for their unused hours upon termination of employment. Pharmacy personnel may not borrow from future PTO at any time. If any personnel are paid for PTO in excess of the time that has been given to them, the Pharmacy will recoup amounts paid for PTO taken in excess of the allotted amounts in their paychecks.
  2. Personnel are expected to use all of their PTO during the current anniversary year. Personnel may not bank or accrue PTO in excess of the amounts described in this policy. Employees who do not use any of their PTO during an anniversary year will lose it.
  3. **Requesting Paid Time-Off**

To ensure that the Pharmacy operates smoothly and efficiently, all personnel must request PTO and obtain approval from their supervisor or the Pharmacy owner as far in advance as is possible. Non-exempt personnel are required to clock out when leaving and to clock in when returning from medical appointments in which they will be gone for only a portion of the day. Time off for personal business will be deducted from the PTO of non-exempt employees.

If the time requested for an extended absence falls during peak periods or conflicts with PTO already approved for another employee within the Pharmacy, the direct supervisor may ask the employee to reschedule their PTO. If personnel need to use their PTO for unexpected reasons such as illness, the illness of a child, or missed travel connections, they are required to call in each day they are going to be out. Employees must use PTO in increments of at least one hour.

* 1. **Compensation**

The amount Pharmacy personnel are paid for their Personal Time Off depends on the number of hours they are regularly scheduled to work.

The Pharmacy reserves the right to request a return-to-work release from the employee’s physician should an absence last three (3) or more days due to a non-work-related illness or injury.

**NOTE:** To the Policy Maker only. Delete prior to publication.A pharmacy may choose to offer PTO, in which it gives employees a certain number of days off depending on length of employment to be used for all time off, including sick leave, vacation, and personal days. Pharmacies normally do not offer PTO in addition to sick leave and vacation time. Therefore, if a Pharmacy chooses to have a PTO policy, it will not need separate vacation, personal time, and sick leave policies. If a Pharmacy does not adopt a PTO policy, we recommend separate sick leave, vacation, and personal time off policies. PTO may be awarded at the time of an employee's anniversary date or it may be accrued over time based upon the number of hours worked.

This policy is only a sample policy and the amounts of PTO granted in this sample policy are for example only. State law and business practices vary widely on PTO practices. We recommend consulting with legal counsel to develop a time off policy that complies with the Pharmacy’s needs and is consistent with applicable state and federal laws.

1. **References:**

* [Policy 3.19 - Attendance and Punctuality](#page83)

1. **Attachments:** N/A

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## 3.18 Code of Conduct

1. **Purpose:** The purpose of this policy is to describe the Pharmacy’s expectations regarding personnel conduct and the types of behaviors that are likely to result in disciplinary action and/ or termination of employment.
2. **Scope:** This policy applies to all Pharmacy personnel.
3. **Definitions:** N/A
4. **Policy:**
5. The Pharmacy expects all personnel to use good judgment in performing their job duties. The Pharmacy expects all personnel to be respectful toward other personnel, business contacts, and customers and to conduct themselves with high ethical standards.
6. Prohibited workplace behavior and conduct includes:

* Failing to be courteous and helpful to customers and potential customers.
  + - Failing to treat customers and potential customers with respect and dignity.
    - Failing to be respectful, polite, and courteous to co-workers.
    - Theft, willful destruction of property, or misappropriation of Pharmacy funds.
    - Disorderly conduct on Pharmacy premises including, but not limited to:
    - Fighting
    - Shouting
    - Abusive language or threats
    - Other intimidating or threatening behavior
    - Bookmaking or other forms of commercial gambling.
    - Failure to observe safety rules and procedures, to wear personal protective equipment, or to observe traffic regulations while driving to conduct Pharmacy business.
    - Violating the confidentiality of patient information.
    - Buying, selling, using, reporting for duty under the influence of, or bringing unauthorized intoxicants, drugs or narcotics onto Pharmacy property.
    - Possession of guns, knives, bats, or any other weapon on Pharmacy property, including personal vehicles parked on Pharmacy property, or in any Pharmacy vehicle or building.
    - Receiving or making excessive personal telephone calls.
    - Discrimination or harassment against any personnel, customer, or vendor.
    - Deliberate or careless damage to the property of the Pharmacy or others.
    - Falsification of information on an employment application, Pharmacy enrollment, benefit claim forms, or other work-related documents.
    - Altering any time card, recording incorrect entries, and/ or signing another employee in or out or permitting a timecard or time records to be altered.
    - Insubordination (refusal or failure to perform work assigned or to comply with the orders and directions of a supervisor or Pharmacy owner).
    - Unauthorized access, use, and/ or disclosure of Pharmacy proprietary or Pharmacy confidential information.
    - Failure to maintain licenses/ certifications.
    - Sleeping during work time or other misuse of Pharmacy time.
    - Tardiness or unexcused absences.
    - Using or asking others to use Pharmacy materials, computers, telephones or other facilities or labor for personal benefit or gain.
    - Failure to cooperate with a Pharmacy investigation.
    - Poor job performance.

1. A violation of this policy constitutes unacceptable performance or misconduct on the part of the employee and appropriate disciplinary action will be initiated. Disciplinary action may include:
   * Verbal reprimand
   * Written notice
   * Suspension without pay
   * Immediate termination of employment
2. Progressive discipline is neither required, nor guaranteed. Termination may occur without cause and without notice.
3. References: Policy 1.02 – Whistleblower Policy

Policy 1.13 – Anti-harassment

Policy 1.14 – Reporting Discrimination and Harassment

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## 3.19 Attendance and Punctuality

1. **Purpose:** This policy is to describe the Pharmacy’s attendance and tardiness policy.
2. **Scope:** This policy applies to all personnel.
3. **Definitions:** N/A
4. **Policy:**
5. Tardiness and poor attendance disrupts workflow and customer service and will not be tolerated.
6. All personnel are expected to engage in carrying out their duties during their scheduled work time and should be ready to begin working at their scheduled starting time. Supervisors should record all absences and, for non-exempt personnel, any tardiness or early departure.
7. Personnel who are frequently away from the premises on behalf of the Pharmacy should inform their supervisor of their whereabouts during working hours.
8. Personnel who are aware of a future absence on a particular day, such as a medical or other appointment, are required to request the time off in writing in advance and to use available PTO or other time off.
9. For unexpected absences, personnel are required to contact their supervisor at least two hours prior to the start of their scheduled shift, or as soon thereafter as practical, if they are going to be absent from work. Contacting a supervisor is defined as speaking directly to them. Supervisors’ cellular phone numbers are made available to personnel if they cannot reach them on the Pharmacy phone line. If a supervisor does not answer their phone, personnel must leave a voice message and attempt to contact them again if they do not hear back in a reasonable amount of time.
10. Text messages, emails, and messages through other personnel are not appropriate forms of contacting a supervisor regarding an absence. Personnel should state the general reason for being absent and the expected date they will return to work. If the return date is uncertain, the supervisor must be called each day within two hours of the beginning of the regularly scheduled shift.
11. If the employee’s supervisor cannot be reached, a member of senior management or the Pharmacy owner must be contacted.
12. Any employee who has an unscheduled absence due to injury or illness of three or more consecutive days will be required to present a doctor’s report, within five days of the absence or tardiness, supporting the necessity of their absence, as well as their ability to return to work. It may also be required that the employee be examined by a physician appointed by the Pharmacy, at the Pharmacy’s expense. If an absence is the result of a personal emergency other than illness or injury, documents showing proof that the absence was necessary also may be required.
13. Unauthorized or excessive absences or tardiness will result in disciplinary action, up to and including termination of employment. An absence is considered to be unauthorized if the employee has not followed proper notification procedures or the absence has not been properly approved in advance.
14. Personnel absent for two consecutive workdays, without giving proper notice, will be considered as having voluntarily resigned.

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## 3.20 Dispute Resolution/Employee Complaint Procedure

1. **Purpose:** The purpose of this procedure is to describe the Pharmacy’s dispute resolution and complaint procedures.
2. **Scope:** This procedure applies to all personnel.
3. **Definitions:** N/A
4. **Safety Requirements:** N/A
5. **Procedure:** If any area of work is a cause of concern for any of the personnel, they have the responsibility to address their concern with a supervisor. Whether the issue is a complaint, suggestion, or an observation, Pharmacy managers want to hear from all personnel. By listening to all comments, the Pharmacy is able to improve, address complaints, and foster better personnel understanding of the rationale for practices, processes, and decisions.

Most problems can and should be solved in discussion with an immediate supervisor; this is encouraged as the first effort to solve a problem. If any personnel are not comfortable discussing the issue or concern with their immediate supervisor, they may also discuss their issues and concerns with the next level of management and/ or Human Resources; they may be re-directed to approach their immediate supervisor, with assistance from the next level of management or Human Resources.

If an employee’s complaint involves a claim of discrimination or harassment, the Pharmacy will take appropriate steps to investigate the complaint as confidentially as possible. If the complaint is substantiated, the Pharmacy will take appropriate steps to correct the discriminatory or harassing behavior. If retaliation has occurred, the Pharmacy will reverse any adverse employment action.

1. **References:** N/A
2. **Attachments:** N/A

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## 3.21 Disciplinary and Corrective Action

1. **Purpose:** This procedure is to describe the various methods for correcting and disciplining Pharmacy personnel.

This procedure is not meant to be exhaustive, and, depending upon the conduct at issue, disciplinary or corrective measures could be immediate termination from employment. Progressive discipline is neither required nor guaranteed by this policy.

1. **Scope:** This policy applies to all personnel.
2. **Definitions:** N/A
3. **Procedure**
4. The first step in addressing unsatisfactory job performance will normally be a verbal discussion between a supervisor and an employee. Personnel and supervisors are expected to be in constant communication regarding job performance, and all personnel should expect to have regular discussions about their job performance and about the Pharmacy’s expectations.
5. If a verbal discussion does not result in improvement, it will normally be followed by a written warning and a plan for improvement. If an employee fails to correct their performance after receiving a written warning, the employee will be subject to further discipline, including, but not limited to, additional written warnings and/ or termination from employment.
6. If an employee must be disciplined for violations of workplace conduct rules, appropriate corrective measures or disciplinary actions will depend upon the seriousness of the employee’s actions.
7. Disciplinary measures may include:

* Verbal and written warnings
* Suspension without pay
* Additional training
* Termination of employment

1. The appropriate measures to take in any given situation are the Pharmacy’s sole discretion. The Pharmacy expressly reserves the right to immediately terminate an employee's employment at any time for any legal reason.

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## 3.22 Hours of Work/Breaks

1. **Purpose:** This procedure describes the hours of work and the Pharmacy’s policy on meal and rest breaks. There is a separate policy that is applicable to pharmacists.
2. **Scope:** This procedure applies to all non-exempt personnel.
3. **Definitions:** N/A
4. **Safety Requirements:** N/A
5. **Procedure:**

Pharmacy hours are from to . Full-time, non-exempt personnel will normally be scheduled to work an 8.5-hour shift, which includes a half-hour meal break. Personnel must clock out at the start of their lunch breaks and clock in at the end of their lunch breaks. Personnel must eat only in designated break areas and may not sit at their desks or work areas during their lunch periods. Personnel who fail to take their scheduled lunch breaks without obtaining advance approval from their supervisor may be disciplined. Non-exempt personnel may not perform any work during their lunch breaks.

In addition to meal breaks, if the workload permits, personnel may take one 15-minute break in the morning and one 15-minute break in the afternoon. Personnel must clock out for any break that will last longer than 20 minutes.

**NOTE:** To the Policy Maker only. Delete Prior to publication. State laws regarding required breaks vary widely. The Fair Labor Standards Act does not require that employers provide any meal breaks or other breaks, but it does require that employees be paid for breaks of fewer than 20 minutes. Consult with a local employment attorney to determine whether this policy needs to be amended to comply with applicable local or state laws.

1. **References:**

* [Policy 3.05 – Job Classifications](#page49)

1. **Attachments:** N/A

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## 3.23 Employee Resignation

1. **Purpose:** This procedure describes the responsibilities of personnel who submit a notice of resignation.
2. **Scope:** This procedure applies to all personnel.
3. **Definitions:** N/A
4. **Safety Requirements:** N/A
5. **Procedure:** Resigning personnel should provide the Pharmacy with at least two weeks advance written notice. Failure to provide at least two weeks advance written notice may result in the employee becoming ineligible for re-employment with the Pharmacy. All personnel are responsible for ensuring that they return all Pharmacy property, keys, credit cards, uniforms, computer equipment, vehicles, and other items in their possession. Failure to do so could result in the cost of that equipment being deducted from their final paycheck.

Personnel who are rehired following a break in service more than sixty days, other than an approved leave of absence, are subject to a probationary period and will be considered a new employee from the effective date of their re-employment for all purposes, including the purposes of measuring benefits.

The Pharmacy does not provide a "letter of reference" to former personnel. Generally, the Pharmacy will confirm, upon written request, a former employee’s dates of employment, work location and job title.

1. **References:** N/A
2. **Attachments:** N/A

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## 3.24 Performance Appraisals

1. **Purpose:** This policy is to describe the performance review process.
2. **Scope:** This policy applies to all personnel.
3. **Definitions:** N/A
4. **Policy:** Personnel performance is important to the Pharmacy, and performance appraisals are important tools in providing guidance for areas of potential improvement and rewarding and recognizing areas of success. The review process is also essential in planning the development of personnel and advancement within the Pharmacy.

Job performance is expected to be an ongoing conversation between personnel and their supervisor. Supervisors are expected to conduct written performance appraisals for the personnel they supervise once each year. The written performance appraisals should be discussed with personnel, and personnel are required to acknowledge the discussion and any performance plans or goals with a signature.

A positive performance evaluation does not guarantee a change in pay or duties. Personnel who do not receive an annual written review are encouraged to contact their supervisor or the Pharmacy owner.

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## 3.25 Merit Increases

1. **Purpose:** This policy describes the Pharmacy’s merit program.
2. **Scope:** This policy applies to all personnel.
3. **Definitions:** N/A
4. **Policy:** It is the Pharmacy’s desire to reward excellent job performance by giving merit increases when appropriate and feasible, depending on business needs. Normally, merit increases will be awarded, if warranted, at the time of an employee’s annual performance appraisal. A positive performance evaluation does not guarantee a change in pay or duties. If personnel wish to discuss their compensation, they are encouraged to contact the Pharmacy owner. All pay increases must be approved in writing by the Director of Pharmacy or their designee.

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## 3.26 Conflict of Interest

1. **Purpose:** This policy describes the Pharmacy’s policy on conflicts of interest.
2. **Scope:** This policy applies to all personnel.
3. **Definitions:** N/A
4. **Policy:**  The Pharmacy strives to adhere to the highest legal and ethical standards. Personnel are required to comply not only with the letter of the law, but also with the spirit of applicable laws and regulations. Personnel must never use their positions with the Pharmacy or their relationships with any of the its clients or referral sources for private gain, to advance personal interests, or to obtain favors or benefits for themselves, members of their families or any other individuals, corporations or business entities.

Pharmacy personnel must conduct their personal affairs in such a manner that their duties and responsibilities to the Pharmacy are not jeopardized and/ or legal questions do not arise with respect to their association or work with the Pharmacy.

There are several situations that may result in a conflict of interest between personnel and the Pharmacy or between personnel and their ethical and or legal duties, such as outside employment, personal friendships with vendors, relationships with subordinate personnel, and financial relationships with referral sources and/ or vendors. If an employee is unsure whether a conflict of interest exists, they must discuss the situation with their supervisor or legal counsel.

The Pharmacy respects an employee’s right to obtain outside employment, so long as that outside employment does not present a conflict of interest or adversely affect the employee’s ability to perform their job duties for the Pharmacy. Pharmacy personnel must notify their supervisor in writing of all outside employment, prior to accepting such employment. The Pharmacy has the right to determine which jobs are considered a conflict of interest with Pharmacy. Failure to obtain permission for conflicting outside employment is grounds for disciplinary action or termination from employment.

Gifts to personnel from an outside source are considered the property of the Pharmacy unless the Pharmacist-in-Charge (PIC) or Director of Pharmacy makes an exception. It is the Pharmacy’s policy that no personnel shall receive any gift, excessive or unusual entertainment, loan, or other favor (valued in excess of $25.00) from any outside source (including customers, clients, and suppliers) without approval from the PIC or Director of Pharmacy.

Personnel failing to abide by this policy are subject to disciplinary action, including immediate termination.

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## 3.27 Personal Injury

1. **Purpose:** This policy describes the process by which personnel may take time off for a personal injury.
2. **Scope:** This policy applies to all personnel.
3. **Definitions:** N/A
4. **Policy:** Personnel who are injured off the job may take time off in accordance with the applicable Pharmacy policy. Personnel must use all available paid time off before taking any unpaid time. If an employee has exhausted all available time off under the Pharmacy’s policy, at the Pharmacy’s discretion, depending on business need, the Pharmacy may grant additional unpaid time off, on a case-by-case basis.

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## 3.28 Work-Related Injury/Illness

1. **Purpose:** This policy describes how Pharmacy personnel may obtain time off for work-related injuries, deaths, and illnesses.
2. **Scope:** This policy applies to all personnel.
3. **Definitions:** The Pharmacy adopts applicable definitions from the state workers’ compensation statutes.
4. **Policy:** As an employment benefit, at no cost to personnel, the Pharmacy maintains workers’ compensation insurance for all its personnel. This insurance will generally compensate personnel for work-related illness, injuries, and time away from work caused by work-related injuries. In some instances, there are death benefits associated with work-related deaths.

If an employee is injured at work or while conducting Pharmacy business, they should notify their supervisor as soon as possible to ensure that the injury is timely reported to the Pharmacy’s insurance carrier. If treatment is necessary, personnel must seek medical treatment as soon as possible at the Pharmacy’s designated facility unless it is an emergency. When at the doctor’s office, all personnel must complete their portion of the report to the Industrial Commission or other appropriate agency and inform the physician of the circumstances of the accident/ injury.

Personnel who need time off to recover may use time that is available under Pharmacy sick, PTO, or FMLA policies, whichever apply.

The Pharmacy has a strict policy against retaliation against employees for engaging protected activity such as reporting work-related injuries.

1. **References:** Policy 1.15 – Policy Against Retaliation

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## 3.29 Exit Interview

1. **Purpose:** This policy describes the Pharmacy’s role in conducting exit interviews.
2. **Scope:** This policy applies to all personnel.
3. **Definitions:** N/A
4. **Policy:**  When personnel leave their employment with the Pharmacy, the Pharmacy may request that they participate in a brief exit interview. In this interview, the Pharmacy will collect all Pharmacy tools, property, keys, etc. and discuss the employee’s continuing obligations to the Pharmacy (such as maintaining confidentiality of patient information and Pharmacy proprietary information). The Pharmacy will notify the employee of the Pharmacy’s policy on giving references.
5. **References:** Policy 3.23 – Employee Resignation

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## 3.30 Pharmacist/Staff Lunch Breaks

1. **Purpose:** This policy describes the Pharmacy’s practices regarding lunch breaks for pharmacists and pharmacy technicians. The policy is in place to reduce the likelihood of prescription and other errors resulting from fatigue.
2. **Scope:** This policy applies to all pharmacists and Pharmacy personnel**.**
3. **Definitions:** N/A
4. **Policy:**  The Pharmacy will not provide pharmacy services, and the Pharmacy will be closed and secured for a period of 30 minutes each day to enable licensed Pharmacy personnel to obtain a 30-minute meal period. Phone lines should be programmed to inform callers that the Pharmacy is closed from to and to request that callers either leave a message or call back when the Pharmacy is open. The lunch period should be the same every day, and a conspicuous sign shall be posted informing customers of the closure.

The sign should be in a form similar to: “THE PHARMACY IS CLOSED FOR LUNCH FROM 12:00 P.M. TO 12:30 P.M. EACH DAY.”

Non-exempt personnel must clock-out during this meal period. Personnel are expected to return from their lunch breaks on time and ready to work.

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## 3.31 Sick Leave

1. **Purpose:** This policy describes the Pharmacy’s guidelines regarding time off due to illness, whether due to a personal or work-related injury or illness.
2. **Scope:** This policy applies to all non-exempt personnel.
3. **Definitions:** N/A
4. **Policy:**  The Pharmacy complies with applicable federal and state laws regarding time off for medical reasons. Each employee will receive five (5) days of paid sick leave each year, renewing on the employee’s anniversary date. This sick leave is to be used for an employee’s illness or to care for a family member who is ill. Sick leave should not be used for personal or vacation days. Personnel who are out of work for a non-work related condition for more than three consecutive days due to illness may be asked to bring a doctor’s note upon return to work.

Personnel who have exhausted their available sick leave and any other available time off and who need additional time off due to a medical condition (i.e., pregnancy) should discuss their need for additional time off with the Pharmacy owner. Additional unpaid time may be granted on a case-by-case basis if business needs permit.

**NOTE:** To the Policy Maker. Delete prior to publication. This policy should not be used in conjunction with a PTO policy, as PTO would include sick leave. Depending upon the size of the Pharmacy and the state in which the Pharmacy is operating, the Pharmacy may be subject to the Family and Medical Leave Act or comparable state laws requiring that employers provide personnel with paid or unpaid time off in the event of illness, the illness of a family member, pregnancy, or similar condition. Pharmacies are strongly encouraged to meet with a local employment attorney to discuss which state and federal laws will apply to them.

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## 3.32 Lactation Breaks

1. **Purpose:** This policy informs nursing mothers of their rights to take lactation breaks.
2. **Scope:** This policy applies to all female personnel who are nursing mothers.
3. **Definitions:** N/A
4. **Policy:** The Pharmacy will provide a reasonable amount of break time to accommodate a female employee's need to extract breast milk for her infant child for up to a year following the infant's birth. The break time should, if possible, be taken concurrently with other break periods already provided. Non-exempt personnel should clock out for any time taken that does not run concurrently with normally scheduled rest periods, and such time generally will be unpaid in accordance with state law. The Pharmacy will provide the employee with the use of a location other than a bathroom that is private for the employee to extract milk in private.

Female personnel should request time from their managers to extract breast milk under this policy.

No provision of this policy applies or is enforced if it conflicts with or is superseded by any requirement or prohibition contained in a federal, state, or local law or regulation. Anyone with knowledge of such a conflict or potential conflict should contact their manager.

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## 3.33 Overtime

1. **Purpose:** This policy describes the Pharmacy’s authorization of overtime pay.
2. **Scope:** This policy applies to all non-exempt personnel.
3. **Definitions:** N/A
4. **Policy:** In accordance with federal and state laws, the Pharmacy will pay overtime to personnel who work overtime, as that term is defined by applicable state or federal law.

Personnel are not permitted to work overtime unless they are first authorized or requested to do so, in writing, by their immediate supervisor, the Pharmacist-in-Charge (PIC), or the Director of Pharmacy. Personnel who work overtime hours without first obtaining written authorization will be paid, but are subject to discipline, up to and including termination from employment.

Personnel are not permitted to take “comp time” in lieu of overtime pay.

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## 3.34 Jury Duty

1. **Purpose:** This policy describes the Pharmacy’s responsibilities with respect to personnel serving as jurors.
2. **Scope:** This policy applies to all personnel.
3. **Definitions:** N/A
4. **Policy:** If an employee is summoned to serve as a juror, they must notify the Pharmacy as soon as practicable of the date(s) of jury service and provide the Pharmacy with a copy of the jury summons. The Pharmacy must not interfere or limit its personnel’s participation in jury duty. If the employee wishes to use PTO during jury service, the Pharmacy will permit the employee to do so provided the employee has PTO available.

If, and only if required by applicable state and federal law, the Pharmacy will compensate personnel for time served as a juror. If an employee is released from jury duty more than two (2) hours prior to the end of the employee’s regularly scheduled work shift, the employee is required to contact their supervisor and come to work if requested.

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## 3.35 Military Leave

1. **Purpose:** This policy describes the Pharmacy’s responsibilities with respect to granting military leave.
2. **Scope:** This policy applies to personnel covered by the Uniformed Services Employment and Reemployment Rights Act (USERRA).
3. **Policy:** The Pharmacy will grant military leaves of absence as required by law. Personnel may take an unpaid leave of absence to perform military training and/ or service, whether the service is voluntary or involuntary, as part of the active and reserve components of the Armed Forces, the Army and Air National Guard, the Commissioned Corps of the Public Health Service, and any other category of persons so designated by the Pharmacy Officers in time of war or emergency.

The duration of other military leave will be the term of the enlistment, plus any additional time that may be required by the government. The Pharmacy generally will provide a reasonable allowance of time for travel and adjustment before the employee returns to work. A member of the U.S. Armed Services or National Guard will be granted a two-week unpaid leave of absence once per year when called for active duty training.

To be eligible for any reinstatement rights under federal law, any employee taking leave from work to serve in the military, including the National Guard, must:

* Provide the Pharmacy with as much advance notice of their service as possible.
* Ensure that the cumulative length of the service does not exceed five years.
* Have been honorably discharged.
* Report to or submit an application for re-employment, as required by federal law, upon return from service.

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## 3.36 Medicare Part D Training

1. **Purpose:** This procedure describes the Medicare Part D prescription drug plan benefit.
2. **Scope:** This procedure applies to pharmacists, pharmacy technicians, and Pharmacy personnel involved with dispensing prescription drugs.
3. **Definitions: The Medicare Part D Prescription Drug Benefit** (also called Part D) is a federal government program to subsidize the costs of prescription drugs and prescription drug premiums for Medicare beneficiaries. The Medicare Part D prescription drug benefit was enacted as part of the Medicare Modernization Act of 2003.
4. **Safety Requirements:** N/A
5. **Procedure:** It is important to understand certain fundamental aspects of the Medicare Part D program so you can better serve our patients/ customers:
6. Individuals on Medicare are eligible to enroll in Part D if already enrolled in Medicare Parts A and/ or B.
7. There are 2 types of plans: plans administered by private insurance companies (stand-alone) for Part D plan for drug coverage only; and Medicare Part C plans that cover hospital and medical services as well as prescription drug coverage.
8. It is important to note that not all prescription drugs are covered at the same out-of-pocket expense to the beneficiary. For example, there may be incentives to use generic drugs versus brand drug or incentives offered through tiered formularies.
9. Medicare's interactive Medicare Plan Finder allows our patients/ customers to compare coverage and costs for all plans in our geographic area (www.medicare.gov/find-a-plan/questions/home.aspx). Each Medicare Part D plan has its own list of covered drugs (formulary). These Part D plans place drugs in different tiers on their formularies with different costs associated with each tier.
10. The standard Part D benefit requires the beneficiary to pay an initial deductible; then a 25% coinsurance payment up to a certain dollar amount (Threshold). Once this threshold amount is met, the beneficiary goes into the "donut hole." In the "donut hole," the beneficiary is responsible for all out-of-pocket expenses. Once the out-of-pocket threshold is met, the beneficiary qualifies for catastrophic coverage, where the federal government again picks up a significant part of the drug costs. The Affordable Care Act passed in 2010 gradually reduces the "donut hole;" by 2020 the donut hole will, for all practical purposes, be closed.
11. There is a low-income subsidy available for beneficiaries with incomes below 150% of the federal poverty level.
12. Medicare does not have an established drug formulary that health plans must follow; Part D coverage excludes drugs not approved by the Food and Drug Administration (FDA), drugs prescribed for off-label use, drugs not available by prescription for purchase in the United States, and drugs for which payment would be available under Medicare Parts A or B. However, Medicare directive establishes that drugs prescribed for off-label use should be covered until the patient can be safely transitioned to another form of treatment.
13. Part D excludes coverage for drugs or classes of drugs such as drugs used for:

* Anorexia, weight loss or weight gain
* Promotion of fertility
* Erectile dysfunction
* Cosmetic purposes
* Symptomatic relief of cough/ cold
* Vitamins and mineral products, except pre-natal vitamins & fluoride preparations

1. Part D plan coverage uses cost utilization measures such as quantity limits, prior authorization, and step therapy.
2. Part D plans are required to offer higher tiered drugs (higher cost) to beneficiaries at a lower tier (lower cost) when medically necessary.
3. Beneficiaries that qualify for both Medicare and Medicaid can receive extra monetary assistance to help pay drug costs through a Medicare Savings Program and Supplemental Security Income (SSI).
4. **References:**

* NABP website
* CMS website
* Commercial insurers websites
* State Boards of Pharmacy websites
* Pharmacy Law Desk Reference
* Pharmaceutical Law

1. **Attachments:** N/A

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## 3.37 Medicaid Training

1. **Purpose:** This procedure describes the state Medicaid social health care program for families and individuals with low-income resources.
2. **Scope:** This procedure applies to pharmacists, pharmacy technicians, and Pharmacy personnel.
3. **Definitions:** The Medicaid health care program was created by the Social Security Amendments of 1965 which added Title XIX to the Social Security Act. Medicaid is jointly funded by each state and the federal government. Medicaid is a government insurance program for persons of all ages whose income and resources are insufficient to pay for health care.
4. **Safety Requirements:** N/A
5. **Procedure:** Since Medicaid is a jointly funded health care program, it is regulated by both states and the federal government. Some fundamental rules and regulations pertinent to pharmacy are:
6. Each state:

* Administers its own Medicaid program;
* Establishes its own eligibility standards;
* Determines the scope and type of services covered; and
* Sets the rate of payment.

1. Eligibility is determined by income; individuals with up to 133% of the federal poverty income level can qualify for coverage according to PPACA (Affordable Care Act), including adults without dependent children.
2. Medicaid does not pay benefits to individuals directly; Medicaid sends benefit payments to health care providers, like pharmacies.
3. Medicaid will only cover medically necessary services.
4. Prescriptions for Medicaid beneficiaries must be written on tamper-resistant paper; to qualify as tamper-resistant paper, the paper must fulfill at least one of the following elements: prevents unauthorized copying; prevents erasure or modification; or prevents use of counterfeit prescriptions.
5. If unsure about tamper-resistant paper, call the prescriber and document on the prescription the initials of the person verifying the prescription, the date verified, and the first and last name of the person who verified the prescription at the prescriber's office.
6. If unsure about tamper-resistant paper and it is an emergency, fill the prescription and obtain a compliant new prescription within 72 hours of dispensing.
7. A tamper-resistant paper prescription is not required if the prescription is faxed to the Pharmacy, verbally communicated or sent electronically.
8. If a Medicaid prescription is transferred to the Pharmacy, you only need to verbally verify the prescription with the transferring pharmacy or receive a fax confirming authenticity from the transferring pharmacy; there is no need to confirm authenticity with the prescriber.
9. Many states have enacted programs to contain the escalating costs of Medicaid prescription drugs. Some of these programs are:

* Preferred drug lists or formularies
* Mandatory generic substitution
* Cost sharing/ co-payments
* Prior authorization
* Disease management

1. If a patient has dual eligibility (has both Medicare & Medicaid), bill Medicare Part D first and the Extra Help Program, which is a federally funded program that pays costs for most prescription drugs. In some instances, Medicaid may pay for a prescription drug that Medicare does not cover.
2. There are certain drugs or drug classes that states may exclude from coverage:

* Some/ all over-the-counter products
* Some products used for cold or cough relief
* Prescriptions for vitamins or mineral products
* Barbiturates or diazepines

1. New/ refilled prescriptions for Medicaid patients not picked up within 10-14 days from date of fill must be returned to stock and the claim reversed. If the medication is returned to stock, please refer to the Return to Stock Policy for correct procedure.
2. **References:**

* CMS website
* State Boards of Pharmacy websites
* NABP website
* NACDS website
* Pharmacy Law Desk Reference

1. Pharmaceutical Law

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# 4.0 Relations Customer Service

## 4.01 Customer Service

1. **Purpose:** This procedure describes how Pharmacy personnel can create an excellent customer service relationship with patients/ customers.
2. **Scope:** This procedure applies to all personnel.
3. **Definitions:** N/A
4. **Safety Requirements:** N/A
5. **Procedure:** Establishing an excellent customer service relationship between patients/ customers and Pharmacy personnel is essential to providing optimal pharmaceutical care, which is the cornerstone of the Pharmacy. To provide optimal pharmaceutical care, Pharmacy personnel must create a feeling of trust, confidence, and caring with patients/ customers that extends far beyond prescription dispensing.

Pharmacy personnel are responsible for the quality of customer service, which includes:

* Adhering to both state and federal pharmacy regulations
* Ensuring accuracy and quality in prescription receipt, processing, and dispensing
* Maintaining confidentiality of electronic Protected Health Information (ePHI) and Individual Identifiable Health Information (IIHI)
* Complying with Pharmacy policy and procedure
* Listening before responding to questions and communications from customers, Pharmacy personnel, and health care professionals
* Responding, always, in a professional and courteous manner
* Treating customers with respect and courtesy
* Resolving customer complaints quickly and efficiently
* Working to support Pharmacy team goals
* Establishing trust and confidence with all Pharmacy personnel

1. **References:** N/A
2. **Attachments:** N/A

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## 4.02 Pharmacy Telephone Etiquette

1. **Purpose:** This procedure describes the appropriate use of Pharmacy telephones to ensure proper etiquette is used in the Pharmacy environment.
2. **Scope:** This procedure applies to all personnel.
3. **Definitions:** N/A
4. **Safety Requirements:** N/A
5. **Procedure:**
6. All telephone calls shall be answered using a friendly, courteous, and clear tone of voice.
7. All callers will be asked to identify themselves if they have not already done so.
8. All personnel must identify themselves when communicating on the telephone.
9. As a general rule, telephones should be answered within three (3) rings. All personnel are responsible for answering the telephone.
10. If callers are put on hold, they should be informed of the status of the call. When personnel put callers on hold, they should never leave them on hold for more than thirty seconds. When resuming the call, personnel should thank the caller for their patience: “Thank you for waiting,” or “I appreciate your patience.”
11. When a caller requests an employee or pharmacist who is not available, the person answering the call will ask, "Can someone else help you?"
12. All personnel should be polite and helpful to project a caring and compassionate attitude over the telephone at all times.
13. If a caller becomes irate, threatening, or abusive, kindly inform the caller the status of the steps being taken to resolve the issue. If needed, escalate the call to the Pharmacist-in-Charge (PIC) or Director of Pharmacy for further assistance in resolving the matter.
14. **References:** N/A
15. **Attachments:** N/A

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## 4.03 Returned Products

1. **Purpose:** This procedure describes the Pharmacy’s guidelines for handling returns of over-the-counter products and returns of prescription medications or products by customers/ patients.
2. **Scope:** This procedure applies to all Pharmacy and front-end personnel.
3. **Definitions:**

**Returned Rx Medications:** Legend drug prescription medications that have been removed from the Pharmacy building by the patient.

**Returned OTC Medications**: Non-prescription, over-the-counter medications purchased by the customer/ patient.

1. **Safety Requirements:** It is the responsibility of the Pharmacy to fully demonstrate that Returned Rx Medications meet the state Board of Pharmacy requirements and regulations and maintain product quality as per United States Pharmacopeia (USP) standards.
2. **Procedure:**
3. **Rx Medication Returns:** Legend drug prescription medications may be returned to the Pharmacy (Returned Rx Medications) but may never be returned to stock or dispensed to other patients.
   * + - The pharmacist must make a record of the returned medication and place it with the stock of medication to be sent to the reverse distributor for destruction.
       - All claims submitted to a third-party payer must be reversed according to that payer’s policies if a medication is accepted back in the Pharmacy as a return.
       - The patient can be refunded the cost of the medication at the discretion of the Pharmacist-in-Charge (PIC).
     + Under no circumstances may the Pharmacy accept returns of controlled substances. Patients should be instructed to look for the next Drug Enforcement Agency (DEA) take back program date and return the drugs to local law enforcement or the DEA.
     + An individual may return his/her unused or unwanted controlled substance prescription medication to any retail pharmacy that is authorized by the DEA to collect unwanted pharmaceutical controlled substances. Alternately, if a pharmacy maintains mail-back packages, individuals may place unused or unwanted medications inside a mail-back package. Individuals may not give these unwanted medications to pharmacy employees but must directly deposit the medications inside a collection receptacle at the pharmacy or inside a mail-back package provided by the pharmacy. Otherwise, the pharmacy cannot accept the returned controlled substances with exception of recall or dispensing error.
4. **Allowable Over-the-Counter (OTC) Medication Returns:** As part of good customer service and public safety, the following guidelines are to be followed in situations requiring OTC medication returns:
   * + All Returned OTC Medications must first be authorized by a licensed pharmacist by following the state Board of Pharmacy requirements.
     + No OTC medication may be returned if there is a question as to the quality of the OTC medication.
5. **Return Medication Inspection:** For returns resulting from a Recall, Market Withdrawal, or Pharmacy error, the pharmacist must inform the Quality Assurance Department (if applicable) for compliance to recall/ market withdrawal requirements or for full investigation and corrective action and prevention of a repeat error.
   * + All actions shall be documented and, where applicable, Pharmacy personnel may require retraining.
     + Any Returned OTC Medication meeting these inspection requirements may be reused.
6. **Returned Rx or OTC Medication Credit:** The Pharmacy will not guarantee a refund of any amount prior to inspection of the Returned Rx or OTC Medication.
   * + Any credit due to the patient will be assessed by the Pharmacy Manager or PIC, upon receipt of the return.
     + Refund amounts will be contingent upon medication inspection result.
     + The patient will be given the opportunity to accept or refuse the credit amount. In the event of refusal, product will be returned to the manufacturer at the cost of the patient.
     + No credit will be given to a product that is deemed unfit for resale.
     + Restocking or disposal fees of up to the full purchase price may apply when deemed appropriate by the Pharmacy Manager.
7. **References:** N/A
8. **Attachments:** N/A

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## 4.04 Patient Medication Pick Up

1. **Purpose:** This procedure describes the Pharmacy’s guidelines when patients pick up their prescription medication(s).
2. **Scope:** This procedure applies to all Pharmacy personnel.
3. **Definitions:**

**Patient Medication Pick Up:** When a patient or patient's caregiver arrives at the Pharmacy to pick up any prescribed medication, the following procedures should be consistently applied.

1. **Safety Requirements:** N/A
2. **Procedure:**
   1. Confirm patient’s name, address and date of birth.
   2. Confirm number of prescriptions to be picked up.
   3. Never verbally disclose the name(s) of the prescription medications being picked up.
   4. Call the pharmacist over to where the patient is, so the pharmacist can counsel the patient. This applies to all new and refill prescriptions.
   5. Ensure the patient signs the dispensing log.
   6. Collect any co-payments or monies due to the Pharmacy.

The federal Health Insurance Portability and Accountability Act as well as many state laws hold pharmacies and other health care providers accountable to secure protected health information (PHI) by creating administrative, physical, and technical safeguards as well as policies and procedures to prevent inadvertent disclosure of PHI. Observance of these procedures when a patient picks up their medication will prevent such an inadvertent disclosure.

**NOTE:** To the Policy Maker only. Delete prior to publication. Counseling requirements or the offer to counsel vary from state-to-state. This Standard Operating Procedure is designed to be a generic sample. Pharmacies are urged to consult with a local attorney or the Board of Pharmacy to ensure this procedure complies with state laws.

1. **References:** N/A
2. **Attachments:** N/A

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## 4.05 Diversity and Pharmacy Communications

1. **Purpose:** This procedure describes the Pharmacy guidelines personnel must follow when communicating with customers or patients from diverse backgrounds.

The Pharmacy is committed to recognizing and respecting people of cultural differences and their right to respect and dignity, and privacy. All reasonable steps will be taken to accommodate communications with customers and patients of diverse backgrounds when providing pharmacy services.

1. **Scope:** This procedure applies to all personnel who communicate with customers or patients.
2. **Definitions:**

**Diversity:** Differences of culture, background and experience among individuals and groups. Such differences include, but are not limited to:

* Race
* Ethnicity
* Nation of origin
* Color
* Gender
* Sexual orientation
* Gender identity
* Age
* Disabilities
* Political and religious affiliation
* Socioeconomic status

1. **Procedure:**
2. **Training:** All Pharmacy personnel who communicate with customers or patients should be trained to follow this procedure.
3. **Recognizing Diversity:**  Pharmacy personnel must follow these rules:
   * + Treat people politely and considerately during all communications.
     + Do not discriminate against customers or patients.
     + Respect and protect people's dignity and privacy. Take all reasonable steps to prevent accidental disclosure or unauthorized access to confidential information. Never disclose confidential information without consent unless required to do so by the law or in exceptional circumstances.
     + Obtain all information required to assess a patient's needs to give the appropriate treatment and care.
     + Make sure there is adequate access to the facilities, equipment, and resources needed to provide professional services safely and effectively.
     + Communicate effectively with patients and the public and take reasonable steps to meet their communication needs.
4. **Verbal and Non-Verbal Communication:** When communicating with a patient or customer from a diverse background treat them with respect and sensitivity. Follow these guidelines for:
   * + Verbal Communications:
       - Find out how well the patient understands written and spoken English by asking simple questions after initially greeting the patient.
       - Use gestures or simple words to communicate where language barriers exist.
       - If the patient has difficulty answering or understanding, locate a pharmacy employee to interpret.
       - Obtain assistance from a co-worker, Pharmacist-in-Charge (PIC), or Director of Pharmacy to assist in facilitating communications or translation service.
       - Pharmacy personnel must inform the interpreter not to change any information and relay it exactly as it is provided.
       - Pharmacy personnel must verify to see if the message was understood by asking the interpreter to repeat the message back in English.
       - If the interpreter process is not suitable or working, inform the PIC and use other Pharmacy aids for communication.
     + Non-Verbal Communications:
       - Follow the patient’s lead regarding voice volume and pitch; do not speak louder than the patient.
       - Allow for pauses in the conversation; allow time for the patient to formulate responses or gather thoughts.
       - Do not interrupt patients while they are speaking.
       - If the patient is accompanied by someone, observe who is asking the questions and direct the conversation to both parties as needed.
       - Look at the patient, but do not force eye contact. Occasionally look away to make them feel more comfortable.
5. **References:**  SOP 4.15 – Communicating with Persons with Limited English Proficiency (LEP)
6. **Attachments:** N/A

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## 4.06 Patient Counseling

1. **Purpose:** This procedure describes the Pharmacy’s patient counseling guidelines that must be followed by all Pharmacy personnel.
2. **Scope:** This procedure applies to all pharmacists (or pharmacist interns working under the supervision of a licensed pharmacist to the extent allowed by state law)who perform patient counseling and to the Pharmacy personnel who interact with patients at medication pickup.
3. **Definitions:**

**Patient counseling:** The information provided and reviewed by the pharmacist with the patient regarding their prescription medication. This information may include:

* Medication therapy
* Indication
* Dosage
* Form
* Route
* Duration
* Pertinent side effects
* Precautions
* Interactions
* Missed dose procedure
* Storage recommendations
* Specific techniques for self-monitoring

The patient counseling will also help the pharmacist to assess the patient's understanding of how to use the medication and what to expect. This two-way dialogue allows for questions to be asked.

1. **Safety Requirements:** Errors can be prevented with appropriate and effective patient counseling. As a part of patient counseling, the pharmacist will verify that the correct medication is being dispensed.
2. **Procedure:**
   1. **Required Patient Counseling:** The pharmacist must counsel the patient or patient's caregiver:
      * Upon dispensing of a new prescription
      * Upon dispensing a new drug order
      * Upon dispensing a refill

Pharmacy technicians or clerks are not allowed to counsel patients.

* 1. **Patient Counseling:** 
     + The pharmacist must initiate the patient counseling.
     + Upon pick-up of medication by a patient or a patient’s caregiver, the Pharmacy technician shall:
       - Review the patient’s record and identify if the prescription is ready.
       - Call the pharmacist over to counsel the patient.
       - Once the pharmacist begins counseling, the patient has the right to refuse patient counseling; this refusal shall be documented. This documentation may be written or electronic, and documentation must be retained by the Pharmacy per state or regulatory agency retention requirements.
  2. **The Counseling Session:** 
     + Patient counseling may only be conducted by a licensed pharmacist or, if state law allows, an intern under the direct supervision of a licensed pharmacist.
     + Counseling shall take place in a segregated well-lit area, with decreased noise level where privacy is provided, and others may not overhear the conversation**.**
     + Counseling must be in person, whenever applicable, may be supplemented with written material, and must include the following elements:
       - The name and description of the drug
       - The dosage form, dose, route of administration, and duration of therapy
       - Intended use of the drug and expected action
       - Special directions and precautions for preparation, administration, and use by the patient
       - Common severe side effects, adverse effects, or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur
       - Techniques for self-monitoring of drug therapy
       - Proper storage
       - Prescription refill information
       - Action to be taken in the event of a missed dose
       - Pharmacist comments relevant to the patient's drug therapy, including any other information peculiar to the specific patient or drug, and/ or answers to any questions the patient may have
  3. **Communicating with Patients with Hearing Loss:** The pharmacist shall provide counseling information as listed in section 3.3 above. In addition, the pharmacist will:
     + Determine the patients preferred method of communication.
     + Speak at a moderate pace and normal tone.
     + Speak directly to the person with the hearing loss.
     + Maintain eye contact.
     + Write legibly when notes are used.
     + Ask open-ended questions.
     + Be patient.

**NOTE:** To the Policy Maker only. Delete prior to publication. The requirements for counseling or offering to counsel vary from state-to-state. This Standard Operating Procedure is designed to be a generic sample. The Pharmacy is urged to consult with a local attorney or the Board of Pharmacy to ensure this procedure complies with your state laws.

1. **References:** N/A
2. **Attachments:** N/A

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## 4.07 Pharmacy Based CLIA- Waived Tests

1. **Purpose:** This policy describes the waived clinical laboratory tests that may be performed in the Pharmacy without having to obtain any additional licenses or licensures.
2. **Scope:** This policy applies to all Pharmacy personnel performing waived laboratory tests.
3. **Definitions:**

**Clinical Laboratory Improvement Amendments (CLIA) Tests:**  Performed on specimens derived from humans for the purpose of providing information for the diagnosis, prevention, or treatment of disease, impairment of, or assessment of health.

**CLIA-waived Tests:** Those tests that have been determined so simple, easily performed, and accurate that there is little risk of harm to the patient, even if the test is performed incorrectly. That is the reason why no additional license/ licensure is required to perform any of these waived tests. The Food and Drug Administration (FDA) is the federal agency that has categorized these laboratory tests as waived.

1. **Policy:** To perform any of these CLIA-waived tests, the Pharmacy:
   * Must obtain and maintain a current CLIA Certificate of Waiver.
   * May be required by the state to obtain a state CLIA certificate.
   * Must renew its CLIA certificate every 2 years.
   * Must notify the appropriate state agency within 30 days of Pharmacy ownership or address changes or if the Pharmacy wants to perform more complex testing.
   * Must follow the manufacturer's instructions for performing waived tests.

* Permit a Center for Medicare and Medicaid Services (CMS) agent to inspect the Pharmacy's laboratory records if the agent is present at the Pharmacy.
* Must maintain CLIA laboratory records for two years.
  + Must train personnel performing waived testing to:
    - Collect specimens appropriately
    - Label and store specimens appropriately
    - Fully understand the manufacturer's instructions for each test performed
    - Know how to perform and document test results
    - Identify inaccurate or failed system results
    - Make sure the specimen is handled properly
    - Observe and evaluate Pharmacy testing personnel to make sure the testing is performed accurately

1. **References:**

* Currently Waived Tests: [www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm)
* Waived Tests, sorted by test categorization date and by test system name: [www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/testswaived.cfm](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/testswaived.cfm)

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## 4.08 Clinical Reference Library

1. **Purpose:** This procedure describes the clinical references that the Pharmacy should have readily available.
2. **Scope:** This procedure applies to all Pharmacy personnel.
3. **Definitions:**

**Clinical Reference Library:** A compendium of clinical reference texts specific to the practice of pharmacy. A compendium consists of a concise compilation of the body of knowledge necessary to provide safe pharmaceutical care. The number and diversity of these clinical texts should be specific to the practitioners, patients, and medications dispensed by the pharmacy. For instance, a nuclear, hospital, or specialty pharmacy will probably require access to clinical texts that would not be needed in a typical community pharmacy setting.

1. **Safety Requirements:** N/A
2. **Procedure:** ThePharmacy will maintain access to all the clinical references that are either required by law or necessary to practice pharmacy safely. These texts may be available either electronically or in hard copy. If clinical texts are maintained in hard copy, the clinical texts should be the current edition of those texts. At a minimum, the Pharmacy will have access to:
   * State and federal drug laws relating to the practice of pharmacy and the legal distribution of drugs
   * A pharmaceutical compendium
   * Maintenance of a patient-oriented reference for guidance in proper drug usage
   * Texts on the proper development, maintenance, and use of a sound drug formulary system
3. **References:** N/A
4. **Attachments:** N/A

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## 4.09 Drug Interaction Prevention

1. **Purpose:** This procedure describes the steps necessary to reduce the chance of an adverse, clinically significant result that can occur when two or more drugs are administered at the same time.
2. **Scope:** This procedure applies to all pharmacists (or pharmacist interns working under the supervision of a licensed pharmacist to the extent allowed by state law) and pharmacy technicians.
3. **Definitions:**

**Drug Interaction**: The pharmacologic or clinical response to the administration of a drug combination different from that anticipated from the known effects of either drug when given separately.

1. **Safety Requirements:** N/A
2. **Procedure:**
3. Since drug interactions can result in unanticipated, clinically significant outcomes, it is important that the pharmacist and pharmacy technicians understand some of the different ways drug interactions can occur:

* One drug may increase or decrease the absorption of the other drug.
* One drug can change the elimination rate of the other, minimizing its clinical effect.
* Modification of the plasma-protein binding site can alter the expected clinical response.
* Competition of the two drugs for a structurally and chemically similar molecule can also minimize the clinical response.

1. It is important for pharmacists and pharmacy technicians to remember that not all drug interactions are clinically significant. Most authoritative clinical sources categorize drug interactions as highly, moderately, or minimally significant. Pharmacy computer programs can assist pharmacists and pharmacy technicians to identify drug interactions. However, the decision whether to override a drug interaction alert and fill the prescription or reach out to the prescriber rests with the professional judgment of the pharmacist. Before a pharmacist makes such a decision, the pharmacist should review the patient’s record and each drug order, noting:

* Allergies
* Rational therapy combinations
* Reasonable dose, duration of use, and route of administration
* Age, gender
* Reasonable directions for use
* Therapeutic duplication
* Abuse/ misuse
* Drug/ disease contraindications
* Proper utilization
* Optimal therapeutic outcome

1. **References:** N/A
2. **Attachments:** N/A

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## 4.10 Selling Durable Medical Equipment

1. **Purpose:** This procedure explains the term durable medical equipment and familiarizes Pharmacy personnel with some of the Center for Medicare and Medicaid Services (CMS) supplier standards that must be met to qualify to bill Medicare/ Medicaid. A full listing of the federal supplier standards is available at ([42 C.F.R. 424.57](http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=5a2dad7f464807cb09a1f2b2e2441c32&ty=HTML&h=L&mc=true&r=PART&n=pt42.3.424#se42.3.424_157)).
2. **Scope:** This procedure applies to all personnel selling or distributing durable medical equipment to Medicare/ Medicaid patients.
3. **Definitions:**

**Durable Medical Equipment (DME):** Any medical equipment used in the home to aid in a better quality of life, such as oxygen tents, catheters, hospital beds, wheelchairs, blood testing strips, blood glucose monitors, etc.

1. **Safety Requirements:** N/A
2. **Procedure:** As noted above, the following abbreviated list of CMS supplier standards are provided to assist Pharmacy personnel when dispensing/ selling DME:

* Professional personnel shall be licensed, certified, or registered and function within their scope of practice as required by the state standards under which the professional is licensed, certified, or registered.
* A supplier must be in compliance with all applicable federal and state licensure and regulatory requirements.
* A supplier must permit CMS or its agents to conduct on-site inspections to ascertain the supplier’s compliance with these standards.
* A supplier is responsible for the delivery of and must instruct beneficiaries on the use of Medicare-covered items and maintain proof of delivery and beneficiary instruction.
* A supplier must answer questions and respond to complaints of beneficiaries and maintain documentation of such contacts.
* A supplier must maintain and replace, at no charge or repair cost either directly or through a service contract with another company, any Medicare-covered items it has rented to beneficiaries.
* A supplier must accept returns of substandard (less than full quality for the particular item) or unsuitable (inappropriate for the beneficiary at the time it was fitted and rented or sold) items from beneficiaries.
* Complaint records must include the following information about the complainant:
  + Name
  + Address
  + Telephone number
  + Health insurance claim number of the beneficiary
  + Summary of the complaint
  + Any actions taken to resolve it
* A supplier must have a complaint resolution protocol established to address beneficiary complaints that relate to these standards. A record of these complaints must be maintained at the physical facility.
* All suppliers must be accredited by a CMS-approved accreditation organization in order to receive and retain a supplier billing number. The accreditation must indicate the specific products and services, for which the supplier is accredited for the supplier to receive payment for those specific products and services (except for certain exempt pharmaceuticals).

1. **References:** N/A
2. **Attachments:** N/A

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## 4.11 Selling Methamphetamine Precursor Products

1. **Purpose:** This procedure describes the requirements for selling Methamphetamine Precursor Products without a prescription.

This procedure complies with the requirements outlined in the Combat Methamphetamine Epidemic Act of 2005, which established quantity restriction requirements for the sale without a prescription of the Scheduled Listed Chemical Products containing Ephedrine, Pseudoephedrine, and Phenylpropanolamine – ingredients that can be used illegally to make methamphetamine or amphetamine.

The law bans over-the-counter sales of cold medicines that contain these ingredients. The sale of cold medicines containing pseudoephedrine is limited to placement of these products behind the counter. The amount of pseudoephedrine that an individual can purchase daily and monthly is limited, and individuals are required to present photo identification to purchase products containing pseudoephedrine.

1. **Scope:** This procedure applies to all Pharmacy personnel. All personnel must be trained in this procedure prior to selling any one of the products containing pseudoephedrine.

Any Pharmacy personnel selling these products must provide proof of Training/ Self Certification to the Attorney General. To achieve ‘self-certification,’ personnel must be trained to the requirements of the Combat Methamphetamine Epidemic Act. The Act states: “A regulated seller may not sell any scheduled listed chemical product at retail unless the seller has submitted a ‘self-certification’ document to the Attorney General."

1. **Definitions:**

**DEA:** The Drug Enforcement Administration is the government agency responsible for enforcing theCombat Methamphetamine Epidemic Act.

**Ephedrine:** A drug used clinically to treat breathing problems. It is also used to make cough, cold, and allergy drug products.

**Pseudoephedrine:** A drug used to treat colds, allergies, and runny noses and is found in both prescription and over-the-counter products. Pseudoephedrine is used to relieve nasal or sinus congestion caused by the common cold, sinusitis, hay fever, and other respiratory allergies.

**Phenylpropanolamine:** A drug that is only sold by prescription for animal use.

**Ephedrine, Pseudoephedrine, and Phenylpropanolamine:** Drugs that are methamphetamine and amphetamine precursors.

**Methamphetamine and Amphetamine:**  Drugs that are often manufactured illegally in laboratories located throughout the country. These drugs are powerful and highly addictive.

1. **Safety Requirements:** N/A
2. **Procedure:**
   1. The Pharmacy must keep all precursors behind-the-counter in the Pharmacy department, where customers do not have direct access to these products prior to the sale.
   2. Precursors must be kept in a secure location in the Pharmacy prescription-filling area or in a locked cabinet that is located in the area of the facility where customers do not have direct access. In all cases, the Pharmacy will deliver the product directly into the custody of the buyer.
   3. A customer requesting to purchase any of these types of medications must:
      * Present a photo ID issued by the state or the Federal Government.
      * Enter into the Pharmacy logbook or, if required by your state, an electronic log book the purchaser’s information, such as: Name, Address, Date and Time of Sale, and Signature.
      * Any Pharmacy personnel selling these products must provide proof of Training/ Self Certification to the Attorney General. To achieve ‘self-certification,’ Pharmacy personnel must be trained to the requirements of the Combat Methamphetamine Epidemic Act. The Act states that “A regulated seller may not sell any scheduled listed chemical product at retail unless the seller has submitted a ‘self-certification’ document to the Attorney General.”
   4. The Pharmacy must:
      * Verify that the customer's name on the photo identification matches the name entered in the logbook and verify that the date and time are entered correctly.
      * Enter in the logbook the name of the product and quantity sold.
      * Give the drug product directly to the customer who signed the logbook.
      * Keep the logbook in a secure location.
   5. No matter how many sales are made to a customer, the Pharmacy cannot legally sell more than 3.6 grams per day of these drug products to the same person.
   6. A customer can only buy a limited amount (9 grams) of these Schedule Listed Chemical Products containing ephedrine, pseudoephedrine, or phenylpropanolamine in a 30-day period.
   7. Records of sales must be maintained for at least 2 years.

**NOTE:** To the Policy Maker only. Delete prior to publication. These are example policies based on the federal Combat Methamphetamine Epidemic Act. Each state has different requirements related to the sale of precursor products without a prescription. It is strongly suggested to consult your local attorney or state Board of Pharmacy to ensure that this procedure complies with state law.

1. **References:**

* For additional informationregarding pseudoephedrine, phenylpropanolamine, ephedrine, or any medications, please contact the Division of Drug Information in the FDA’s Center for Drug Evaluation and Research (CDER) at: 888-INFOFDA (888-463-6332), or email at: [druginfo@fda.hhs.gov](mailto:druginfo@fda.hhs.gov) or visit the website at: <http://www.deadiversion.usdoj.gov>

**VII. Attachments:** N/A

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## 4.12 Pharmacy OTC Sales of Syringes

1. **Purpose:** This policy describes the process Pharmacy personnel must use when selling syringes and needles without a prescription.
2. **Scope:** This procedure applies to all Pharmacy personnel.
3. **Definitions:**

**Syringe:**  A tube with a nozzle and piston or bulb for sucking in and ejecting liquid in a thin stream and that can be used for cleaning wounds or body cavities. It can be fitted with a hollow needle for injecting or withdrawing fluids.

**Needle:** A very fine, slender, and hollow piece of metal that is attached to a syringe. The needle inserted into the body for injecting or withdrawing fluids.

1. **Policy:** Sales of needles and syringes are regulated by state laws. The main legal influences on the retail sale of syringes are drug paraphernalia laws. It is the policy of the Pharmacy to comply with these applicable state laws when selling needles and syringes. It is also the policy of the Pharmacy to act responsibly as a caring health care provider when selling needles and syringes.

Pharmacy personnel may only sell needles and syringes when:

* + 1. The patient has a valid prescription for the needles and syringes written by an authorized prescriber; or
    2. State law allows the sale of the needles or syringes without a prescription.

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## 4.13 HIPAA Policy

1. **Purpose:** This policy provides guidance for Pharmacy personnel on the management of confidential patient information and material in accordance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and its regulatory and statutory updates. This HIPAA Policy is the governing document for all activities related to patient privacy and related internal procedures. Any changes or recommendations shall be submitted to the Privacy Officer.
2. **Scope:** This policy applies to all Pharmacy personnel.
3. **Definitions:**

**IIHI (ePHI)/ Individual Identifiable Health Information:** Information that is a subset of PHI including demographic information collected from an individual and created or received by a health care provider, health plan, employer, or health care clearinghouse, and relates to:

* Past, present, or future physical or mental health or condition of an individual
* Provision of health care to an individual
* Past, present, or future payment for the provision of health care to an individual
* Identification of the individual
* Or where there is a reasonable basis to believe the information can be used to identify the individual

Examples (this is not an exhaustive list):

* Names
  + Individuals
  + Employers
  + Relatives
* Addresses
  + Street, City, County
  + Zip Code
  + More than 3 digits
  + Any other geographical codes
* Telephone/Fax Numbers
  + Home
  + Business
* Social Security Numbers
* Dates (except for years):
  + Date of Birth
  + Admission Dates
  + Rx Fill/Refill Dates
  + Discharge Dates
  + Date of Death
* All ages > 89 and all elements of dates indicative of such age
* Internet Information
  + Email
  + URLs
  + IP Addresses
* Medical Record Numbers
  + Rx Numbers
* Health Plan Beneficiary Numbers
* Account Numbers
* Certificate/ License Numbers
* Vehicle Identifiers
  + Serial Numbers
  + VINs
  + License Plate
* Device Identifiers
  + Serial Numbers
* Biometric Identifiers
  + Finger / voice prints
  + Photographs
* Or any other unique identifying numbers

**Privacy Officer (PO):** The assigned personwho isoverall responsible for the conduct of this program.

**Security Officer (SO):**  The person who is overall responsible for Information Technology Systems, training requirements for the system, and Security.

**DHHS-OCR:** U.S. Department of Health & Human Services, Office for Civil Rights. This government agency outlines the breach notification requirements.

1. **Policy**

TheHealth Insurance Portability and Accountability Act of 1996 (HIPAA) is federal legislation covering three (3) areas:

* 1. **Privacy and Security**

Under HIPAA, health care providers must use methods to ensure a patient’s medical information remains private and secure. Information that is covered by HIPAA is individually identifiable health information (IIHI). At its highest level, IIHI includes the following:

* General Information:
* Patient’s Name
* Medical Record Number
* Social Security Number
* Address
* Date of Birth
* Health Information:
* Diagnosis
* Medical History
* Medications
  1. **Insurance Portability**

This section of HIPAA gives individuals the ability to maintain health insurance coverage when they switch from one health plan to another. In addition, it prevents health plans from denying coverage to an individual who has a pre-existing health condition.

* 1. **Administrative Simplification**

This requires health care providers and insurance plans to standardize the processes used to electronically transfer patient-related information.

**Responsibility**

1.0 **The PO and SO**

The Pharmacy shall identify a Corporate Privacy Officer (PO).The PO is overall responsible for the conduct of the program. There shall also be an assigned Corporate Security Officer - SO.

The PO’s specific duties are to:

* Monitor HIPAA and industry changes to patient confidentiality regulations.
* Inform personnel and clients of program changes.
* Update and implement this Policy to comply with state and federal guidelines (HIPAA).
* Conduct periodic audits to ensure compliance and report to Management.
* Provide and ensure personnel training in patient confidentiality.
* Investigate and resolve HIPAA violation claims.

The SO’s specific duties are:

* Information Technology Systems:
  + Training requirements for the system
  + Security
* Periodic audits to ensure compliance

1. **Personnel, Clients, and Third-Party Support**

Personnel and clients shall adhere to the procedures within this Policy. Personnel responsibilities include:

* Provide ongoing feedback for program improvement.
* Comply with internal corporate and general industry requirements regarding patient confidentiality and security.
* Attend scheduled Confidentiality & Security Training (optional for clients).
* Immediately report any violations of the program, whether perceived or not, to the PO and Management.

**Program Monitoring**

Program monitoring will be conducted quarterly through internal audits and using a HIPAA Audit Checklist. The following areas and business/ medical functions must be monitored to ensure program compliance:

* Administration and Management
* Contracting
* Human resources
* Billing and collections
* Training
* Compliance
* Marketing material
* Operations (OPS)
* Patient scheduling and processing procedures (Treatment Planning)
* Operational forms, distribution thereof and access to \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* Visitor registration and escort procedures
* Physical site security
* Patient file storage (archiving) and destruction procedures
* Third party guidance for contractors, consultants, couriers, etc.
* Information Technology Management (IT)
* Printers, copiers, and facsimiles
* Computer network
* Internet security and access
* Work station security – time-out intervals (lock-out)

**Reporting, Reports and Checklists**

This Policy requires documentation to validate the success of this program. There are three types of documents that require periodic use and updating.

1.0 Reporting Inappropriate Use of Patient Information

If you feel that a patient’s privacy or confidentiality has been violated, immediately report the incident to your Manager and to the Privacy Officer for immediate investigation.

If the violation is verified by the PO, follow the breach notification requirements at: (<http://www.hhs.gov/ocr/privacy/hipaa/administrative/breachnotificationrule/brinstruction.html>)

2.0 Reports to the DHHS-OCR

Reports are the responsibility of the PO and must meet the requirements listed in U.S. Department of Health & Human Services, Office for Civil Rights - HHS.gov breach notification requirements.

(<http://www.hhs.gov/ocr/privacy/hipaa/administrative/breachnotificationrule/brinstruction.html>)

3.0 Checklists

Audit checklists will be used when conducting Quarterly inspections.

**Training**

1.0 Training Objectives

This HIPAA Policy and training will enhance our ability to maintain the highest standards and safeguards for any and all activity related to patient treatment. The Pharmacy will focus on the following Training Objectives:

* How to Protect Patient Privacy
* Patient Privacy as related to HIPAA
* Patient Privacy as related to Corporate Security

2.0 Training Requirements

All personnel are required to read this Policy and complete the annual training. Annual training will be facilitated and coordinated by the Training Administrator/ Department.

All new personnel will be trained to this Policy during New Personnel Orientation.

All training will be documented, and records maintained by the Training Department.

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## 4.14 Security of Health Information

1. **Purpose:** This procedure describes how Pharmacy personnel can protect the security of patient Protected Health Information (“PHI”).
2. **Scope:** This procedure applies to all Pharmacy personnel.
3. **Definitions:** N/A
4. **Safety Requirements:** N/A
5. **Procedure:**

The Pharmacist-in-Charge and/ or the Privacy Officer shall periodically monitor the Pharmacy’s compliance regarding its reasonable efforts to safeguard PHI.

Pharmacy personnel are responsible for the following:

1. Patient counseling and telephone conversations disclosing PHI shall be located in as private an area as possible. PHI discussions should be limited to the minimum amount necessary to accomplish the purpose of the use or disclosure. Reasonable measures should be taken to assure that unauthorized persons do not overhear conversations involving PHI.
2. All documents and/ or records containing PHI should be stored appropriately to reduce the potential for incidental use or disclosure. Documents should not be easily accessible to any unauthorized personnel or other patients.
3. Prescriptions or records shall not be left unattended on a front desk or counter where customers and unauthorized individuals could easily view the records.
4. All users of computer equipment or register terminals must have unique logins and passwords. Passwords shall be changed every 90 days.
5. Posting, sharing, and any other disclosure of passwords and/ or access codes is strongly discouraged.
6. Access to computer-based PHI shall be limited to personnel who need the information for treatment, payment, or health care operations.
7. Computer monitors shall be positioned so that unauthorized persons cannot easily view information on the screen.
8. Printers will be located in areas not easily accessible to unauthorized persons.
9. Documents containing PHI that must be disposed of due to error in printing or otherwise will be destroyed by shredding or by placing the document in a secure recycling or shredding bin until destroyed.
10. Pharmacy personnel shall log off their workstation when leaving the work area.
11. Personnel access privileges will be removed promptly following their departure from employment.
12. Personnel will immediately report any violations of these procedures to their supervisor or Privacy Officer.
13. **References:** N/A
14. **Attachments:** N/A

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## 4.15 Communication with Persons with Limited English Proficiency (LEP)

1. **Purpose**: To ensure that all persons, including those with Limited English Proficiency (LEP), have meaningful access and an equal opportunity to participate in services, activities, programs and other benefit and create processes to create forms and signs to notify patients.
2. **Scope**: This procedure applies to all Pharmacy personnel.
3. **Definitions**:
4. **LEP**: Limited English Proficiency, or primary language is something other than English.
5. **Policy**: It is our policy that LEP patients/clients and their authorized representatives involved in their medical condition and treatment are able to conduct meaningful communications with our staff. The policy also provides for communication of information contained in vital documents, including but not limited to, waivers of rights, consent to treatment forms, financial and insurance benefit forms, etc. All interpreters, translators and other aids needed to comply with this policy shall be provided without cost to the person being served, and patients/clients and their families will be informed of the availability of such assistance free of charge.

Language assistance will be provided through use of competent bilingual staff, staff interpreters, contracts or formal arrangements with local organizations providing interpretation or translation services, or technology and telephonic interpretation services. All staff will be provided notice of this policy and procedure, and staff that may have direct contact with LEP individuals will be trained in effective communication techniques, including the effective use of an interpreter.

We will conduct a regular review of the language access needs of our patient population, as well as update and monitor the implementation of this policy and these procedures, as necessary.

1. **Procedure:**
2. **Identifying LEP Persons and Their Language:** We will promptly identify the language and communication needs of the LEP person. If necessary, staff will use a language identification card (or “I speak cards,” available online at www.lep.gov) or posters to determine the language. In addition, when records are kept of past interactions with patients (clients/residents) or family members, the language used to communicate with the LEP person will be included as part of the record.
3. **Obtaining A Qualified Interpreter:**

* Identify responsible staff, and phone numbers, responsible for:
  + Maintaining an accurate and current list showing the name, language, phone number and hours of availability of bilingual staff;
  + Contacting the appropriate bilingual staff member to interpret, in the event that an interpreter is needed, if an employee who speaks the needed language is available and is qualified to interpret;
  + Obtaining an outside interpreter if a bilingual staff or staff interpreter is not available or does not speak the needed language.
* *(Identify the agency(s) name(s) with whom you have contracted or made arrangements) have/has agreed to provide qualified interpreter services. The agency’s (or agencies’) telephone number(s) is/are (insert number (s)), and the hours of availability are (insert hours).*
* Some LEP persons may prefer or request to use a family member or friend as an interpreter. However, family members or friends of the LEP person will not be used as interpreters unless specifically requested by that individual and **after** the LEP person has understood that an offer of an interpreter at no charge to the person has been made by the facility. Such an offer and the response will be documented in the person’s file. If the LEP person chooses to use a family member or friend as an interpreter, issues of competency of interpretation, confidentiality, privacy, and conflict of interest will be considered. If the family member or friend is not competent or appropriate for any of these reasons, competent interpreter services will be provided to the LEP person.
* Children and other clients/patients will **not** be used to interpret, in order to ensure confidentiality of information and accurate communication.

1. ***Access to Language Assistance:*** *We will take reasonable steps to provide meaningful access, free of charge and in a timely manner to provide effective communication with LEP patients. These steps may include:*

* *Electronic and information technology programs or activities will be made available to individuals with disabilities unless it is financially or administratively burdensome and we cannot provide these programs or activities. Any financial or administrative burden will be documented.*
* *Offered language assistance and any refusal of such services may be documented.*
* *Pharmacy may develop a language access plan.*

1. **Notices of Nondiscrimination and Taglines**:

* We will inform LEP persons of the availability of language assistance, free of charge, by providing written notice in languages that the LEP persons will understand. At a minimum, notices and signs will be posted and provided in intake areas and other points of entry. Notification will also be provided through one or more of the following: outreach documents, telephone voice mail menus, local newspapers, radio and television stations, and/or community-based organizations (include those areas applicable to your facility).
* We will provide notice regarding nondiscrimination and available language assistance services in conspicuous physical location (e.g., in store), online (if applicable), and in substantial publications with 15 taglines, or short statements written in non-English languages that indicate the availability of language assistance services free of charge.
* Translated Resources found on DHHS website (*available at* <http://www.hhs.gov/civil-rights/for-individuals/section-1557/translated-resources/index.html>). Language Assistance Services resources (*available at* <http://www.hhs.gov/civil-rights/for-individuals/language-assistance/index.html>).
* For Sample Notification *see* [FM-10](#FM10).

1. **Monitoring Language Needs and Implementation:** On an ongoing basis, we will assess changes in demographics, types of services or other needs that may require reevaluation of this policy and its procedures. In addition, we will regularly assess the efficacy of these procedures, including but not limited to mechanisms for securing interpreter services, equipment used for the delivery of language assistance, complaints filed by LEP persons, feedback from patients and community organizations, etc. (include those areas applicable to your facility).
2. **References**:

* Section 1557 of the Patient Protection and Affordable Care Act, [42 U.S.C. § 18116](https://www.gpo.gov/fdsys/pkg/USCODE-2010-title42/pdf/USCODE-2010-title42-chap157-subchapVI-sec18116.pdf)
* DHHS, Nondiscrimination in Health Programs and Activities Final Rule, [45 CFR Part 92, 81 Fed. Reg. 31376](https://www.gpo.gov/fdsys/pkg/FR-2016-05-18/pdf/2016-11458.pdf)
* [DHHS, Section 1557 of the Patient Protection and Affordable Care Act](http://www.hhs.gov/civil-rights/for-individuals/section-1557/index.html)
* [DHHS, Translated Resources for Covered Entities](http://www.hhs.gov/civil-rights/for-individuals/section-1557/translated-resources/index.html)
* [DHHS, Language Assistance Services](http://www.hhs.gov/civil-rights/for-individuals/language-assistance/index.html)

1. **Attachments**:

* [DHHS, Language Access Plan](http://www.hhs.gov/sites/default/files/open/pres-actions/2013-hhs-language-access-plan.pdf)
* [FM-10: Sample Nondiscrimination and Language Assistances Services Notification](#FM10)

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# 5.0 Operations

## 5.01 Non-Sterile Compounding Practices

1. **Purpose:** This procedure describes the general non-sterile compounding practices to be followed by trained Pharmacy personnel when performing non-sterile compounding preparations. Non-sterile compounding primarily pertains to Oral and Topical Medications.
2. **Scope:** This procedure applies to trained Pharmacy personnel who perform non-sterile compounding activities at the Pharmacy. Compounding personnel are responsible for compounding preparations of acceptable strength, quality, and purity and in accordance with the prescription or medication order and verification by a licensed pharmacist.
3. **Definitions:**

**Compounding:** (As defined in Chapter 795 of the United States Pharmacopeia (USP 795).) Preparation, mixing, assembling, altering, packaging, and labeling of a drug, drug-delivery device, or device in accordance with a licensed practitioner's prescription, medication order, or initiative, based on the practitioner-patient-pharmacist-compounder relationship in the course of professional practice. Compounding includes the following:

* Preparation of drug dosage forms for both human and animal patients.
* Preparation of drugs or devices in anticipation of prescription drug orders, on the basis of routine, regularly observed prescribing patterns.
* Reconstitution or manipulation of commercial products that may require the addition of one or more ingredients.
* Preparation of drugs or devices for the purposes of or as incident to research (clinical or academic), teaching, or chemical analysis.
* Preparation of drugs and devices for a prescriber's office use where permitted by federal and state law.

1. **Safety Requirements:** Pharmacy personnel shall follow Pharmacy safety policy and procedures and United States Pharmacopeia 795 for Non-Sterile Compounding. This includes attending required training and annual refresher training.
2. **Procedure:**

**Allowable Non-Sterile Compounding**

1. When pharmacists or pharmacy technicians working under the direct supervision of pharmacists prepare compounded drugs, they must adhere to any relevant standards detailed in the *U.S. Pharmacopeia* or the *National Formulary*. If such standards do not exist, exact details on how and why the product was compounded must be recorded and made available to regulators. Pharmacists and trained compounding Pharmacy personnel may compound:

* In reasonable quantities, drug preparations that are not commercially available in the marketplace if a pharmacist–patient–prescriber relationship exists, and a valid prescription is presented.
* Compound nonprescription medications in commercially available dosage forms or in alternative dosage forms to accommodate patient needs, as allowed by individual state Boards of Pharmacy.
* Compound drugs in limited quantities prior to receiving a valid prescription, on the basis of a history of receiving valid prescriptions that have been generated solely within an established pharmacist–patient–prescriber relationship and provided that the prescriptions are maintained on file for all such preparations dispensed at the Pharmacy.

1. Pharmacists should not offer compounded medications to other pharmacies for resale; however, a practitioner may obtain compounded medication to administer to patients, but it should be labeled as: “For Office Use Only,” with the date compounded, use-by date, name, strength, and quantity of active ingredients. An exception to this may be the outsourcing of some compounded preparations by hospitals to contract compounding pharmacies.
2. Compounding pharmacies may advertise that they provide this service.

**Procedure: Non-Sterile Compounding**

1. The Compounding Environment:

* Adequate space, including orderly placement and storage of equipment
* Controlled temperature and lighting
* Clean work areas
* Sink with hot/ cold running water for hand washing and equipment cleaning

**\*** If both sterile and non-sterile compounding occur in the Pharmacy, there shall be separate and distinct areas for the compounding of each.

1. Compounding Equipment and Maintenance:

* Appropriate in design and size for intended purpose.
* Always cleaned immediately after each use.
* Properly maintained and calibrated.
* Separate and distinct areas for compounding sterile and non-sterile preparations.
* Compounding equipment types as listed in the chart below:

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| --- |
| **Compounding Equipment** |
| Electronic or class A torsion balance |
| Powder papers or weigh boats |
| Brass weight sets with class A torsion balances |
| Graduates/ mortars & pestles |
| Ointment slab (pill tile) & spatulas |
| Trituration, levigation, geometric dilution |
| Electronic mortar & pestle |
| Hot plates/ strainers/ stirring rods/ stir plates w/ magnetic bars |
| Refrigerator with freezer |
| Molds for suppository, troche |
| Blenders/ mixers/ motorized stirrers |
| Capsule-filling equipment |

1. Stability and Beyond Use Dating of Preparations:

* Primary packaging to protect drug from light/ heat/ moisture/ air/ microbial contamination.
* Beyond Use Data (BUD) on all compounded medication labeling for:
* Aqueous (water-based) or non-aqueous
* Expiration dates of ingredients used
* Storage temperature
* Reference with established stability data and or USP guidance information

1. Selecting Ingredients:

* USP or National Formulary (NF) chemicals preferred.
* Pharmacist is responsible for selection of ingredients:
* Must meet purity and safety standards.
* Purchase from certified or accredited vendors.
* Should not use drugs or chemicals withdrawn from the market.

1. Compounding Preparation Guidelines:

* Compound formula should contain 90-110% of active ingredient.
* Dosage forms:
  + Capsules
  + Powders
  + Lozenges
  + Tablets
  + Emulsions
  + Solutions
  + Suspensions
  + Suppositories
  + Creams
  + Topical gels
  + Ointments
  + Pastes

1. The Compounding Process:

* The goal of the compounding process is to "minimize error and maximize prescriber's intended medication order.”
* Pharmacist must evaluate the appropriateness of the order.
* Only ONE preparation should be compounded at one time in order to avoid errors and cross contamination.

1. Steps in the Compounding Process**:**

* Use only approved Formula Records.
* Calculate amount of ingredients for preparation.
* Identify equipment needed.
* Use proper hygiene (hand wash) and wear proper attire or PPE.
* Clean compounding area and the equipment to be used.
* Collect and setup all materials and ingredients.
* Compound exactly in the order listed on the Formula record.
* Document on the Compounding Record as described in this procedure.
* Use patient-specific packaging: unit of use, single unit, unit-dose or other packaging/ materials.
* Label final preparation appropriately (per current state and federal labeling requirements).
* Clean and store equipment and area.

1. Quality Control:

There shall be written quality control procedures in place for following best practices or good manufacturing practices:

* Formal training of Pharmacy personnel
* Compounding
* Use/ maintenance of Pharmacy equipment
* Checkpoints in the compounding process
* End product testing

Quality Control includes:

* Production guidelines
* Clear procedures
* Documentation of compounded preparations
* Pharmacy personnel training
* Documentation on Formula record as proof procedures were followed
* Proper storage of compounded medication to maintain quality
* A system in place for recalling any batch of product

1. Final Check Process: The pharmacist is responsible for checking final preparation, including:

* Using appropriate ingredients
* Using correct equipment
* Calculating correctly
* Measuring accurately
* Weight variation
* Proper mixing
* Odor/ color/ consistency
* pH, as needed
* Checking consistency of calculated yield with actual yield
* Submitted/ complete testing that meets specification or standard
* Proper labeling and packaging
* Pharmacist’s signature and date on the prescription to document verification and ensure quality
* Informing the compounder of actions to take to either correct the preparation and or destroy it if corrections/ errors are identified

1. Compounding Record:

USP Chapter 795 requires that pharmacies maintain Formulation Master Records. These must be maintained either electronically or in hard copy.

* There shall be a compounding record for each compounded preparation.
* The Formulation Record for a prepared medication shall be filed alphabetically, shall list all the ingredients used with lot number and compounding equipment used, and must list the instructions for preparing the formula.
* There shall be a log of the actual compounded preparation, including:
* Whether for individual prescription or as a batch in anticipation of orders
* Manufacturer and lot numbers of chemicals
* Date of preparation
* Internal assigned identification or lot number
* Beyond use date
* Names of the individuals who prepared and who verified

1. Compound Record Maintenance and Record Retention:

* The Compounding record for a batch is filed by lot number.
* The Compounding record for an individual prescription must contain a chronological list of preparations made.
* Formulation and Compounding Records may be maintained in hard copy or electronically.
* The Pharmacist-in-Charge (PIC) shall comply with state or other regulatory record retention laws. Records and reports should be retained for the period of time required by state laws and regulations for the retention of prescription files. It is advisable that the Pharmacy have full knowledge of all applicable regulations and abide by the most stringent for record retention.
* All records and reports should be readily available in the Pharmacy for authorized inspection during the retention period.
* Pharmacy may add what their record retention timeline is here:

1. Types of Compounded Medications: There shall be written procedures for the proper compounding guidelines for each type of medication.

* Ointment
* Cream
* Solutions
* Suspensions
* Suppositories
* Lozenge/ troches
* Capsules

1. Expired Medications:

Daily, weekly, and monthly, compounding pharmacists or personnel must check inventory in the Pharmacy and have the responsibility of disposing of expired medications and chemicals.

1. Personnel Training/ Competency:

Prior to commencing any compounding, the PIC and compounding personnel shall perform thorough didactic instruction in the theory and practice of non-sterile preparations, with evaluation of technique annually.

Compounder evaluations should include a formal written exam and practical evaluation of technique, at minimum annually.

1. **References:**

* USP (795) Pharmaceutical Compounding Non-sterile Preparations

1. **Attachments:** N/A

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| Prepared by/Date: | Approved by/Date: |

## 5.02 Sterile Compounding Practices

1. **Purpose:** This procedure describes the general sterile compounding practices to be followed by trained Pharmacy personnel when performing sterile compounding preparations. Sterile compounding primarily pertains to Infusions and Injections.
2. **Scope:** This procedure applies to trained Pharmacy personnel who perform sterile compounding activities at the Pharmacy.
3. **Definitions:**

**Sterile Compounding:** (As defined by Chapter 797 of the United States Pharmacopeia (USP 797).) Any manipulation of a sterile or non-sterile product intended to produce a final sterile product. Sterile compounding includes the following:

* Preparations prepared according to manufacturer’s labeled instructions and other manipulations that expose the contents to potential contamination.
* Preparations containing non-sterile components or devices that must be sterilized before administration.
* Biologics, diagnostics, drugs, nutrients, and radiopharmaceuticals that possess either of the characteristics above.

1. **Safety Requirements:** Pharmacy personnel shall follow Pharmacy safety policy and procedures and the United States Pharmacopeia 797 for Sterile Compounding. Safety responsibilities of personnel include:

* Ensuring that the CSP is accurately identified.
* Ensuring that the CSP is measured, diluted, mixed and correctly purified, sterilized, packaged, sealed, labeled, stored, dispensed, and distributed.
* Maintaining appropriate cleanliness.
* Providing labeling and supplementary instructions for proper clinical administration of CSPs.
* Manipulating sterile products aseptically.
* Ensuring that open, partially used packages for subsequent use are properly stored, clearly labeled with date/ time opened or date/ time of expiration.
* Ensuring that labels on products list names/ amounts added and concentration of all ingredients.
* Visually inspecting products prior to dispensing.
* Basing beyond use dates (BUDs) on direct text or interpretations of reliable literature or other documentation.

1. **Procedure:**

**Allowable Sterile Compounding**

When pharmacists or pharmacy technicians working under the supervision of a pharmacist prepare sterile compounded drugs, they must adhere to the relevant standards detailed in the U.S. Pharmacopeia/ National Formulary. Exact details on how and why the sterile product was compounded must be recorded and made available to regulators. Pharmacists and trained Pharmacy personnel must identify the appropriate risk level (low, medium or high) assigned according to the corresponding probability of contamination with:

* Microbials (organisms, spores, endotoxins)
* Foreign chemicals or physical matter

Characteristics serve as a guide and are not prescriptive. Risk level assignment should ultimately be determined by professional judgment.

**Risk Classification**

1. Low Risk

* Products compounded with aseptic technique within ISO 5 quality air using only sterile ingredients, products, components, or devices.
* Involves only transfer, measuring, and mixing with closed or sealed packaging systems performed promptly and attentively.
* Manipulations limited to aseptically opening ampuls, penetrating sterile stoppers on vials with sterile needles and syringes, and transferring sterile liquids in sterile syringes to other sterile products.

1. Medium Risk

Includes all low-risk conditions in addition to one or more of the following:

* Multiple individual or small doses of sterile products are combined to prepare a product administered to multiple patients or one patient on multiple occasions.
* Compounding includes complex aseptic manipulations other than single volume transfer.
* Compounding requires unusually long duration to complete dilution or homogeneous mixing.
* Product does not contain bacteriostatic substances and is administered over several days.

1. High Risk

Includes all low- and medium-risk conditions plus one or more of the following:

* Non-sterile ingredients are incorporated, or a non-sterile device is employed before terminal sterilization.
* Sterile ingredients, components, devices, and mixtures are exposed to air quality inferior to ISO class 5.
* Non-sterile preparations are stored for more than 6 hours before being sterilized.

**Verification of Accuracy and Sterilization**

* Physical inspection before dispensing or before product leaves the storage area:

Finished product free of particulate matter and visual defects

Integrity of container closure

* Compounding accuracy checks:

Written procedures for double-checking compounding accuracy.

Double check should include label accuracy and accuracy of the additive of all products or ingredients.

Used containers and syringes should be quarantined with the final product until the double check is performed.

Double check should be performed by a person other than the compounder.

**Sterilization and Bacterial Endotoxin Testing**

* Required for high-risk level products that involve non-sterile products or devices.
* Products must be labeled according to USP Chapter 85 (Bacterial Endotoxin Test).
* Sterilization Methods:

Dry heat (250 degrees centigrade for 2 hours)

Steam (121 degrees centigrade at 15 p.s.i. for 20-60 minutes)

Filtration 0.2-micron filter certified to retain 10 (7th power) Brevundimonas Diminuta cm (squared)

Must verify sterilization procedures

**Personnel Requirements**

* Food, drink, and materials exposed in a patient care area shall not enter ante areas, buffer areas, or segregated compounding areas where CSPs are present.
* If compounding involves blood derived or other biologic material, the manipulations shall be clearly separated from routine material handling procedures and equipment used in CSP preparation activities.
* Packaged compounding supplies and components, such as needles, syringes, tubing sets, and small/ large volume parenterals should be wiped down with a disinfectant that leaves no residue.
* Personnel hand hygiene and garbing procedures should be performed in ante area.
* Ante area may contain a sink that enables hands-free use with closed system of soap dispensing.
* Some demarcation that separates the ante area from the buffer area.
* Adequate provision for performing antiseptic hand cleansing using alcohol-based hand scrub.
* Donning of sterile gloves should be provided after entry into buffer area.
* Training in theoretical principals and practical skills of aseptic manipulations.

Skill level assessment/ knowledge must be:

Performed annually for low/ medium-risk level CSPs

Performed semi-annually for high-risk level CSPs

**Environmental Monitoring**

* Air quality inspections every 6 months.
* Certification of hoods and barrier isolators every 6 months.
* Evaluation of airborne micro-organisms monthly for low/ medium-risk level CSPs and weekly for high-risk level CSPs.

**Equipment**

* Written SOPs outlining required equipment calibration and annual maintenance.
* Monitoring for proper function.
* Control procedures for use of equipment, specified time frames for the established activities.
* Routine maintenance and frequencies outlined in SOPs.
* Results from equipment calibration.
* Annual maintenance reports and routine maintenance reports kept on file for the life of the equipment.
* Personnel prepared through a combination of specific training and experience to operate or manipulate any piece of equipment.
  + Training including the ability to determine if any equipment is operating properly or malfunctioning.

**Storage and Beyond Use Dating**

BUDs and expiration dates are not the same thing. Expiration dates are determined from results of rigorous testing. BUDs for CSPs that lack justification from appropriate literature sources by direct testing shall be assigned BUDs as described in “Stability Criteria and Beyond Use Dating under Pharmaceutical Compounding – Non-Sterile Preparations (USP 795).” When assigning a BUD, compounding personnel should consult and apply drug-specific and general stability documentation and literature where available, considering the nature of the drug and its degradation mechanism, the container in which the CSP is packaged, expected storage conditions, and intended duration of therapy (see Expiration Date and BUD under Labeling in the General Notices and Requirements section of USP 797). It must be understood that predicted BUDs introduce varying degrees of assumptions and therefore the likelihood of error or inaccuracy. Truly valid evidence of stability for predicting BUDs can only be obtained through product-specific experimental studies. Some examples of BUD for CSPS taken from USP 797 are:

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| --- | --- | --- | --- |
| **Risk Level** | **Room Temp.** | **Refrigerated** | **Frozen** |
| **Low** | 48 hours | 14 days | 45 days |
| **Medium** | 30 hours | 9 days | 45 days |
| **High** | 24 hours | 3 days | 45 days |

**Quality Assurance**

A formal quality assurance (QA) program must be in place to monitor, evaluate, correct, and improve the activities and processes for compounding CSPs. The QA program must follow up after any corrective action is taken for an identified problem. The QA Plan must:

* Be written
* Consider all aspects of preparation and dispensing including environmental testing and verification results
* Describe specific monitoring and evaluation activities
* Specify how results are to be reported and evaluated
* Identify appropriate follow up mechanisms when action limits/thresholds are exceeded
* Delineate individuals responsible for each aspect of the QA program
* Reassess the QA program annually

**Drug Quality and Security Act (DQSA)**

The DQSA grants the Food and Drug Administration (FDA) more authority to regulate and monitor the manufacturing of compounded drugs. The DQSA has 2 distinct components: (1) The Compounding Quality Act (CQA) and (2) The Drug Supply Chain Security Act.

For purposes of this SOP, the discussion below will focus exclusively on the Compounding Quality Act.

The CQA identifies a new type of compounding pharmacy, specifically an “outsourcing facility.” An outsourcing facility is a facility that engages in compounding sterile drugs and has elected voluntarily to register with the FDA as an outsourcing facility. Outsourcing facilities are subject to certain compounding constraints and inspection requirements. Outsourcing facilities must register with the FDA and list the sterile products being compounded. There are also labeling requirements that attach to be an outsourcing facility, such as: (1) statements that identify the drug as a compounded drug, the outsourcing facility contact information, the lot number, the date compounded, the expiration date, storage and handling instructions; (2) a statement that the compounded drug is not for resale; and (3) a list of both inactive and active ingredients. Outsourcing facilities must report adverse events to the FDA and conduct risk-based inspections based on compliance history, the record and nature of recalls, and the inherent risk of compounded products.

1. **References:**

USP (797) Pharmaceutical Compounding – Sterile Preparations

USP (795) Pharmaceutical Compounding – Nonsterile Preparations

ASHP Guidelines on Compounding Sterile Preparations

ISMP Sterile Preparation Compounding Safety Summit: Guidelines for SAFE Preparation of Sterile Compounds

1. **Attachments:** N/A

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## 5.03 Controlled Substance Prescription Monitoring Program

1. **Purpose:** This procedure describes the Pharmacy’s process for reporting controlled substance information to the state's Controlled Substances Prescription Monitoring Program (CSPMP). This is a program (state database) developed to promote the public health and welfare by detecting diversion, abuse, and misuse of prescription medications classified as controlled substances (CS). The law requires anyone who dispenses Schedule II, III, or IV controlled substances to report the dispensing of these drugs to the database. Mandatory reporting by pharmacies is required.
2. **Scope:** This procedure applies to licensed pharmacists who are responsible for reporting Control Substance Prescription information to their state's CSPMP compliance program using the guidelines outlined in this procedure. Each pharmacist is responsible for understanding their specific State's CSPMP and Schedule Controlled Substances reporting system and requirements.
3. **Definitions:**

**Schedule II Controlled Substances:** Substances in this schedule have a high potential for abuse which may lead to severe psychological or physical dependence. Examples of single entity Schedule II narcotics include:

* Morphine
* Opium
* Hydromorphone (Dilaudid®)
* Methadone (Dolophine®)
* Meperidine (Demerol®)
* Oxycodone (OxyContin®)
* Fentanyl (Sublimaze® or Duragesic®)

Examples of Schedule II stimulants include:

* Amphetamine (Dexedrine®, Adderall®)
* Methamphetamine (Desoxyn®)
* Methylphenidate (Ritalin®)

Other Schedule II substances include:

* Combination products containing less than 15 milligrams of hydrocodone per dosage unit (Vicodin®)
* Cocaine
* Amobarbital
* Glutethimide
* Pentobarbital

CII chemical powders used in medication compounding include:

* Morphine
* Oxycodone
* Hydrocodone
* Codeine
* Methylphenidate
* Hydromorphone

**Schedule III Controlled Substances:** Substances in this schedule have a potential for abuse less than substances in Schedules I or II, and abuse may lead to moderate or low physical dependence or high psychological dependence. Examples of Schedule III narcotics include:

* Products containing not more than 90 milligrams of codeine per dosage unit (Tylenol with codeine®)
* Buprenorphine products (Suboxone® and Subutex®) used to treat opioid addiction

Examples of Schedule III non-narcotics include:

* Benzphetamine (Didrex®)
* Phendimetrazine
* Ketamine
* Anabolic steroids, such as oxandrolone (Oxandrin®)

**Schedule IV Controlled Substances:** Substances in this Schedule have a low potential for abuse relative to substances in Schedule III. Examples of Schedule IV narcotics include:

* Propoxyphene (Darvon® and Darvocet-N 100®)
* Alprazolam (Xanax®)
* Clonazepam (Klonopin®)
* Clorazepate (Tranxene®)
* Diazepam (Valium®)
* Lorazepam (Ativan®)
* Midazolam (Versed®)
* Temazepam (Restoril®)
* Triazolam (Halcion®)

1. **Safety Requirements:** N/A
2. **Procedure:**

**Reporting Controlled Substance Prescription Information to CSPMP**

1. The purpose for a State CSPMP program is to establish a controlled substances prescription monitoring program that:

* Includes a computerized central database tracking system to track the prescribing, dispensing, and consumption of Schedule II, III, and IV controlled substances.
* Assists law enforcement in identifying illegal activity related to the prescribing, dispensing, and consumption of Schedule II, III, and IV controlled substances.
* Provides information to patients, medical practitioners, and pharmacists to help avoid the inappropriate use of Schedule II, III, and IV controlled substances.
* Is designed to minimize inconvenience to patients, prescribing medical practitioners, and pharmacies while effectuating the collection and storage of information.

1. Each licensed pharmacist must be registered in their state's CSPMP. Follow the instructions for registration on your state Board of Pharmacy website for the CSPMP program.
2. The Pharmacy will only dispense controlled substance medication pursuant to a valid order written by an authorized registrant designed for a legitimate patient.

* The pharmacist is responsible for using his or her professional judgment to determine whether an order for a controlled substance is reasonable for the medical condition and in quantity.
* Due diligence will be performed by the pharmacist to ensure legitimacy of a prescription order. Questionable or suspicious prescription orders will not be filled.
* Registrants and registration numbers shall be verified at the point of service utilizing (but not limited to) the following:
  + <http://www.deadiversion.usdoj.gov/>
  + Home state medical board of prescriber
* The pharmacist MUST monitor the patient’s Controlled Substance Activity using the state’s CSPMP on each controlled substance prescription received prior to dispensing.

1. The pharmacist must follow the CSPMP's reporting timeline and report all required information. Typically, a CSPMP may require that pharmacies that dispense controlled substances listed in Schedule II, III, and IV to a patient report prescription information to the CSPMP on a weekly basis.
2. Authorized persons may request information from this repository to assist them in treating patients and identifying and deterring drug diversion, consistent with A.R.S. § 36-2604. Assuring confidentiality and the security of the data is a primary consideration for this program for all aspects to include data collection and storage, transmission of requests, and dissemination of reports.
3. **References:**

* [www.deadiversion.usdoj.gov](http://www.deadiversion.usdoj.gov)

1. **Attachments:** N/A

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## 5.04 DEA Form 222 Ordering/ Processing/ Receiving

1. **Purpose:** This procedure outlines the processes associated with ordering DEA Form 222, Processing, and Receiving.
2. **Scope:** This procedure applies to any Pharmacy personnel with authorization for ordering hard copy DEA Form 222 or the electronic equivalent using the e-222 form through the DEA CSOS program.
3. **Definitions:**

**DEA:** The Drug Enforcement Administration serves as the primary federal agency responsible for the enforcement of federal drug laws.

1. **Safety Requirements:** N/A
2. **Procedure:**
3. General DEA Form 222 Information

This form is required to be filled out by the Pharmacy and submitted to a wholesale supplier when ordering Class II Narcotics Controlled Substances only. Schedule III, IV and V narcotics can be phoned or faxed in with other Pharmacy orders.

* The Pharmacy must submit specific copies (1 and 2) of the 222 Form and retain copy 3.
* The supplier shall fill the order and retain their required copies, then ship the order to the Pharmacy. If the order cannot be filled in its entirety, it may be filled in part and the balance supplied by additional shipments within 60 days. No DEA Form 222 is valid more than 60 days after its execution by the Pharmacy.
* If an error is made on your Form 222, please void the form and begin again with a new form. Any form that has been altered will be returned.

1. Ordering DEA Form 222

* Power of Attorney:
  + Pharmacy Management may authorize one or more individuals to obtain and execute DEA Form 222 by granting a power of attorney to these individuals. The power of attorney must be signed by the same person who signed the most recent application for registration or renewal registration, as well as the person being authorized to obtain and execute DEA Form 222. For the Pharmacy power of attorney process, contact the Pharmacy owner.
* 222 Forms are obtained by ordering through the local DEA Office, by calling the DEA Headquarters Registration Section at 1-800-882-9539, or by following the online instructions at: <http://www.deadiversion.usdoj.gov/>

**\*** For online ordering, a valid DEA registration number, business name, and contact telephone number are required.

* Upon receipt of ordered forms, verify the sequential numbering of all received forms; if any are discovered missing, lost or stolen, the Pharmacy must immediately report the loss to the local DEA Diversion Field Office and provide the serial numbers of each lost or stolen order form. If an entire book or multiple books of order forms are lost or stolen and the serial numbers of the missing forms cannot be identified, the Pharmacy must report the approximate date of issuance (in lieu of the serial numbers) to the DEA. If an unused order form reported stolen or lost is later recovered or found, the Pharmacy must immediately notify the local DEA Diversion Field Office.
* All received and unused DEA Forms 222 are to be maintained in a locked and secure area within the Pharmacy.

1. Filling Out a DEA Form 222

* Each time you place an order for Schedule II controlled substances, a properly completed original Federal DEA Form 222 is required.
* DEA Form 222 is a triplicate form.
* Complete instructions for completing a Form 222 are found on the back of each Form 222. For additional instructions reference: <http://www.deadiversion.usdoj.gov/>
* If a Purchase Order number is needed on the packing slip, include a note requesting this when submitting your DEA Form 222 to the supplier.
* No cross-outs, “write-overs,” or initials are allowed on Form 222, and it may not contain alterations. If an error is made by the Pharmacy when filling out a Form 222, please void the form by drawing a line through the form and printing “void,” and begin again with a new form. Voided forms must be retained by the Pharmacy with controlled substance records.
* Any form that has been altered or is not filled in correctly will be returned.
* After completing the form, remove the last copy (blue) and retain it for your records. Do not separate the first two copies (brown and green), and do not remove the carbon paper between these two copies. By regulation, DEA can only accept forms where the brown and green copies are NOT separated, and carbons are intact.
* Cancellation and Voiding an Official Order Form:
* A purchaser may cancel an order (or partial order) on a DEA Form 222 by notifying the supplier in writing. The supplier must indicate the cancellation on Copies 1 and 2 of the DEA Form 222 by drawing a line through the cancelled item(s) and printing “cancelled” in the space provided for the number of items shipped.
* A supplier may void part or all of an order on a DEA Form 222 by notifying the purchaser in writing. The supplier must indicate the voiding in Copies 1 and 2 of the DEA Form 222 by drawing a line through the cancelled item(s) and printing “void” in the space provided for the number of items shipped.
* **C**ontrolled substance records (Pharmacy copy of DEA Form 222 and invoice) shall be filed separately from other records in the Pharmacy and made readily available for inspection by state auditors or DEA officials.

1. Receiving Controlled Substance Orders

* When receiving a Controlled Substance order in the Pharmacy, the DEA Registrant or Authorized User must verify the contents and immediately rectify any discrepancies.
* After confirming the accuracy of the received order, sign and date the purchase receipt and/ or invoice and file it with the matching DEA Form 222 and the controlled substances records. Provide a copy of the receipt to the DEA Registrant.
* When a pharmacist has not received an expected shipment of controlled substances, he/ she should first contact the supplier to determine whether the original DEA Form 222 was received. If the original order form has been lost or stolen, the pharmacist must complete a second order form so the supplier can fill the original order. The pharmacist must also prepare a statement which includes the first order form’s serial number and date and verify that the drugs ordered were never received. The pharmacist must attach a copy of the statement to the second order form that is sent to the supplier. In addition, the pharmacist must keep a copy of the statement with copy three from the first and second order forms.
* All received and inspected controlled substance inventory shall be immediately placed into secure storage with limited access by authorized personnel.

1. DEA - CSOS Program:

DEA revised its regulations to provide an electronic equivalent to the DEA official order Form 222; this became effective on May 31, 2005. This regulation allows, but does not require, registrants to order Schedule I and II substances electronically and maintain the records of these orders electronically. This will reduce paperwork and transaction times for DEA registrants who handle, sell, or buy these controlled substances. This rule has no effect on a patient’s ability to receive prescriptions for controlled substances from practitioners, nor on their ability to have those prescriptions filled at pharmacies.

* DEA's CSOS program allows for secure electronic controlled substances orders without the supporting paper DEA Form 222. Using a technology called PKI, CSOS requires that each individual purchaser enroll with DEA to acquire a CSOS digital certificate.
* Benefits of Using the CSOS System:
* Ordering Freedom: CSOS transactions are the only allowance for electronic ordering of Schedule I and II controlled substances but may also be used for Schedule III-V substances. Additionally, CSOS has no line item limit for a single order.
* Faster Transactions: CSOS certificates contain the same identification information as DEA Form 222, which allows for timely and accurate validation by the supplier. Faster transactions allow for just-in-time ordering and smaller inventories.
* Accurate Orders: CSOS reduces the number of ordering errors.

1. **References:**

* U.S. Department of Justice - DEA - [Pharmacist's Manual-Section I to VIII](http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/index.html)
* DEA E-Commerce Program website - [www.DEAecom.gov.](http://www.DEAecom.gov)

1. **Attachments:** N/A

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## 5.05 Theft of Controlled Substances

1. **Purpose:** This procedure describes the investigation and reporting process the Pharmacy shall follow upon discovery of missing or loss of controlled substances.
2. **Scope:** This procedure applies to all authorized licensed pharmacists who are responsible for reporting missing or loss of controlled substances to their state's DEA Diversion Field Office.
3. **Definitions:**

Note, these definitions are from the US Department of Justice Drug Enforcement Administration Office of Diversion Control. Drugs and other substances that are considered controlled substances under the Controlled Substances Act (CSA) are divided into five schedules. An updated and complete list of the schedules is published annually in [Title 21 Code of Federal Regulations (C.F.R.) §§ 1308.11 through 1308.15](http://www.deadiversion.usdoj.gov/21cfr/cfr/2108cfrt.htm). Substances are placed in their respective schedules based on whether they have a currently accepted medical use in treatment in the United States, their relative abuse potential, and likelihood of causing dependence when abused.

**Schedule I Controlled Substances:** Substances in this schedule have no currently accepted medical use in the United States, a lack of accepted safety for use under medical supervision, and a high potential for abuse. Some examples are:

* Heroin
* Lysergic acid diethylamide (LSD)
* Marijuana (cannabis)
* Peyote
* Methaqualone
* 3,4-methylenedioxymethamphetamine ("Ecstasy")

**Schedule II/IIN Controlled Substances (2/2N):** Substances in this schedule have a high potential for abuse which may lead to severe psychological or physical dependence. Examples include:

* Hydromorphone (Dilaudid®)
* Methadone (Dolophine®)
* Meperidine (Demerol®)
* Oxycodone (OxyContin®, Percocet®)
* Fentanyl (Sublimaze®, Duragesic®)

Other Schedule II narcotics include:

* Combination products containing less than 15 milligrams of hydrocodone per dosage unit (Vicodin®)
* Morphine
* Opium
* Codeine

Examples of Schedule IIN stimulants include:

* + Amphetamine (Dexedrine®, Adderall®)
  + Methamphetamine (Desoxyn®)
  + Methylphenidate (Ritalin®)
  + Other Schedule II substances include:
  + Amobarbital
  + Glutethimide
  + Pentobarbital

**Schedule III/IIIN Controlled Substances (3/3N):**  Substances in this schedule have a potential for abuse less than substances in Schedules I or II, and abuse may lead to moderate or low physical dependence or high psychological dependence. Examples of Schedule III narcotics include:

* Products containing not more than 90 milligrams of codeine per dosage unit (Tylenol with Codeine®)
* Buprenorphine (Suboxone®)

Examples of Schedule IIIN non-narcotics include:

* Benzphetamine (Didrex®)
* Phendimetrazine
* Ketamine
* Anabolic steroids, such as Depo®-Testosterone

**Schedule IV Controlled Substances:**  Substances in this schedule have a low potential for abuse relative to substances in Schedule III. Examples of Schedule IV substances include:

* Alprazolam (Xanax®)
* Carisoprodol (Soma®)
* Clonazepam (Klonopin®)
* Clorazepate (Tranxene®)
* Diazepam (Valium®)
* Lorazepam (Ativan®)
* Midazolam (Versed®)
* Temazepam (Restoril®)
* Triazolam (Halcion®)

**Schedule V Controlled Substances:**  Substances in this schedule have a low potential for abuse relative to substances listed in Schedule IV and consist primarily of preparations containing limited quantities of certain narcotics. Examples of Schedule V substances include:

* Cough preparations containing not more than 200 milligrams of codeine per 100 milliliters or per 100 grams (Robitussin AC®, Phenergan with Codeine®)
* Ezogabine

1. **Safety Requirements:** All controlled substance inventory shall be stored in a secure location within the Pharmacy that has limited access by authorized Pharmacy personnel. Quarterly or Annual Inventory of Controlled Substances must be performed in accordance with state Pharmacy law requirements and Pharmacy procedures and are critical to identifying missing or loss of these controlled substances.
2. **Procedure:**

**Theft or Significant Loss Investigation and Reporting**

1. The Pharmacist-in-Charge (PIC) MUST perform required documented inventory monitoring of controlled substances as required by state or other regulatory requirements and Pharmacy procedures. The PIC shall immediately report any theft or significantloss of a controlled substance to senior management.
2. An immediate investigation will begin by the Pharmacy. As needed, assistance by Quality Assurance, Operations Management, or the Legal Department shall be immediately provided.
3. The PIC and Pharmacy personnel shall cooperate fully during investigations for missing controlled substances and shall cooperate with the Legal Department and Operations Management to determine whether to notify local law enforcement, DEA, and or other state regulatory agencies.
4. In addition to initiating an internal investigation, Federal Regulations ([21 CFR 1301.76(b)](http://www.deadiversion.usdoj.gov/21cfr/cfr/1301/1301_76.htm)) require that registrants must notify the DEA Diversion Field Office in their area within 1 business day of discovery of a theft or significant loss of a controlled substance. The reporting must be in writing using DEA Form 106 - "Report of Theft or Loss of Controlled Substances."

* Complete DEA Form 106 online by accessing the form at the DEA Website: <http://www.deadiversion.usdoj.gov/>
* Follow the online instructions for filling out DEA Form 106 and the submission process.
* **For further questions contact the DEA Call Center at 1-800-882-9539.**

1. **The PIC must maintain a copy of all reports submitted on file in the Pharmacy. Filed records for** controlled substances shall be separate from other records in the Pharmacy and made readily available for inspection by State auditors or DEA officials.
2. **References:**

* U.S. Department of Justice Drug Enforcement Administration Office of Diversion Control Website.
* [Title 21 Code of Federal Regulations (CFR) Part 1300](http://www.deadiversion.usdoj.gov/21cfr/cfr/2100cfrt.htm)

1. **Attachments:** N/A

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## 5.06 Dispensing CII Controlled Substances

1. **Purpose:** This procedure describes the requirements for dispensing Schedule II Controlled Substances.
2. **Scope:** This procedure applies to all licensed pharmacists (or pharmacist interns working under the supervision of a licensed pharmacist to the extent allowed by state law) who are responsible for prescription verification, filling, and dispensing CII substance medications.
3. **Definitions:**

**Schedule II Controlled Substances:** Substances in this schedule have a high potential for abuse which may lead to severe psychological or physical dependence. Examples of CII narcotics include:

* Morphine
* Opium
* Hydromorphone (Dilaudid®)
* Methadone (Dolophine®)
* Meperidine (Demerol®)
* Oxycodone (OxyContin®)
* Fentanyl (Sublimaze® or Duragesic®)

Examples of Schedule II stimulants include:

* Amphetamine (Dexedrine®, Adderall®)
* Methamphetamine (Desoxyn®)
* Methylphenidate (Ritalin®)

Other Schedule II substances include:

* Cocaine
* Amobarbital
* Glutethimide
* Pentobarbital

1. **Safety Requirements:** N/A
2. **Procedure:**

**General Requirements**

1. Before dispensing a controlled substance, the pharmacist must verify that the prescription is valid, and the prescriber meets the legal requirements of the state Board of Pharmacy to write for a controlled substance.
2. A prescription failing to meet the requirements outlined in the federal Controlled Substances Act and the state Controlled Substances Act for the state where the Pharmacy is located will not be dispensed by the pharmacist.
3. Prescription Verification: To be considered valid, a prescription for a controlled drug in any class must be issued for a legitimate medical purpose by a practitioner acting in the usual course of sound professional judgment. Each prescription must be written with ink, indelible pencil or typewriter, dated on the date issued, must be manually signed by the practitioner, and contain ALL of the following:

* The full name and address of the patient
* The drug name, strength, dosage form, quantity prescribed, and directions for use
* The name, address, and DEA registration number of the practitioner

**\*** Prescriptions for drugs classified as Schedule II are not permitted to be refilled. A facsimile (fax) or a verbal interaction with a pharmacist for a medication classified as Schedule II will not be accepted as valid prescription order.

**NOTE**: To the Policy Maker only. Delete prior to publication. Controlled substance prescription requirements are state specific. Choose one of the options below to comply with relevant state laws.

For state specific e-prescribing requirements, please review question #4 in the Bula Controlled Substances module at <https://in.bulalaw.com/ModuleReport/Detail/84?Questions=4&States>=

* No prescription orders via e-prescribing software shall be accepted for controlled substances classified as Schedule II.
* Only prescription orders for controlled substances submitted via e-prescribing shall be accepted.

1. Registration Number Verification: Registrants and registration numbers shall be verified at the point of service, using (but not limited to) the following:
   * + - <http://www.deadiversion.usdoj.gov/>
       - Home state medical board of prescriber
2. Monitoring: The pharmacist MUST monitor the patient’s Controlled Substance Activity using the state’s SCPMP (reference SOP 5.03 - Controlled Substance Prescription Monitoring Program) on each controlled substance prescription received prior to dispensing.
3. Emergency Dispensing:The Controlled Substances Act permits the dispensing of Schedule II controlled substances in an emergency situation as defined as:

* Immediate administration of the controlled substance is necessary for proper treatment of the intended ultimate user; and
* No appropriate alternative treatment is available.

The practitioner may only through an oral order authorize the Pharmacy to dispense a quantity limited to the amount adequate to treat the patient during the emergency period. The pharmacist will reduce the verbal order to writing, which must contain all of the information required for a valid prescription (see section 3.0).

The pharmacist will make all reasonable attempts to determine that the oral authorization came from a registered individual practitioner.

The practitioner must deliver to the Pharmacy a valid written prescription within 7 days of the emergency dispensing. The valid prescription must contain the words "Authorization for Emergency Dispensing."

**\*** In the event that the practitioner fails to provide the Pharmacy with a valid prescription, the pharmacist is required to report this to the local DEA office. Failure to report this voids the authority to fill an emergency oral order (the pharmacist is liable for violating the Controlled Substance Act).

1. Partial Fills: A pharmacist may partially fill a CII prescription if the pharmacist is unable to fill the prescription for the full amount:

* The balance must be dispensed within 72 hours or not at all.
* If the balance is not dispensed within 72 hours, the prescriber must be notified.

1. The Pharmacy will not fill prescription orders for “Office Use” for a controlled substance classified as Schedule II.
2. Transfer of a Schedule II Prescription: CII prescriptions may not be transferred.

**VI. References:**

* [21 CFR 1306.05(a)](http://www.deadiversion.usdoj.gov/21cfr/cfr/1306/1306_05.htm)
* DEA Prescriptions for Controlled Substances FAQ available at: [US DOJ DEA: Questions and Answers](http://www.deadiversion.usdoj.gov/faq/prescriptions.htm)
* [SOP 5.03 – Controlled Substance Prescription Monitoring Program](#page150)

**VII. Attachments:** N/A

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## 5.07 Dispensing CIII - V Controlled Substances

1. **Purpose:** This procedure describes the requirements for dispensing Schedule III-V Controlled Substances at the Pharmacy.
2. **Scope:** This procedure applies to all licensed pharmacists (or pharmacist interns working under the supervision of a licensed pharmacist to the extent allowed by state law) who are responsible for prescription verification, filling, and dispensing CIII-V controlled substance medications.
3. **Definitions:**

**Schedule III Controlled Substances:** Substances in this schedule have a potential for abuse less than substances in Schedules I or II, and abuse may lead to moderate or low physical dependence or high psychological dependence. Examples of Schedule III narcotics include:

* Products containing not more than 90 milligrams of codeine per dosage unit (Tylenol with codeine
* Buprenorphine products (Suboxone® and Subutex®) used to treat opioid addiction

Examples of schedule III non-narcotics include:

* Benzphetamine (Didrex®)
* Phendimetrazine
* Ketamine
* Anabolic steroids, such as oxandrolone (Oxandrin®)

**Schedule IV Controlled Substances:** Substances in this schedule have a low potential for abuse relative to substances in Schedule III. Schedule IV substances include:

* Propoxyphene (Darvon® and Darvocet-N 100®)
* Alprazolam (Xanax®)
* Clonazepam (Klonopin®)
* Clorazepate (Tranxene®)
* Diazepam (Valium®)
* Lorazepam (Ativan®)
* Midazolam (Versed®)
* Temazepam (Restoril®)
* Triazolam (Halcion®)

**Schedule V Controlled Substances:** Substances in this schedule have a low potential for abuse relative to substances listed in Schedule IV and consist primarily of preparations containing limited quantities of certain narcotics. These are generally used for antitussive, antidiarrheal, and analgesic purposes. Examples include:

* Cough preparations containing not more than 200 milligrams of codeine per 100 milliliters or per 100 grams (Robitussin AC® and Phenergan with Codeine®)

1. **Safety Requirements:** N/A
2. **Procedure:**

**General Requirements**

1. Before dispensing a controlled substance, the pharmacist must verify that the prescription is valid and the prescriber meets the legal requirements of the state Board of Pharmacy to write for a controlled substance.
2. A prescription failing to meet the requirements outlined in the federal Controlled Substances Act and the state Controlled Substances Act for the state where the Pharmacy is located will not be dispensed by the pharmacist.
3. Prescription Verification:

To be considered valid, a prescription for a controlled drug in any class must be issued for a legitimate medical purpose by a practitioner acting in the usual course of sound professional judgment. Each prescription must be written with ink, indelible pencil or typewriter, dated on the date issued, must be manually signed by the practitioner, and contain ALL of the following:

* The full name and address of the patient
* The drug name, strength, dosage form, quantity prescribed, and directions for use
* The name, address, and DEA registration number of the practitioner

Refills for Prescriptions for Schedule III-V drugs are permitted, but a prescription drug order for a Schedule III-V drug cannot be filled or refilled more than six (6) months after date of issue and may not be refilled more than five (5) times. In addition, the authorized number of refills must be noted on the prescription or other document that must be uniformly maintained and readily retrievable.

**\*** Prescriptions for drugs classified as Schedule II are not permitted to be refilled. A facsimile (fax) or a verbal interaction with a pharmacist for a medication classified as Schedule II will not be accepted as valid prescription order.

**NOTE**: To the Policy Maker only. Delete prior to publication. Controlled substance prescription requirements are state specific. Choose one of the options below to comply with relevant state laws.

For state specific e-prescribing requirements, please review question #4 in the Bula Controlled Substances module at <https://in.bulalaw.com/ModuleReport/Detail/84?Questions=4&States>=

* No prescription orders via e-prescribing software shall be accepted for controlled substances classified as Schedule II.
* Only prescription orders for controlled substances submitted via e-prescribing shall be accepted.

A facsimile (fax) of written, signed prescription transmitted by the practitioner or the practitioner's agent to the Pharmacy is acceptable for CIII-V controlled substances.

An oral prescription made by an individual practitioner and promptly reduced to writing by the pharmacist containing all information required for a valid prescription, except for the signature of the practitioner is acceptable for CII-V controlled substances.

Electronic prescriptions for Schedule III-V must meet DEA requirements for such prescriptions – reference "Electronic Prescriptions for Controlled Substances.” The rule is available online at: <http://www.deadiversion.usdoj.gov/fed_regs/rules/2010/fr0331.pdf>

1. Changes to a Controlled Substance Schedule III-V Prescription:

A pharmacist may add or change the patient’s address upon verification. The pharmacist may add or change the dosage form, drug strength, drug quantity, directions for use, or issue date only after consultation with an agreement of the prescribing practitioner. Such consultations and corresponding changes should be noted by the pharmacist on the prescription. Pharmacists and practitioners must comply with any state/ local laws, regulations, or policies prohibiting any of these changes to controlled substance prescriptions.

The pharmacist is never permitted to make changes to the patient’s name, controlled substance prescribed (except for generic substitution permitted by state law), or the prescriber’s signature.

1. Registration Verification:

Registrants and registration numbers shall be verified at the point of service, utilizing (but not limited to) the following:

* + - * <http://www.deadiversion.usdoj.gov/>
      * Home state medical board of prescriber

1. Monitoring:

The pharmacist MUST monitor the patient’s Controlled Substance Activity using the state’s SCPMP (reference SOP 5.03 - Controlled Substance Prescription Monitoring Program) on each controlled substance prescription received prior to dispensing.

1. Emergency Dispensing:

The Controlled Substances Act permits the dispensing of Schedule II controlled substances in an emergency situation as defined as:

* Immediate administration of the controlled substance is necessary for proper treatment of the intended ultimate user; and
* No appropriate alternative treatment is available.

The practitioner may only through an oral order authorize the Pharmacy to dispense a quantity limited to the amount adequate to treat the patient during the emergency period. The pharmacist will reduce the verbal order to writing, which must contain all of the information required for a valid prescription (see section 3.0).

The pharmacist will make all reasonable attempts to determine that the oral authorization came from a registered individual practitioner.

The practitioner must deliver to the Pharmacy a valid written prescription within 7 days of the emergency dispensing. The valid prescription must contain the words "Authorization for Emergency Dispensing."

**\*** In the event that the practitioner fails to provide the Pharmacy with a valid prescription, the pharmacist is required to report this to the local DEA office. Failure to report this voids the authority to fill an emergency oral order (the pharmacist is liable for violating the Controlled Substances Act).

1. Transfer of a prescription order for a controlled substance classified as Schedule III, IV, or V is permitted for the purposes of refill dispensing between pharmacies on a one-timebasis only.

Transfer of such prescription(s) in or out shall be conducted by a licensed pharmacist. Licensed interns or technicians are not permitted to conduct such a transfer.

Transfer information shall be recorded on the prescription via electronic means in the Pharmacy management system, including:

* Name of pharmacy transferring or receiving Rx
* Address
* Telephone number
* Transfer date
* Transferring pharmacist
* Receiving pharmacist
* DEA number of pharmacy
* Or as required by federal or state regulatory requirements for Transferred Prescriptions

1. Partial Fills: The Pharmacy will not partially fill a prescription order for a controlled substance classified as Schedule II; if the Pharmacy does not have sufficient product on hand, it may dispense the amount on hand, and then dispense the remaining balance within 72 hours. If the remaining balance is not received by the Pharmacy within 72 hours, it cannot be dispensed.
2. The Pharmacy will not fill prescription orders for “Office Use” for a controlled substance classified as Schedule III-V.

**VI. References:**

* [21 CFR 1306.05(a)](http://www.deadiversion.usdoj.gov/21cfr/cfr/1306/1306_05.htm)
* DEA Prescriptions for Controlled Substances FAQ available at: [US DOJ DEA: Questions and Answers](http://www.deadiversion.usdoj.gov/faq/prescriptions.htm)
* [SOP 5.03 – Controlled Substance Prescription Monitoring Program](#page150)

**VII. Attachments:** N/A

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## 5.08 Controlled Substance Inventory

1. **Purpose:** This procedure describes the process and requirements for Controlled Substance Inventory at the Pharmacy. Controlled substance inventory is one of the most important aspects of the DEA program. Inventory maintenance is the key to the loss detection, theft, and diversion of controlled substances.
2. **Scope:** This procedure applies to any Pharmacy pharmacist registered with the DEA and who performs inventory of controlled substances in compliance with: [Title 21 United States Code (21 U.S.C.) 801-971](http://www.deadiversion.usdoj.gov/21cfr/21usc/index.html); the DEA regulations Title 21, Code of Federal Regulations [(21 C.F.R.), Parts 1300 to End](http://www.deadiversion.usdoj.gov/21cfr/cfr/index.html); and State regulatory requirements.

**NOTE:** It is the responsibility of the Registrant to remain aware and current of laws and regulations affecting the controlled substance inventory process.

1. **Definitions:**

**Controlled Substances:**  Substances designated as Schedule I-V (C-I, C-II, C-III, C-IV and C-V) according to their medical use, potential for abuse, safety, or dependence liability.

**Inventory**: A complete and accurate list of all stocks and forms of controlled substances in the possession of the registrant as determined by an actual physical count for Schedule II controlled substances and an estimated count or measure of the contents of a Schedule III, IV, or V controlled substance (unless the container holds more than 1,000 tablets or capsules, in which case an exact count of the contents must be made).

**Inventory Records**: The forms or logs where the results of the inventory have been documented. All inventory records must be maintained at the registered location in a readily retrievable manner for at least 2 years for copying and inspection. In addition, the inventory records of Schedule II controlled substances must be kept separate from all other controlled substances.

1. **Safety Requirements:** N/A
2. **Procedure:**

**General Information and Inventory Requirements**

1. It is the responsibility of each registrant to list and inventory all controlled substances in stock at the appropriate times.
2. The normal inventory date is May 1st ANNUALLY for ALL controlled substances. Any deviation from the May 1st date of the inventory requires notification of the Drug Enforcement Administration (DEA) of a new "fixed "date and approval by the state Board of Pharmacy.
3. When a medication is added to the controlled substance list, that product will be inventoried on the date the rule becomes effective.
4. If the inventory is taken during open hours of the Pharmacy, inventory quantities shall be adjusted to reflect actual quantities on hand at either the open or close of business of the date of inventory.
5. CII Inventory: Exact counts shall be made on all CII medications.
6. CIII, CIV, and CV counts may be estimated if bottle size is for 1,000 dosage units or less.
7. In addition to the normal May 1st inventories required, a full inventory of ALL Controlled Substances medications shall be performed:

* Within 10 days of assumption of Pharmacist-in-Charge (PIC) duties;
* Immediately upon change of ownership of the Pharmacy; and
* As part of the procedures for closing the Pharmacy.

1. All losses of controlled substance medications shall be reported as per the DEA and State regulatory requirements.

**Initial Inventory**

1. When issued a DEA registration, a registrant must perform an initial inventory or physical count of all controlled substances in their possession. The Inventory Record must include:

* The name, address, and DEA registration number of the registrant
* The date of the inventory
* Whether the inventory was taken at the beginning or close of business
* The name of each controlled substance inventoried
* The finished form of each of the substances (e.g., 10 milligram tablet)
* The number of dosage units of each finished form in the commercial container (e.g., 100 tablet bottle)
* The number of commercial containers of each finished form (e.g., four 100 tablet bottles)
* A count of the substance: If the substance is listed in Schedule II, an exact count or measure of the contents; or if the substance is listed in Schedules III, IV, or V, an estimated count or measure of the contents, unless the container holds more than 1,000 tablets or capsules, in which case, an exact count of the contents is required
* The signature of the person or persons responsible for taking the inventory

1. If there is no stock of controlled substances on hand, the registrant should make a record showing a zero inventory.
2. If during the inventory process for controlled substances the following are identified, the Pharmacy must follow procedure SOP 5.09 - Disposing of Controlled Substances for the proper disposal process and documentation required:

* Unused, unwanted, expired, recalled, damaged, deteriorated, or other quality issue, rendering medication unsafe for use

1. All inventory records must be maintained at the registered location in a readily retrievable manner for at least two years for copying and inspection.

**Annual Inventory**

1. Per Pharmacy policy, the registrant is required to comply with the state legal requirements for inventory of controlled substances. Typically, this may be an annual inventory (once per year) and requires the same information as the initial inventory (see list above) of all controlled substances on hand. If an annual inventory is required per state regulation, it will take place on May 1st each year before the open of business or after the close of business. If this date falls on a day when business is closed, the inventory shall take place the preceding Friday at close of business. Annual Inventory records must be filed and maintained at the registered site in a readily retrievable manner for at least two years or as per state regulation.

**Biennial Inventory**

1. Per Federal Regulatory Requirement: Following the initial inventory, the registrant is required to take a biennial inventory (every 2 years), which requires the same information as the initial inventory (see list above) of all controlled substances on hand. The biennial inventory may be taken on any date which is within 2 years of the previous inventory date. Biennial Inventory records must be filed and maintained at the registered site in a readily retrievable manner for at least 2 years or as per State regulation.

**Newly Scheduled Controlled Substance Inventory**

1. When a drug not previously listed as a controlled substance is scheduled or a drug is rescheduled, the drug must be inventoried as of the effective date of scheduling or change in scheduling.
2. **References:**

* [Title 21 United States Code (21 U.S.C.) 801-971](http://www.deadiversion.usdoj.gov/21cfr/21usc/index.html)
* DEA regulations, Title 21, Code of Federal Regulations [(21 C.F.R.), Parts 1300 to End](http://www.deadiversion.usdoj.gov/21cfr/cfr/index.html)
* [SOP 5.09 - Disposing of Controlled Substances](#page173)

1. **Attachments:** N/A

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## 5.09 Disposing of Controlled Substances

1. **Purpose:** This procedure describes the process for disposal of controlled substances by the Pharmacy.
2. **Scope:** This procedure applies to pharmacists registered with the DEA who perform periodic inventory of controlled substances or through daily work processes may identify: unused, unwanted, expired, recalled, damaged, deteriorated, or other quality issues that render medication unsafe for use.
3. **Definitions:**

**Reverse Distributor:** A company that collects controlled or non-controlled substances from registrants (Pharmacy) and either returns them to the manufacturer for credit or arranges for their disposal. Reverse distributors provide a service to pharmacies by processing unused drug inventory, while also helping to protect public health by maintaining compliance with federal and state laws and regulations.

1. **Safety Requirements:** NOTE: It is the responsibility of the registrant to remain aware and current of laws and regulations affecting reverse distributors and controlled substance disposal.
2. **Procedure:**
3. The Pharmacy may transfer controlled substances to a DEA registered reverse distributor who handles the disposal of controlled substances. All state laws or regulations for the disposal of controlled substances shall be followed in this process.
4. The Pharmacy may only use a reverse distributor that is registered with the DEA. The Pharmacy should contact their local [DEA Diversion Field Office](http://www.deadiversion.usdoj.gov/offices_n_dirs/fielddiv/index.html) for an updated list of DEA registered reverse distributors.
5. All controlled substances identified for return and/ or disposal in the Pharmacy shall be stored in a locked and segregated area until scheduled for pickup by the reverse distributor.
6. Prior to a scheduled pickup by the reverse distributor, the Pharmacy shall prepare and package all identified products for return and complete a request for controls by providing a complete count of all controlled substances to be sent back through the reverse distributor.
7. Schedule II Controlled Substances: When the Pharmacy transfers Schedule II controlled substances to a reverse distributor for destruction, the reverse distributor must issue an official order form (DEA Form 222) or the electronic equivalent to the Pharmacy.
8. Schedules III-V Controlled Substances: When Schedules III-V controlled substances aretransferred to a reverse distributor for destruction, the Pharmacy must maintain a record of distribution that lists the drug name, dosage form, strength, quantity, and date transferred.
9. Once processed, all items are either sent directly to the manufacturer or disposed of according to all federal and local rules and regulations.
10. The DEA registered reverse distributor who will destroy the controlled substances is responsible for submitting a DEA Form 41 ([Registrant Record of Controlled Substances Destroyed](http://www.deadiversion.usdoj.gov/21cfr_reports/surrend/index.html)) to the DEA when the controlled substances have been destroyed.
11. A DEA Form 41 should not be used to record the transfer of controlled substances between the Pharmacy and the reverse distributor disposing of the drugs.
12. In no case should drugs be forwarded to the DEA unless the registrant has received prior approval from the DEA.
13. The Pharmacy must maintain all inventory records at the registered location in a readily retrievable manner for at least 2 years for copying and inspection.
14. **References:**

* [Title 21 United States Code (21 U.S.C.) 801-971](http://www.deadiversion.usdoj.gov/21cfr/21usc/index.html)
* DEA regulations, Title 21, Code of Federal Regulations [(21 C.F.R.), Parts 1300 to End](http://www.deadiversion.usdoj.gov/21cfr/cfr/index.html)
* **Disposal of Controlled Substances**

The Pharmacy should contact the local [DEA Diversion Field Office](http://www.deadiversion.usdoj.gov/offices_n_dirs/fielddiv/index.html) for an updated list of DEA registered reverse distributors.

* **Reverse Distributors Authorized to Dispose Controlled Substances**

A paper version of the DEA Form 41 may be requested by writing to:

* Drug Enforcement Administration  
  Attn: Registration Section/ODR  
  P.O. Box 2639  
  Springfield, Virginia 22152-2639

1. **Attachments:**  N/A

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## 5.10 Purchasing, Receiving, and Storage of Controlled Substances

1. **Purpose:** This procedure describes the process and requirements for Purchasing, Receiving, and Storage of Controlled Substances at the Pharmacy.
2. **Scope:** This procedure applies to any Pharmacy pharmacist registered with the DEA and authorized to perform Purchasing, Receiving, and Storage of controlled substances in compliance with the Controlled Substance Act (CSA): [Title 21 United States Code (21 U.S.C.) 801-971](http://www.deadiversion.usdoj.gov/21cfr/21usc/index.html); the DEA regulations, Title 21, Code of Federal Regulations [(21 C.F.R.), Parts 1300 to End](http://www.deadiversion.usdoj.gov/21cfr/cfr/index.html); and state regulatory requirements.

**NOTE:** To the Policy Maker only. Delete prior to publication. It is the responsibility of the Registrant to remain aware and current of laws and regulations affecting controlled substances.

1. **Definitions:**

**Controlled Substances:**  Substances designated as Schedule I-V (C-I, C-II, C-III, C-IV and C-V) according to their medical use, potential for abuse, safety, or dependence liability.

**Wholesale Distributor:** Licensed and registered manufacturers, suppliers, or distributors. Controlled substances distributors can be chemical suppliers, pharmaceutical vendors, or drug manufacturers. A licensed distributor must exercise due diligence and obtain verification documentation from the licensed registrant (Pharmacy) to ensure controlled substances are shipped only to individuals authorized for such access.

**Inventory Records**: These are the forms or logs where the results of the inventory have been documented. All inventory records must be maintained at the registered location in a readily retrievable manner for at least two years for copying and inspection. In addition, the inventory records of Schedule II controlled substances must be kept separate from all other controlled substances.

1. **Safety Requirements:** N/A
2. **Procedure:**

**Purchasing and Ordering Controlled Substances**

1. A Federal Drug Enforcement Agency (DEA) license and DEA requisition number are required for purchasing controlled substances.
2. The Pharmacy will only order Controlled Substances from registered and licensed wholesale distributors. Orders may be placed electronically (CSOS) or in hard copy by using appropriate forms (DEA Form 222 or 223) in compliance with all federal and state regulatory requirements.
3. The registered pharmacist must maintain proper inventory "par levels" of controlled substances to prevent out-of-stock situations. When par levels warrant, controlled substances will be ordered for purchase following the process below.
4. The Pharmacist-in-Charge (PIC) must work directly with the wholesale distributor and provide the necessary information to establish that he/ she is authorized to receive controlled substances or drugs. The controlled substance is shipped to the registrant and address as indicated on the DEA registration.
   * Schedule I and II Controlled Substances: Only Schedules I and II controlled substances are ordered with [**an official order form, DEA Form 222**](http://www.deadiversion.usdoj.gov/drugreg/index.html#2), or the electronic equivalent (see *Controlled Substance Ordering System (CSOS) – Electronic Order Forms*). A DEA Form 222 is required for each distribution, purchase, or transfer of a schedule II-controlled substance.

**Power of Attorney to Sign an Official Order Form:** Any registrant (pharmacy) may authorize one or more individuals, whether or not they are located at the registered location, to obtain and execute DEA Forms 222 by granting a power of attorney to each such individual. The power of attorney must be signed by the same person who signed the most recent application for registration or renewal registration, as well as the individual being authorized to obtain and execute the DEA Forms 222.The power of attorney may be revoked at any time by the person who granted and signed the power of attorney. Only if the renewal application is signed by a different person is it necessary to grant a new power of attorney when the pharmacy completes a renewal registration.  The power of attorney should be filed with executed DEA Forms 222 as a readily retrievable record.  The power of attorney is not submitted to DEA. (See Section 13.0 [Forms: FM-08](file:///C:\Users\Laura_2\Downloads\phcy-Forms-FM-08-DEA-POA-222-Rev.docx)).

* + Schedule III and IV Controlled Substances: Registrant must keep a receipt (invoice or packing slip) on which it records the date the drugs were received and confirm that the order is accurate. These receipts must also contain the name of each controlled substance, the finished form, the number of dosage units of finished form in each commercial container, and the number of commercial containers ordered and received. In addition, these receipts must be maintained in a readily retrievable manner for inspection by the DEA.

The PIC is responsible for maintaining adequate records regarding ordering, chain of custody, receiving, storage, and distribution of all controlled substances.

**Receiving Controlled Substance Orders**

1. Upon receipt of a Controlled Substance order in the Pharmacy, the DEA Registrant or Authorized User must verify the contents and immediately rectify any discrepancies.
2. Inspection:

* Controlled substances must be in their original shipping container.
* Physical condition is satisfactory.
* Official seal (if present) is unbroken.
* Identification on the package matches that described in the accompanying records.
* After confirming the accuracy of the received order, sign and date the purchase receipt and/ or invoice, and file it with the matching DEA Form 222 with the controlled substances records.

1. Inspection Discrepancy:Immediate action is taken to document and reconcile any abnormalities and/ or discrepancies such as:

* Conflicting sample numbers
* Broken seals
* Breakage
* Leakage or thawing

If discrepancies cannot be readily addressed and resolved with the wholesale distributor, contact the local DEA office for assistance.

1. Controlled Substance Documentation:Receipt of controlled substances must be documented with a record of the chain of custody, including each point where the substance changes hands or is used.

* A usage log is then maintained by the authorized user until the controlled substance is consumed or properly disposed of.
* The records of Schedule II controlled substances must be kept separate from all other controlled substances.

1. Orders Not Received:When a pharmacist has not received an expected shipment of controlled substances, he/ she should first contact the supplier to determine whether the original DEA Form 222 was received. If the original order form has been lost or stolen, the pharmacist must complete a second order form, so the supplier can fill the original order. The pharmacist must also prepare a statement which includes the first order form’s serial number and date and verify that the drugs ordered were never received. The pharmacist must attach a copy of the statement to the second order form that is sent to the supplier.  In addition, the pharmacist must keep a copy of the statement with copy three from the first and second order forms.
2. Storage of Controlled Substances

* All received and inspected controlled substance inventory shall be immediately placed by the DEA Registrant or Authorized User into secure and locked storage.
* Secure storage will have limited access by authorized personnel who need access in the performance of their official duties.
* Controlled substances will be stored in their proper environmental storage per the manufacturer's requirements.
* For refrigerated and frozen sample storage locations, the storage temperature must be monitored and recorded daily using an appropriate measurement device (calibrated thermometers, thermocouples interfaced with computer systems, or temperature recorders).
* Entrances to controlled substance secure locations must be monitored by an authorized employee, security guard, or video monitoring.
* Doors are equipped with high-security locks or card readers with alarm contacts.
* High-security locks are keyed “separately” from the building master key system.
* Locks or their combinations are changed if:
  + The key or combination has been compromised;
  + The area has been discovered unsecured or unattended; or
  + An employee no longer needs access due to transfer, termination, or retirement.
* Housekeeping: Controlled areas are cleaned only during normal working hours and under the supervision of an authorized employee or security guard.
* Inventory monitoring is required as outlined in SOP 5.08 - Controlled Substance Inventory. In the event a theft or a significant loss of controlled substance medication/ drugs is identified, immediately reference and follow SOP 5.05 - Theft of Controlled Substances.

1. **References:**

* [Title 21 United States Code (21 U.S.C.) 801-971](http://www.deadiversion.usdoj.gov/21cfr/21usc/index.html)
* DEA regulations, Title 21, Code of Federal Regulations [(21 C.F.R.), Parts 1300 to End](http://www.deadiversion.usdoj.gov/21cfr/cfr/index.html)
* <http://www.deadiversion.usdoj.gov/> - Pharmacist's Manual-Section I-VIII
* DEA E-Commerce Program website - [www.DEAecom.gov.](http://www.DEAecom.gov)
* [SOP 5.04 - DEA Form 222 Ordering/ Processing/ Receiving](#page154)
* [SOP 5.05 - Theft of Controlled Substances](#page158)
* [SOP 5.08 - Controlled Substance Inventory](#page170)

1. **Attachments:** N/A

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## 5.11 Prescription Management System

1. **Purpose:** This procedure describes the contents of a Prescription Management System.
2. **Scope:** This procedure applies to pharmacists, pharmacy technicians, and Pharmacy personnel.
3. **Definitions:**

**Prescription Management System:**  A computerized system but can be a combination of a computerized and hard copy system committed to continuous improvement and providing current quality products, controls, and audit systems to ensure the accuracy of legal Pharmacy practice and financial information in a timely and useful manner.

1. **Safety Requirements:** N/A
2. **Procedure:**

Prescription Management Systems provide the pharmacists, Pharmacy technicians, and Pharmacy personnel with the following information:

* Legal responsibilities of the pharmacist/ Pharmacy personnel.
* Requirements for the acquisition/ distribution of pharmaceutical products.
* Legal requirements of a prescription order.
* Requirements to properly dispense pharmaceutical products including controlled substances pursuant to a prescription order.
* Requirements/ conditions to make an offer to counsel.
* Requirements to dispense non-prescription items, including controlled substances.
* Procedures for maintenance of proper Pharmacy records/ patient confidentiality.
* Requirements for the proper storage/ distribution of pharmaceutical products.
* Various licensure/ certification/ registration requirements for Pharmacy personnel, practice settings, or business entities.
* Operational requirements for a particular practice setting.
* Rules/ laws that regulate the manufacturing, storage, distribution, and dispensing of pharmaceutical products, including controlled substances.
* Regulatory authorities that enforce the various laws/ rules affecting the manufacturing, storage, distribution, and dispensing of pharmaceutical products, including controlled substances.

1. **References:**

* United States Pharmacopeia
* CMS website
* National Association of Boards of Pharmacy
* Various state Boards of Pharmacy websites
* ASHP website

1. **Attachments:** N/A

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## 5.12 Disposing of Biohazard Waste

1. **Purpose:** This procedure describes the process for proper disposal of biohazard waste in the Pharmacy.
2. **Scope:** This procedure applies to all Pharmacy personnel.
3. **Definitions:**

**Biohazard Waste:** Also called infectious waste or biomedical waste, is any waste containing infectious materials or potentially infectious substances such as blood. Of special concern in the Pharmacy are sharp wastes such as needles, blades, glass pipettes, and other wastes that can cause injury while handling.

**Sharps:** A medical term for devices with sharp points or edges that can puncture or cut skin. Examples of sharps include:

* **Needles:** A very fine, slender and hollow piece of metal that is attached to a syringe. The needle inserted into the body for injecting or withdrawing fluids.
* **Syringes:** A tube with a nozzle and piston or bulb for sucking in and ejecting liquid in a thin stream and can be used for cleaning wounds or body cavities. It can be fitted with a hollow needle for injecting or withdrawing fluids.
* **Lancets:** Also called “fingerstick” devices – instruments with a short, two-edged blade used to get drops of blood for testing. Lancets are commonly used in the treatment of diabetes.
* **Auto Injectors:** Including epinephrine and insulin pens – syringes pre-filled with fluid medication designed to be self-injected into the body

1. **Safety Requirements:** All Pharmacy safety policy and procedures should be followed.
2. **Procedure:**

**General Information**

1. The Pharmacy must identify hazardous drugs or materials used in the workplace and identify proper handling and disposal methods that meet the requirements of state, federal, OSHA, and EPA regulatory requirements.
2. The Pharmacy must provide personnel with the appropriate personal protective equipment (PPE) required for handling hazardous materials.
3. The Director of Pharmacy must ensure all personnel are properly trained and follow all procedures relating to safety, handling, and disposal of hazardous materials and have knowledge and access to material safety data sheets (MSDS).

**Pharmacy Biohazard Waste and Disposal**

1. This procedure primarily outlines the proper disposal of biohazard waste generated in the Pharmacy environment, including:
   * + Human blood, blood products, and human body fluids
     + Microbiological waste: Laboratory wastes containing or contaminated with concentrated forms of infectious agents, including:
       - Discarded specimen cultures
       - Stocks of etiologic agents
       - Discarded live and attenuated viruses
       - Blood or body fluids known to contain infectious pathogens
       - Wastes from the production of biological and serums
       - Disposable culture dishes
       - Devices used to transfer, inoculate and mix cultures
2. Pharmacy-generated biohazard waste shall be disposed of into labeled biohazard containers, properly packaged, and removed from the pharmacy by a contracted biohazard waste disposal company on a regular basis.
3. Safe Sharps Disposal:

* Used needles and other sharps are dangerous to people and pets if not disposed of safely because they can cause injuries and spread infections. The most common infections are:
* Hepatitis B (HBV)
* Hepatitis C (HCV)
* Human Immunodeficiency Virus (HIV)
* “Biohazard waste” warning labels must be affixed to all sharps disposal containers.
* Biohazardous [sharps](http://www.stericycle.com/bio-hazard-waste/sharps-disposal) material must be disposed of and packaged in sharps containers, which will be either transported or placed in another container to be transported.
* Sharps containersare durable sharps bins that do not puncture, leak, or break on impact. A sharps bin shall:
  + - Have a secure closing mechanism
    - Be of a size and design to accommodate disposal of the largest sharp used
    - Have guards that prevent your hands from entering the sharps bin
    - Have an opening that is visible and clear before use
    - Promote one-hand disposal
    - Be safe
    - Have a stable mounting system
* Sharps Containers Access, Disposal, and Removal: Sharps containers must:
  + - Have handles that facilitate safe use, removal, and transport.
    - Be located away from wall switches, clear of impact zone, and obstacles.
    - Be placed within arms’ reach and below eye level at point of use.
* Full Sharps Bin(s): When the Pharmacy sharps bins are full, simply secure the seal, dispose the sharps bin into a larger sized biohazard waste bin that contains a red labeled biohazard bag, and tie securely. Place the tied bag in the Pharmacy area designated for biohazard waste removed from the pharmacy by the contracted service. Call the contract company for pickup.
* Other Biohazard Waste Containers:When other biohazard waste containers are full, tie the red biohazard labeled bags securely and place in the Pharmacy designated area for biohazard waste removal. Call the contract company for removal.

1. **References:** N/A
2. **Attachments:** N/A

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## 5.13 Expired Inventory or Returned Products

1. **Purpose:** This procedure describes the process for managing disposal of expired products or handling returned products at the Pharmacy.
2. **Scope:** This procedure applies to pharmacists or Pharmacists-in-Charge (PICs) who: perform periodic inventory of medications/ products in the Pharmacy; through daily work, process returned medications/ products; or identify unused, unwanted, expired, recalled, damaged, deteriorated, or other quality issue that renders medication unsafe for use.
3. **Definitions:**

**Reverse Distributor:** A company that collects controlled or non-controlled substances from registrants (Pharmacy) and either returns them to the manufacturer for credit or arranges for their disposal. Reverse distributors provide a service to pharmacies by processing unused drug inventory, while also helping to protect public health by maintaining compliance with federal and state laws and regulations.

**Legend Drug:**  Legend drugs means drugs that are approved by the U.S. Food and Drug Administration (FDA) and that are required by federal or state law to be dispensed to the public only on prescription of a licensed physician or other licensed provider.

**Returned Medications:**  Medications that have been removed from the Pharmacy and, for various reasons as outlined in this procedure, may be brought back to the pharmacy.

1. **Safety Requirements:**  NOTE: It is the responsibility of the registrant to remain aware and current of laws and regulations affecting reverse distributors and proper medication disposal.
2. **Procedure:**

**General Information**

1. This procedure does NOT apply to any controlled substance. For controlled substance returns or disposal process, reference SOP 5.09 - Disposing of Controlled Substances.
2. It is the responsibility of the Pharmacy to fully demonstrate that returned medications meet the state Board of Pharmacy requirements and regulations and maintain product quality as per United States Pharmacopeia (USP) standards. For processing returned products, reference SOP 4.03 - Returned Products.
3. The Pharmacy shall follow all state laws or federal regulations for the return or disposal of legend drugs.
4. The Pharmacy may only use a registered reverse distributor for pickup and disposal of returned or expired legend drugs.
5. The Pharmacy must maintain all inventory records at the registered location in a readily retrievable manner for at least two years for copying and inspection

**Reverse Distributor Process**

1. All legend drugs, medications, or products identified as returns, expired, unwanted, or soon to expire (less than 30 days) shall be placed in a container labeled "For Reverse Distributor Pickup."
2. The container must be kept in a segregated area of the Pharmacy until scheduled for pickup by the reverse distributor. As needed, these products will be kept separate and identified within the container as “For Drug Disposal” or “For Return Only.”
3. Prior to placing any products into the Reverse Distributor Pickup container, the PIC is responsible for proper accounting of these in the Pharmacy inventory system and maintaining inventory documentation that meets regulatory compliance.
4. For any "returned products" associated with a quality investigation, the PIC must coordinate with Quality Assurance before reverse distributor pickup for any further process required (for example, picture, testing, visual verification, etc.). For returns allowed/ not allowed, inspection process, credit, or return reuse policy, reference SOP 4.03 - Returned Products procedure.
5. Prior to a scheduled removal by the reverse distributor, the Pharmacy shall prepare and package all identified products for return with a complete inventory and count of products to be sent back through the reverse distributor. A copy of this record must be maintained in the Pharmacy.
6. Once processed and removed, the reverse distributor is responsible for returning directly to the manufacturer or disposal of medications according to all federal and local rules and regulations.
7. **References:**

* [SOP 5.09 - Disposing of Controlled Substances](#page173)
* [SOP 4.03 - Returned Products](#page109)

1. **Attachments:** N/A

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## 5.14 Biennial and Quarterly Inventory

1. **Purpose:** This procedure describes the process and requirements for Biennial and Quarterly Inventory of all legend drugs, medications, or other products stocked in the Pharmacy. Inventory maintenance is the key to loss detection, theft, and preventing out-of-stock situations.
2. **Scope:** This procedure applies to any pharmacist, Pharmacist-in-Charge (PIC), or authorized persons responsible for complying with current laws and regulations for Pharmacy inventory requirements. NOTE: It is the responsibility of the pharmacist to remain aware and current of laws and regulations regarding inventory compliance.
3. **Definitions:**

**Inventory:** The amount of Pharmacy stock merchandise that is available for sale to customers. Adequate inventory is generally defined as basic stock + safety stock. Efficient inventory management is an accurate prediction of inventory needs and is important to good customer satisfaction and good supplier relationships. Inventory is determined by an actual physical count of stock merchandise on a periodic basis.

**Inventory Records:** The forms or logs where the results of the physical inventory are documented. All inventory records must be maintained in the Pharmacy in a readily retrievable manner for at least two years for copying and inspection.

1. **Safety Requirements:** For controlled substance inventory and record management, reference SOP 5.08 - Controlled Substance Inventory.
2. **Procedure:**

**General Information and Inventory Requirements**

1. It is the responsibility of the PIC or authorized Pharmacy personnel to perform physical inventory of merchandise in stock at the appropriate times and manner as described in this procedure.
2. The PIC must review all inventory records and levels to determine the following and to make the appropriate procurement and operational profit decisions based on inventory goals:

* Maintain Basic Stock to meet an average demand level.
* Maintain Safety Stock inventory for fluctuations in demand and in order cycle times.
* Determine and identify Slow Turning Inventory.
* Determine the Order Cycle Time between placing an order and receipt of the merchandise.
* Investigate identified missing inventory that cannot be accounted for.
* Accurately document inventory and record maintenance.

**Quarterly Inventory**

1. Quarterly (every three months): The PIC or authorized pharmacy personnel shall conduct a physical inventory of all merchandise in the Pharmacy. The inventory should ideally be performed prior to store opening or after closing for minimal disruption.
2. The inventory shall be documented on Pharmacy inventory forms/ logs or in the Pharmacy electronic inventory system if applicable.
3. TheInventory Record must include:

* The name, address, and DEA registration number of the registrant (if applicable)
* The date of the inventory
* Whether the inventory was taken at the beginning or close of business
* The name of each medication/drug/product inventoried
* The finished form (e.g., 10 milligram tablet)
* The number of dosage units of each finished form in the commercial container (e.g., 100 tablet bottle)
* The number of commercial containers of each finished form (e.g., four 100 tablet bottles)
* A count of the medication/drug/product inventoried - an exact count or measure of the contents unless the container holds more than 1,000 tablets or capsules in which case, an exact count of the contents is required.
* The signature of the person or persons responsible for taking the inventory

1. If there is no stock on hand, the registrant should make a record showing a zero inventory.
2. If during the inventory process the following are identified, the Pharmacy must follow procedure SOP 5.09 - Disposing of Controlled Substances or SOP 5.13 - Expired Inventory or Returned Products for the proper process for pick-up and disposal:

* Unused, unwanted, expired, recalled, damaged, deteriorated, or other quality issue is found rendering medication unsafe for use.

1. All inventory records must be maintained at the registered location in a readily retrievable manner for at least two years for copying and inspection.

**Annual Inventory**

NOTE: To the Policy Maker only. Delete prior to publication. Only if required per state or regulatory requirements.

1. The Pharmacy will only perform an annual inventory (once per year) if required to comply with the state or other regulatory requirements.
2. Annual inventory requires the same inventory record information as listed in the Quarterly Inventory section 3.0.
3. An annual inventory will be taken on May 1st each year before open of business or after close of business. If this date falls on a day when business is closed, the inventory shall take place the preceding Friday at close of business.
4. Annual inventory records must be filed and maintained at the Pharmacy in a readily retrievable manner for at least two years or as per state regulation.

**Biennial Inventory**

1. A biennial inventory (every two years) requires the same inventory record information as listed in the Quarterly Inventory section 3.0.
2. The biennial inventory may be taken on any date which is within two years of the previous inventory date.
3. Biennial inventory records must be filed and maintained at the registered site in a readily retrievable manner for at least two years or as per state regulation.

**VI. References:**

* [SOP 5.08 - Controlled Substance Inventory](#page170)
* [SOP 5.09 - Disposing of Controlled Substances](#page173)
* [SOP 5.13 - Expired Inventory or Returned Products](#page184)

**VII. Attachments:** N/A

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## 5.15 Ordering and Receiving

1. **Purpose:**  This procedure describes how to order and receive new inventory.
2. **Scope:**  This procedure applies to all Pharmacy personnel.
3. **Definitions:** N/A
4. **Safety Requirements:** N/A
5. **Procedure:**
6. Ordering:
   * Inventory should be ordered from an authorized distributor.
   * If the order has been automatically generated by the computer system, a technician or clerk should verify that the out-of-stock products for customers who are waiting are on the order.
   * Based on inventory, edit the number of products or bottle sizes to be purchased.
   * Check the invoice from the previous order to see which items were shorted (product invoiced and not sent). Based on necessity (i.e. is the customer waiting, is it a seasonal item, does it tend to be on backorder, are a lot of customers are on this medication) and cost, the pharmacist may order from a secondary supplier (if applicable).
   * Order any over-the-counter products requested by customers.
7. Receiving:
   * When the order arrives, verify the number of totes and the store number labeled on the totes before the delivery carrier leaves.
   * Verify the count of CII scheduled products with the invoice before the delivery carrier leaves. Give any new completed CII order forms to the carrier for the next delivery.
   * Identify the cold items tote first. Verify items received with the invoice. Properly store refrigerated items as quickly as possible.
   * Put the item stickers on all of the products (if applicable).
   * Controlled Substance Invoices:
     + Place a red controlled substance receiving stamp on all controlled substance invoices.
     + A pharmacist must sign and date the invoice. If other personnel are present, they must sign and date as well. Otherwise, mark as indicated.
     + Retain invoices accordingly.
     + Update computer inventory.
8. **References:**  N/A
9. **Attachments:** N/A

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## 5.16 Shelving Medications / Sticker and Medication Storage

1. **Purpose:**  This procedure describes how to store/ shelve and sticker medications.
2. **Scope:**  This procedure applies to all Pharmacy personnel.
3. **Definitions:** N/A
4. **Safety Requirements:** N/A
5. **Procedure:**
6. Medications must be stored according to manufacturer recommendations.
7. Store the most dispensed medications in a “fast-mover” section closest to the dispensing area of the Pharmacy.
8. Label/ sticker medications that look alike or sound alike to prevent storage or dispensing errors.
9. Store newer inventory in the back to use older inventory first.
10. Divide medication storage bays into sections and assign technicians/ clerks/ pharmacists to perform weekly and/ or monthly shelf maintenance, including:
    * Removing expired/ expiring medications.
    * Labeling expirations on the bottle.
    * Verifying inventory with the computer.
11. **References:**  N/A
12. **Attachment:** N/A

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## 5.17 Refrigerator and Freezer Temperature Maintenance

1. **Purpose:** This procedure describes the requirements for refrigerator and freezer temperature monitoring and maintenance at the Pharmacy.
2. **Scope:** This procedure applies to the Pharmacist-in-Charge (PIC) or any Pharmacy personnel with responsibility for proper storage of medication, drugs, Pharmacy products, and daily monitoring or maintenance of refrigerators or freezers as described in this procedure to meet state or other regulatory requirements.
3. **Definitions:**

**Temperature Monitoring:** A system used to record temperatures at various or continuous intervals to ensure that medications are stored at the appropriate temperature and that the equipment is working properly. Information from temperature monitoring helps to identify low-performing equipment that may need repair or replacement.

1. **Safety Requirements:** Medications, drugs, or other Pharmacy products shall be stored in accordance with manufacturer or USP storage requirements.
2. **Procedure:**

**General Information, Cleaning, and Maintenance**

1. All refrigerators/ freezers should be cleaned regularly and as necessary for spills.
2. Personnel Use Only Refrigerators: Refrigerators designated for personnel use only shall be cleaned and food shall be discarded on a regular schedule every 2 weeks.
3. No personnel food or beverage may be stored in a refrigerator or freezer that is used to store medicine in the Pharmacy.
4. All materials stored in the refrigerators or freezers must be separated in boxes/ bags on separate shelves from other items and must be adequately labeled for content to prevent mix-up or contamination.
5. Medications that require refrigeration shall be stored according to manufacturer’s instructions and will be appropriately labeled (i.e., with the patient’s name, drug name/ dosage and date).
6. Any refrigerator or freezer identified as malfunctioning, not holding temperature, stopped working, or other problem shall not be used. The PIC shall be immediately informed, and corrective action taken.
7. All contents from a malfunctioning unit shall be immediately removed, inspected for quality by the PIC, placed into other working units, and/ or properly disposed of per Pharmacy procedures.
8. A common cause of temperature failure or alarms is a refrigerator or freezer door left partially open. Pharmacy personnel must make sure that doors are closed securely each time.
9. Repair/Maintenance: Only a certified repair company knowledgeable with the equipment shall be contacted to evaluate and correct equipment problems. Maintenance or repair shall be documented and retained in the Pharmacy.

**Temperature Monitoring**

1. Only an accurately "calibrated thermometer" or digital probe may be used and kept in each refrigerator and freezer at all times. Calibration shall be performed on a periodic basis by a certified calibration company and records maintained in the Pharmacy.
2. There are 2 options for temperature monitoring devices for refrigerators and freezers:

* Use of a digital thermometer or other type of thermometer appropriate for use in refrigerators or freezers that Pharmacy personnel can manually read and log temperature daily on a temperature log.
* A digital temperature automated monitoring system that monitors temperature in refrigerators and freezers 24/7 and immediately notifies responsible persons by email, text and/ or alarm if the temperature goes above or below the required set range.

1. Temperature Range Settings: - please verify these suggested temperature ranges as appropriate.

* It is a best practice recommendation to set minimum/ maximum temperature alert limits that will notify personnel before a temperature range is exceeded.
* The temperature in a refrigerator used to store medicine in the Pharmacy must be maintained between 36 - 46 degrees Fahrenheit (2 - 8°C).
* A freezer that is used to store medicine in the Pharmacy must be maintained below 32 degrees Fahrenheit (between -100°C and -200°C or -40°F and 140°F)

1. Out-of-Spec/ Range Temperatures:If temperatures register above or below the appropriate range, all stored items shall be removed, the PIC immediately notified for product inspection to determine if medications are safe to keep or should be discarded. Any products determined unsafe for use shall be disposed of by following the applicable Pharmacy procedures for this process.
2. Monitoring During Non-Open Hours: For monitoring of refrigerators or freezers during closed hours or days, the temperature will be checked and logged for that timeframe upon return on the next open business day.

* For alarms or notification of an out-of-spec temperature range using a digital temperature monitoring system, the notified Pharmacy personnel must immediately contact the PIC for the appropriate corrective action plan.
* The PIC shall ensure that action is taken to correct the temperature in the refrigerator or freezer.

1. Report Review: The PIC or authorized person shall review Temperature Monitoring logs/ reports printed from the digital monitoring system weekly to ensure that recorded temperature ranges are within specification. The reviewer shall sign/ date these documents and file in the Pharmacy.
2. **References:** N/A
3. **Attachments:** N/A

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## 5.18 Receiving Prescription Orders

1. **Purpose:** This procedure describes the process for receiving a prescription order at the Pharmacy.
2. **Scope:** This procedure applies to all licensed pharmacists (or pharmacist interns working under the supervision of a licensed pharmacist to the extent allowed by state law) responsible for the receipt and verification of prescription orders prior to dispensing. It is the pharmacist’s responsibility to ensure the requirements listed meet state or other regulatory requirements.
3. **Definitions:**

**Prescription:** A direction or instruction, usually written by a physician, dentist, etc., to a pharmacist, stating the form, dosage strength, etc., of a drug to be issued to a specific patient.

1. **Safety Requirements:** N/A
2. **Procedure:**

**Receiving Prescription Orders**

1. A prescription order may come into the Pharmacy the following ways:

* A written hard copy
* A fax
* Electronically transmitted
* Orally/ verbally

1. Prescription Requirements: (Pharmacy to verify these requirements meet your state regulatory requirements.) Due diligence will be performed by the pharmacist to ensure legitimacy of a prescription order. Questionable or suspicious prescription orders will not be filled. Registrants and registration numbers shall be verified at the point of service by the pharmacist.

The pharmacist must ensure that a received prescription order includes the following information:

* Date of issuance
* Name and address of the patient for whom or the owner of the animal for which the drug or device is dispensed
* Drug name, strength, and dosage form or device name
* Name of the drug's or device's manufacturer or distributor if the prescription order is written generically or a substitution is made
* Prescribing medical practitioner's directions for use
* Date of dispensing
* Quantity prescribed and, if different, quantity dispensed
* For a written prescription order, the medical practitioner's signature
* For an electronically transmitted prescription order, the medical practitioner's digital or electronic signature
* Name or initials of the dispensing pharmacist

Controlled Substances: For a prescription order for a controlled substance, the prescription must include the medical practitioner's address and DEA number.

**NOTE:** To the Policy maker only. Delete prior to publication. Controlled substance prescription requirements are state specific. Choose one of the options below to comply with relevant state laws. For state specific e-prescribing requirements, please review question #4 in the Bula Controlled Substances module at <https://in.bulalaw.com/ModuleReport/Detail/84?Questions=4&States>=

* Orders for Schedule II controlled substances require a written prescription form that is manually signed by the authorized prescriber or an electronic prescription that meets all DEA requirements for electronic prescriptions for controlled substances.
* Orders for substances classified as Schedule III, IV, or V shall be transmitted via paper, facsimile, e-prescribing software, or verbal communication directly from the practitioner to a licensed pharmacist.
* All controlled substance prescriptions must be transmitted via e-prescribing software.

1. Verbal Prescription Orders:

* Once received, a verbal order must be immediately transcribed as a written order.
* Only a pharmacist may receive a verbal order. When receiving a verbal order, the pharmacist shall:
  + Write down the complete order information or enter it into a computer.
  + Read the order back to the individual giving the order.
  + Receive confirmation for accuracy.
  + After confirmation, the pharmacist taking a verbal order shall immediately sign, date, and time the order.
* It is also a best practice to limit the number of personnel who may receive telephone orders to help ensure familiarity with the guidelines in this procedure and the ability to recognize the caller, which may reduce the potential for fraudulent telephone orders.
* Verbal Order Clarifications: Questions or clarification on a verbal order are usually instigated by the pharmacist to clarify a prescription and make it safe. This is accepted practice.
* If a change to the verbal order is needed, the pharmacist will amend a prescription with clear annotation of the change, the doctor's name, the pharmacist's name, and the date of the amendment. This does not need to be countersigned by a doctor.

1. A pharmacist may furnish a copy of a prescription order to the patient for whom it is prescribed or to the authorized representative of the patient if the copy is clearly marked "COPY FOR REFERENCE PURPOSES ONLY" or other similar statement. A copy of a prescription order is not a valid prescription order, and a pharmacist shall not dispense a drug or device from the information on a copy.
2. Prescription Record Retention: A prescription order is kept by the pharmacist or Pharmacy as a record of the dispensing of a drug or device for seven years from the date the drug or device is dispensed, except for a drug or device personally administered by a medical practitioner to the medical practitioner's patient and the dispensing of the drug or device complies with the packaging requirements of the official compendium and state and federal law.
3. **References:** N/A
4. **Attachments:** N/A

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## 5.19 Clerk Responsibilities

1. **Purpose:** This policy describes a Pharmacy clerk's responsibilities and duties.
2. **Scope:** This policy applies to clerks working in the Pharmacy.
3. **Definitions:** A clerk in the Pharmacy assists the pharmacist and pharmacy technician to provide pharmacy services to the customer. The Pharmacy clerk position is often referred to as a pharmacy aide. The clerical services provided are non-clinical duties, like cashiering. A pharmacy clerk cannot perform any duties prescribed by pharmacy rules and regulations either to a pharmacist or a pharmacy technician.
4. **Policy:** The duties and responsibilities of a Pharmacy clerk include the following:

* Taking messages.
* Answering and forwarding phone calls in a professional and courteous manner.
* Answering non-medication related questions.
* Operating a cash register.
* Performing courier duties.
* Completing daily reports and balancing daily receipts.
* Maintaining store signage and displays.
* Merchandising.
* Taking periodic inventory.
* Receipt of prescriptions from customers.
* Handing completed prescription orders to customers while observing patient confidentiality and being compliant with the Health Insurance Portability and Accountability Act (HIPAA) requirements and asking if the customer has any questions for the pharmacist.
* Keeping the Pharmacy clean and organized.
* Making sure customers are satisfied.

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## 5.20 Pharmacist-in-Charge Responsibilities

1. **Purpose:** This policy describes the duties and responsibilities of the Pharmacist-in-Charge of the Pharmacy.
2. **Scope:** This policy applies to all Pharmacists-in-Charge.
3. **Definitions:**

**Pharmacist-in-Charge (PIC):** A pharmacist currently licensed in this state who accepts responsibility for the operation of the Pharmacy in conformance with all the state and federal laws pertinent to the practice of pharmacy and the distribution of drugs and who is personally in full and actual charge of the Pharmacy and the Pharmacy's personnel.

1. **Policy:** The duties of the PIC include the following:

* Establishing and supervising the method and manner of drug storage.
* Safekeeping of the pharmaceuticals.
* Maintaining security provisions when the Pharmacy is closed.
* Establishing and supervising the recordkeeping system for the purchase, sale, delivery, possession, storage and safekeeping of drugs.
* Complying with state and federal regulations concerning drug inventories, such as the biennial controlled substances inventory.
* Notifying the Board of Pharmacy (BOP) when departing the PIC position, a change in Pharmacy ownership, a change in Pharmacy location, or if the Pharmacy is permanently closing.
* Establishing a quality assurance program to monitor quality of care.
* Maintaining the confidentiality of protected health information (PHI).
* Assuring the automated dispensing system is in good working order.
* Assuring all pharmacists and Pharmacy technicians are appropriately licensed, certified, or registered according to state law.
* Reporting theft or suspected theft or diversion of any prescription drugs within \_\_\_ business days of discovery to the state BOP and to the Drug Enforcement Administration (DEA) or within 24 hours of discovery if the theft or suspected theft or diversion involves controlled substances. Reviewed/revised 12/06/2017.

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## 5.21 Store Manager Responsibilities

1. **Purpose:** This policy describes the responsibilities of the front store manager.
2. **Scope:** This policy applies to all front store managers.
3. **Definitions:**

**Store Managers:**  Perform essential administrative and labor management duties to make sure the front store operates efficiently, consistent with good customer care.

1. **Policy:** Store manager duties may include the following:

* Filing paper work
* Budgeting
* Payroll
* Ordering front store products and supplies
* Analyzing front store sales
* Labor management
* Merchandising
* Interviewing potential front store associates
* Training new front store hires
* Creating front store personnel work schedules
* Monitoring front store team performance
* Coaching team members
* Greeting customers
* Providing assistance to front store personnel
* Completing front store transactions

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## 5.22 Pharmacy Technician Responsibilities

1. **Purpose:** This policy describes the duties and responsibilities of pharmacy technicians.
2. **Scope:** This policy applies to all pharmacy technicians.
3. **Definitions:**

**Pharmacy Technician:**  An individual who is certified/ licensed or registered with the state Board of Pharmacy. Under the supervision of a registered pharmacist, pharmacy technicians may assist in the performance of various Pharmacy functions.

1. **Policy:** Pharmacy technicians, under the supervision of a registered pharmacist, may assist a registered pharmacist in the performance of the following Pharmacy functions:

* Dispensing, by counting tablets, pouring liquids and labeling prescription vials/ bottles.
* Retrieving medications needed to fill a prescription.
* Stocking or re-stocking prescriptions and other medications.
* Cleaning the Pharmacy area.
* Maintaining equipment in good working order.
* Providing medication and healthcare products to patients/ customers.
* Checking the accuracy of the information on a prescription.
* Checking that the prescription has been completed correctly.
* Packaging the prepared medication for pick up by the patient/ customer.
* Entering patient and prescription information into the Pharmacy computer system.
* Updating inventory records.
* Preparing medical insurance forms and processing medical coverage claims.
* Tracking inventory.
* Answering and forwarding phone calls in a professional and courteous manner.
* Answering non-medication related questions.
* Completing cash register transactions.
* Recording on the original prescription order, the prescription number and the date dispensed.
* Initiating or accepting verbal or electronic refill authorizations from a medical practitioner or the practitioner's agent.
* Compounding of medications.

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## 5.23 Pharmacy Staff Ratios

1. **Purpose:** This procedure identifies the number of pharmacy technicians that each registered pharmacist can supervise in accordance with state rules and regulations.
2. **Scope:** This procedure applies to all pharmacists and pharmacy technicians.
3. **Definitions:**

**Pharmacy Staff Ratios:**  Refers to various state Boards of Pharmacy rules and regulations that restrict the number of pharmacy technicians that a registered pharmacist can supervise at the same time. It should be noted that there are approximately 13 states that do not have rules and regulations addressing pharmacist to pharmacy technician ratios. A few examples of these states with no rules on pharmacy staff ratios are Arizona, Illinois, Iowa, Kentucky, New Hampshire, and Pennsylvania. A few states, including New Mexico, Rhode Island, Vermont, and West Virginia, do not mandate a specific ratio, but require PIC and/ or pharmacy owner to determine sufficient ratio.

1. **Safety Requirements:** N/A
2. **Procedure:** State Boards of Pharmacy have either created rules and regulations or have not created rules and regulations addressing pharmacist to pharmacy technician ratios. In the states that have created these ratios, there is considerable variation in allowable ratios. One state can restrict a pharmacist to supervision of 2 pharmacy technicians, while another state can allow a pharmacist to supervise 5 or 6 pharmacy technicians, or even a greater number of pharmacy technicians if one or more of the pharmacy technicians is nationally certified. Regardless of the pharmacy staff ratio allowed by regulation it is important to remember the following:

* Patient safety and dispensing accuracy are paramount.
* Pharmacy technicians are valued members of the Pharmacy team and are of great assistance to the pharmacist.
* Regardless of the Pharmacy staff ratio that is permitted or employed by the Pharmacy, it is clear that the registered pharmacist is responsible and accountable for the activities of pharmacy technicians under his/ her supervision.
* There should be uniform training and education of Pharmacy technicians.
* In addition to training and education, Pharmacy technicians must be properly prepared to work with pharmacists.
* The roles and responsibilities of Pharmacy technicians must be clearly defined.

1. **References:** N/A
2. **Attachments:** N/A

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## 5.24 Temporary Absence of a Pharmacist

1. **Purpose:** This procedure describes the activities that may or may not occur in the Pharmacy and if the Pharmacy can remain open when the registered pharmacist is absent from the Pharmacy.
2. **Scope:** This procedure applies to the Pharmacy and all the Pharmacy personnel.
3. **Definitions:**

**Temporary Absence of a Pharmacist:**  When no registered pharmacist is present in the Pharmacy for a period of time to supervise Pharmacy personnel and Pharmacy activities.

1. **Safety Requirements:** N/A
2. **Procedure:** When there is no registered pharmacist present in the Pharmacy, the Pharmacy and the Pharmacy personnel must comply with state law. It is extremely important from a legal and patient safety perspective that the Pharmacy complies with their state laws. State pharmacy regulations may require the following:

* The Pharmacy must be closed and possibly physically secured as well.
* A sign stating that the pharmacist is not on duty shall be conspicuously posted in the Pharmacy.
* No clinical activities can occur in the Pharmacy, if closed.
* No prescription can be dispensed.
* Prescriptions that have already been checked by the pharmacist can be delivered to the patient/ customer.
* Pharmacy technicians can continue their assembling of prescriptions duties but may not finish any prescription being assembled until reviewed and checked by the pharmacist upon his/ her return.
* Policies and procedures must be in place defining the activities that can occur in the Pharmacy when the registered pharmacist is absent.

**\*** All Pharmacy-related clinical activities occurring in the Pharmacy are performed under the legal authority of the registered pharmacist. If the registered pharmacist, the legal Pharmacy authority, is not present, it is clear that an actual Pharmacy transaction, like dispensing, cannot take place unless that prescription being dispensed has been previously checked by the registered pharmacist.

1. **References:** N/A
2. **Attachments:** N/A

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## 5.25 End of Day

1. **Purpose:** This procedure describes the procedures that must be followed each day prior to the closing of the Pharmacy.
2. **Scope:** This procedure applies to all Pharmacy personnel.
3. **Definitions:**

**End of Day:**  The closing of the Pharmacy, when all Pharmacy business activities cease.

1. **Safety Requirements:** N/A
2. **Procedure:** When it is time to close the Pharmacy, a variety of procedures must be employed to make sure the Pharmacy is prepared for the next business day:

* Reconcile the cash register receipts with the cash on hand.
* Close out all credit card transactions.
* Ensure that:
  + The Pharmacy inventory has been secured and temperature sensitive drugs have been refrigerated.
  + Any drug shipments received during the day have been checked against the manufacturer/ wholesaler invoice and have been properly stored.
  + The Schedule II drugs and narcotics are securely locked in the safe.
  + The perpetual inventory of Schedule II drugs and narcotics has been reconciled.
  + The hard copy or electronic dispensing log has been signed off and checked for accuracy.
* The voice mail or communication system for patients/ customers and prescribers is turned on and working.
* The Pharmacy equipment has been properly cleaned and put away.
* All outstanding messages from patients/ customers or prescribers have been responded to or appended for response the following day.
* All entrance and exit doors have been locked and secured.
* The physical barrier and/or alarm has been properly activated.

1. **References:** N/A
2. **Attachments:** N/A

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## 5.26 Transferring Prescriptions

1. **Purpose:** This procedure describes the procedures that must be used to transfer a prescription to another pharmacy.
2. **Scope:** This procedure applies to all pharmacists (or pharmacist interns working under the supervision of a licensed pharmacist to the extent allowed by state law), Pharmacy technicians, and Pharmacy personnel.
3. **Definitions:**

**Transfer of a Prescription:**  The transfer of original prescription information between two pharmacies for the purpose of refill dispensing.

1. **Safety Requirements:** N/A
2. **Procedure:** When transferring a non-controlled prescription or a controlled Schedule III, IV, or V prescription, electronically or manually, to another pharmacy for the purpose of refill dispensing, the following procedures must be followed:

* The prescription information must be communicated directly between two pharmacists if a controlled substance medication is transferred, or between two pharmacists and/ or two certified pharmacy technicians (if state law allows) if the transferred prescription was for a non-controlled medication.
* The word "void" must be written on the face of the transferred prescription.
* Record on the reverse side of the invalidated prescription:
  + The name and address of the pharmacy to which it was transferred.
  + The name of the pharmacist or certified technician that received the prescription information.
  + If the transferred prescription is for a Schedule III, IV, or V medication, also record the DEA number of that pharmacy.
* Record the date of the transfer and the name of the pharmacist or certified pharmacy technician transferring the prescription information.
* The pharmacist or certified pharmacy technician (if state law allows for non-controlled medication transfers) receiving the transferred prescription information shall ensure that all the required information is recorded and reduce the following to writing:
* “Transfer” on face of the prescription
* Date of issuance of original prescription
* Original number of refills authorized on the original prescription
* Date of original dispensing
* Number of valid refills remaining and date of previous fills
* Pharmacy's name, address, prescription number from which the prescription information was transferred, and the pharmacy's DEA registration number if the transferred prescription was a controlled substance
* Name of the transferring pharmacist or certified pharmacy technician (if state law allows) if the prescription was for a non-controlled medication or the name of the transferring pharmacist if the prescription was for a controlled substance

**\*** The transfer of Schedule III, IV, or V medications is permissible between pharmacies on a one-time basis only, unless the pharmacies share a real-time online database; in that case the maximum number of refills may be transferred as permitted by law and authorized by the prescriber.

**\*** Pharmacies sharing a real-time common electronic database used to maintain required dispensing information are not required to transfer a prescription as long as the common database file contains a complete record of the prescription order and all the fills and refills of that prescription order.

1. **References:** N/A
2. **Attachments:** N/A

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## 5.27 Pharmacy Maintenance

1. **Purpose:** This procedure describes the various equipment and patient records that must be maintained by the Pharmacy according to state and federal law.
2. **Scope:** This procedure applies to pharmacists, pharmacy technicians, and Pharmacy personnel.
3. **Definitions:** N/A
4. **Safety Requirements:**  N/A
5. **Procedure:**  Maintenance of Pharmacy records pertaining to equipment and Pharmacy/ patient computerized systems used in the practice of pharmacy is extremely important to both patient safety and the practice of pharmacy in compliance with state and federal laws. Examples of records required to be maintained by the Pharmacy include the following:

* Patient record system.
* Dispensing records for prescription orders.
* Security/ confidentiality records and policies and procedures to safeguard protected health information (PHI), including the patient's name, address, DOB, gender, list of prescription orders dispensed for each patient, etc.
* Pharmacy computer system maintenance according to manufacturer recommendations.
* Maintenance of other equipment used in the practice of pharmacy, like automatic counting machines, according to manufacturer recommendations.
* List of all prescription orders dispensed by the Pharmacy for the preceding \_\_\_ years.
* Prescription files.
* Prescription drug inventories as required by state and federal law, such as the biennial controlled substance inventory required by the Controlled Substances Act.
* Drug orders/ receipts from wholesalers or manufacturers as well as drug disposition records.
* Current state and federal regulations and statutes relating to the practice of pharmacy.
* Records of all state/ federal inspections of the Pharmacy as well as letters of warning, etc.
* Records of personnel on duty in the Pharmacy.
* Pharmacy personnel job descriptions.
* Quality assurance records.
* Policies and procedures for processing prescriptions.
* Records that Pharmacy personnel read and understood the Pharmacy policies and procedures.
* Records of immunizations, including the patient receiving the immunization, who administered the immunization, the vaccine administered, etc.
* Any collaborative protocols with practitioners.

1. **References:** N/A
2. **Attachments:** N/A

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## 5.28 Manual Operations

1. **Purpose:** This procedure describes the manual operating procedures to be employed during the time period when Pharmacy automated systems are inoperative.
2. **Scope:** This procedure applies when any of the Pharmacy-related automated systems are incapacitated for any reason.
3. **Definitions:**

**Manual Operations:** Conducting the business of a pharmacy when automated or computerized systems have failed.

1. **Safety Requirements:** N/A
2. **Procedure:** To operate the Pharmacy when automated or computerized systems have failed, Pharmacy personnel must follow and comply with the following Pharmacy practices:

* Evaluate if the Pharmacy can continue to operate given the system(s) failures.
* Comply with federal and state laws, regardless of the status of Pharmacy operating systems.
* Always operate the Pharmacy in the best interests of the patients served.
* Notify the Board of Pharmacy if the compromised system(s) situation rises to the level of an emergency or disaster that poses a threat to the safe operation of the Pharmacy.
* Ensure all of the clinical, demographic, and other information required to be collected and maintained by state and federal law continues to be captured and recorded during the manual operation.
* Prevent the illegal use and disclosure of protected health information (PHI).
* Assess the appropriate personnel required to operate the Pharmacy during manual operation.
* Make sure all of the required dispensing functions, like performing DUR, identifying potential drug interactions, therapeutic duplications, under/ over utilization are not compromised.
* Assess if some or all prescriptions/ workload needs to be transferred to another Pharmacy for a time period to meet the needs of the patients and to remain in compliance with state and federal laws.

1. **References:** N/A
2. **Attachments:** N/A

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## 5.29 Daily Closing Procedures

1. **Purpose:**  This procedure describes the procedures that must be followed when closing the Pharmacy each day.
2. **Scope:**  This procedure applies to all Pharmacy personnel.
3. **Definitions:** N/A
4. **Safety Requirements:** N/A
5. **Procedure:** When it is time to close the Pharmacy, a variety of procedures must be employed to make sure the Pharmacy is secure:
6. Dispensing Area:
   * Put away medication bottles.
   * Put any PHI in shred bins.
   * Clean off the counting trays.
   * Refill prescription bottles and lids.
7. Data Entry Area:
   * File all prescriptions properly in their folders.
   * Scan all prescriptions remaining if not able to process them in time.
   * Check the fax machine for prescriptions.
   * Refill paper in fax machine.
   * No prescriptions or personal health information should be left out where people can see.
8. Checkout Area:
   * Close registers.
   * Take register tills up front.
   * Replenish bags.
   * Return prescription storage bags to verification area.
9. Drive-thru Area:
   * Close registers.
   * Take register tills up front.
   * Close window.
   * Get new signature log sheet ready for the next day.
   * Replenish bags.
   * Return prescription storage bags to verification area.
10. Store:
    * Log off all computer terminals and turn off monitors.
    * Log refrigerator and freezer temperatures.
    * Pharmacists:
      + Put away all CII medications.
      + Lock the controlled substance safe.
      + Lock all windows, doors, and gates.
11. **References:**  N/A
12. **Attachments:** N/A

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## 5.30 Emergency Preparedness and Disaster Recovery

1. **Purpose**: The purpose of this procedure is to assist pharmacy personnel in disaster preparedness and recovery as well as processes to provide medication services and supplies in emergency situations.
2. **Scope**: This applies to all Pharmacy personnel.
3. **Definitions**: N/A
4. **Procedure**:

**Emergency Preparedness**

* 1. Emergency Preparedness
     + Never block access to fire extinguishers, sprinkler heads, or dry chemical nozzles.
     + Never block or padlock any emergency exits from inside or outside.
     + Ensure exit signs are always illuminated.
     + Mark all evacuation route maps with information such as emergency exits, primary and secondary evacuation routes, locations of fire extinguishers, and fire alarms.
     + Ensure no merchandise or flammable objects are placed near light fixtures.
  2. Disasters
     + **The number one priority is safety** of pharmacy personnel, patients, and customers.
     + Follow the instructions from Pharmacist-in-charge, pharmacy owner, or other individual in charge.
     + Ensure security of pharmacy and all paper records.
     + If pharmacy must close and is unable to remain open, post a sign indicating the pharmacy is closed.
     + Contact appropriate agencies in case of emergency medical or fire disaster.
     + Ensure all personnel have access to first aid kids and can utilize when necessary.
     + If possible, turn radios or TVs to emergency stations.
  3. Power Failures
     1. Total Power Failure
        + If a total power failure occurs, close the pharmacy and take immediate action to secure cash registers, doors, and controlled substances. If lights are out, use flashlights – do not light candles or use fire of any kind.
     2. Backup Generator or Battery
        + Computer terminals may operate on backup generator or battery for a specific period of time. Pharmacy personnel must determine source and estimated duration of the power failure. If the duration is longer than the period of time the computers may operate on backup generator or battery, safely shutdown the pharmacy terminal.
        + Notify patients and customers of power outage and estimated wait time.
        + If Pharmacy maintains medications, vaccines, or other products in the pharmacy refrigerator or freezer, monitor time power is down. If power outage lasts longer than four hours, refrigerator and freezer must be packed with dry ice. Avoid exposure to skin, use gloves and caution when handling dry ice. A pharmacist must remain on duty to ensure the integrity of temperature-sensitive products, even if pharmacy closes before normal hours.
        + If Pharmacy power is not restored before normal closing hour, pharmacist must determine what actions need to be taken to minimize products being compromised
  4. Types of Disasters – Regardless of type of disaster, keep pharmacy personnel, patients, and customers away from windows or other hazardous areas. Do not leave pharmacy until it is safe.
     + Tornado: If it is safe, evacuate all people from the building. If evacuation is not possible, find shelter under work counters, desk, interior doorways, walk-in coolers, or other designated tornado shelters. Stay away from merchandise shelves.
     + Earthquake: Immediately stop and take cover under the nearest work counter, desk, interior doorway, or walk-in cooler. Do not run. When safe, evacuate the building. Stay away from merchandise shelves. Do not smoke or light any matches, lighters, or candles because of potential gas leaks from earthquake.
     + Fire: Call 911 immediately. If the fire is localized and can be extinguished without risk, do so immediately. If the building requires evacuation, the pharmacist must secure controlled substances and the pharmacy if possible without risking own safety.
     + Flood: Attempt to protect all drug products by moving them from low shelves to higher shelves. Relocate the refrigerator and freezer, if possible. Seal exterior doors with duct tape, barricades, sandbags, or plastic to minimize damage. Protect power box if possible. Protect the computer system and terminals as best as possible.
  5. Post Disaster Response
     + Pharmacy personnel must assist clean-up and preparation of the pharmacy to reopen as soon as possible.
     + Before opening, review product inventory and check quality and integrity, including product stored in the refrigerator or freezer.
     + Report any lost controlled substances to the DEA.

**Disaster Recovery**

* 1. Data Back-Up. The pharmacy has developed a disaster recovery plan that covers data back-up, storage, and recovery.
     + All data is protected at the point of origin, in transit, and at the destination regardless of backup or failover method used.
  2. Contacting customers, suppliers, vendors. The pharmacy will contact customers, suppliers, and vendors following a disaster.
  3. Insurance. The pharmacy will have adequate insurance coverage to offset damage, clean-up, business interruption and other recovery costs.
  4. Restoring operations. The pharmacy will have a recovery plan that addresses restoring operations at the existing site or at an alternative location.
  5. Emergency Dispensing.
     + The pharmacy may only dispense emergency prescriptions as provided by federal and state law.
     + For emergency dispensing of controlled substances, *see* SOP 5.06 – Dispensing CII Controlled Substances and SOP 5.07 – Dispensing CIII – V Controlled Substances.

1. **References**:

* [SOP 5.06 – Dispensing CII Controlled Substances](#page162)
* [SOP 5.07 – Dispensing CIII – V Controlled Substances](#page165)

1. **Attachments**: N/A

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## 5.31 Mail Order Services

1. **Purpose**: The purpose for this standard operating procedure is to comply with establish practices for mail order services.
2. **Scope**: This procedure applies to all Pharmacy personnel involved in mail order services.
3. **Definitions**: N/A
4. **Procedure**:
   1. **Licensure**: Pharmacy shall be properly licensed and in good standing in the states where drugs and devices are shipped to as required by federal and state law.
   2. **Recordkeeping:** To comply with potential inspection or Board of Pharmacy requests, records for those drugs and devices shall be maintained separate based on the state in which they are shipped.
   3. **On-Call Hours:** To provide patient counseling and answer any patient questions, pharmacy shall maintain a toll-free telephone with Pharmacist access during normal business hours (for a minimum of 40 hours per week). The toll-free telephone number may be equipped with an interactive voice response system (e.g., press 1 to speak with a Pharmacist).

* During hours outside normal business hours, the Pharmacy shall maintain an on-call Pharmacist who is able to address urgent needs and clinical questions.
* On-call pharmacists must have access to patient records and profiles to adequately provide counseling services.
  1. **Delivery:** Pharmacy is responsible for the integrity of the drugs during delivery and must establish proper protocols and procedures.
* Protocols may include delivery times and methods including the use of common couriers including UPS, FedEx, or other third-party couriers. Pharmacy must verify the common couriers have in place adequate security provisions, such as criminal background checks or random drug screens on employees who have access to the drugs.
* All shipments should be tracked, and Pharmacy shall have a method to verify that the patient or authorized recipient has actually received the drugs.
* If a shipment is lost, damaged, or in any other way adulterated, the product will be replaced as quickly as possible.
* If the drugs are not delivered or deliverable, the Pharmacy must properly transfer the prescription information to an alternative pharmacy of the patient’s choice.
  1. **Temperature**: Pharmacy shall ensure any drugs shipped maintain their integrity through adequate shipping protocols including use of cold packs, temperature monitoring, or other equipment necessary to keep the drugs at the proper temperature.
  2. **Controlled Substances**: Any shipments of controlled substances must be lawful under DEA regulations and state law. All necessary requirements must be met before shipping including registration with DEA, labeling, and packaging.
  3. **Unavailable Product:** If the drug ordered is not available from the Pharmacy, the pharmacist will inform the patient that they are unable to fill the drug. If the drug is back ordered or out of stock, the pharmacist should inform the patient when they expect the drugs to be available and delivered. If the patient does not agree with the new delivery date, the pharmacist shall contact the prescriber to confirm an alternative pharmacy through which the drug can be filled. The patient will be contacted and informed of the alternative pharmacy.
  4. **State and Federal Law:** Pharmacy shall follow all applicable state and federal law when providing mail order services.

1. **References**: N/A
2. **Attachments**: N/A

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## 5.32 Nondiscrimination and Grievance Procedure

1. **Purpose**: The purpose for this procedure is to protect individuals from discrimination in health coverage and care.
2. **Scope**: This procedure applies to all Pharmacy personnel.
3. **Definitions**: N/A
4. **Policy**: It is the policy of the Pharmacy not to discriminate on the basis of disability, race, color, national origin, age or sex, including discrimination based on pregnancy, gender identity, and sex stereotyping prohibited by Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. § 794) and Section 1557 of the Affordable Care Act.
5. **Procedure**:
   1. **Coordinator**: *If the Pharmacy employs 15 or more employees*, the Pharmacy shall designate a responsible employee to serve as the Coordinator of this procedure and the requirements under Section 504 of the Rehabilitation Act of 1973 and Section 1557 of the Affordable Care Act.
   2. **Grievance Procedures:** *If the Pharmacy employs 15 or more employees*, the Pharmacy shall implement the following grievance procedures.

* Policy – The Pharmacy adopts the grievance procedure outlined below providing for prompt and equitable resolution of complaints alleging any action prohibited by Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. § 794) and Section 1557 of the Affordable Care Act.  Section 504 and 1557 prohibit discrimination on the basis of disability, race, color, national, origin, age, and sex in any program or activity receiving Federal financial assistance.
* Grievances – Any person who believes she or he has been subjected to discrimination on the basis of disability, race, color, national, origin, age, or sex may file a grievance under this procedure. It is against the law for the Pharmacy to retaliate against anyone who files a grievance or cooperates in the investigation of a grievance.
  + Grievances must be submitted to the Coordinator within a timely manner of the date the person filing the grievance becomes aware of the alleged discriminatory action.
  + A complaint must be in writing, containing the name and address of the person filing it. The complaint must state the problem or action alleged to be discriminatory and the remedy or relief sought.
  + The Coordinator shall maintain the files and records relating to such grievances, including the confidentiality of the complaint as necessary.
* Investigation - The Coordinator (or her/his designee) shall conduct an investigation of the complaint. This investigation may be informal, but it must be thorough, affording all interested persons an opportunity to submit evidence relevant to the complaint.
  + The Coordinator shall issue a written decision on the grievance no later than 30 days after its filing.
* Appeal – The person filing the grievance may appeal the decision of the Coordinator by writing to the Pharmacy Owner or other individual or entity tasked with the appeals process within 15 days of receiving the Coordinator’s decision. The Pharmacy Owner or other individual or entity tasked with the appeals process shall issue a written decision in response to the appeal no later than 30 days after its filing.
* Filing a Complaint – The availability and use of this grievance procedure does not prevent a person from filing a complaint of discrimination on the basis of disability, race, color, national, origin, age, or sex with the U. S. Department of Health and Human Services, Office for Civil Rights.
* The Pharmacy will make appropriate arrangements to ensure that disabled persons or persons with language assistance are provided other accommodations, if needed, to participate in this grievance process.
  1. **Assurance of Compliance:** When applying for federal funding, Pharmacy shall submit an Assurance of Compliance (*available at* <http://www.hhs.gov/sites/default/files/hhs-690.pdf>*)*

1. **References**:

* Section 1557 of the Patient Protection and Affordable Care Act, [42 U.S.C. § 18116](https://www.gpo.gov/fdsys/pkg/USCODE-2010-title42/pdf/USCODE-2010-title42-chap157-subchapVI-sec18116.pdf)
* DHHS, Nondiscrimination in Health Programs and Activities Final Rule, [45 CFR Part 92, 81 Fed. Reg. 31376](https://www.gpo.gov/fdsys/pkg/FR-2016-05-18/pdf/2016-11458.pdf)
* Section 504 of the Rehabilitation Act of 1973, [29 U.S.C. § 794](https://www.gpo.gov/fdsys/pkg/USCODE-2006-title29/html/USCODE-2006-title29-chap16-subchapV-sec794.htm)
* [DHHS, Section 1557 of the Patient Protection and Affordable Care Act](http://www.hhs.gov/civil-rights/for-individuals/section-1557/index.html)

1. **Attachments**:

* [DHHS, Assurance of Compliance](http://www.hhs.gov/sites/default/files/hhs-690.pdf)

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# 6.0 Billing

## 6.01 Managed Care Policy

1. **Purpose:** This procedure describes the relationship between a patient, a physician, and a health care plan.
2. **Scope:** This procedure applies to pharmacists, pharmacy technicians, and Pharmacy personnel.
3. **Definitions:**

**Managed Care:** Intended to reduce unnecessary health care costs through a variety of mechanisms, including: economic incentives for physicians and patients to select less costly forms of care; programs for reviewing the medical necessity of specific services; increased beneficiary cost sharing; controls on in-patient admissions and length of stay; the establishment of cost-sharing incentives for out-patient surgery; selective contracting with healthcare providers; and the intensive management of high cost health care cases. The programs may be provided in a variety of settings, such as Health Maintenance Organizations (HMOs) and Preferred Provider Organizations (PPOs).

1. **Safety Requirements:** N/A
2. **Procedure:** Characteristicsofmanaged care plans:

* Engage the primary care physician as the gatekeeper for specialized care and surgery.
* Most managed care plans will have drug formularies.
* Most managed care plans will only pay for medications listed on the formulary.
* Beneficiary co-pay depends on whether a brand or generic drug is dispensed.
* Most managed care plans will have a high deductible; the beneficiary pays the entire drug cost until the deductible has been met.
* HMOs, PPOs, and Point of Sale Service (POS) are the most prevalent managed health care plans.
* In an HMO, the patient must receive care from an in-network primary care physician.
* In a PPO, anyone in network can provide care; there is no need to select a primary care provider; no referrals needed.
* In a POS, the beneficiary can choose to go out of network, but pays more for the health care received; there is flexibility to allow the primary care provider to manage care or go out of network without a referral.

**NOTE:** To the Policy Maker only. Delete prior to publication. It is important to remember the characteristics of managed care since the Pharmacy may not be reimbursed for delivered services if the beneficiary violates the managed care plan's rules and regulations.

1. **References:**

* NAPB website
* CMS website
* Pharmacy Law Desk Reference
* Pharmacy Malpractice: Law and Regulations
* Pharmaceutical Law

1. **Attachments:** N/A

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## 6.02 Medicare Part D Policy

1. **Purpose:** This procedure describes the Medicare requirements for the Pharmacy to participate in Medicare's Part D program.
2. **Scope:** This procedure applies to pharmacists, pharmacy technicians, and Pharmacy personnel.
3. **Definitions:**

**Medicare Part D Program:** A federal program that subsidizes the cost of prescription drugs to Medicare beneficiaries.

1. **Safety Requirements:** N/A
2. **Procedure:** Pharmacies that participate in the Medicare Part D program must meet a number of requirements to maintain status as an in-network pharmacy. Some of these requirements are:

* Maintain current pharmacy and pharmacy personnel licenses.
* Credential pharmacy personnel.
* Maintain a quality assurance program.
* Comply with applicable federal and state laws and the professional judgment of the pharmacist.
* Verify beneficiaries’ eligibility through Medicare's on-line claims system.
* Obtain beneficiary's or designated representative's signature in hard copy or electronically to confirm receipt of the prescriptions.
* Review all DUR messaging from the plan sponsor; the pharmacist must exercise professional judgment in resolving DUR issues.
* Support plan sponsor's drug formulary and formulary initiatives and inform beneficiary when a non-formulary drug has been prescribed.
* Support generic dispensing when permitted by law and the prescriber, and support Part D's generic programs.
* Support the clinical programs and services of the Part D program.
* Do not support automatic refills of a prescription drug until such refill has been authorized by the beneficiary.
* Agree to investigate and resolve complaints, grievances, and appeals.
* Maintain accurate and complete records.
* Comply with the plan sponsor's prior authorization program.
* Submit claims in conformance with current NCPDP data format.
* Comply with electronic prescription standards adopted by CMS, DEA, and other federal and state regulatory agencies.

1. **References:**

* NABP and CMS websites
* Pharmacy Law Desk Reference
* Pharmacy Malpractice: Law and Regulations
* Pharmaceutical Law

1. **Attachments:** N/A

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## 6.03 Medicaid - Pharmacy Requirements

1. **Purpose:** This procedure describes the state Medicaid program and the regulatory requirements that the Pharmacy must meet to participate in the Medicaid program.
2. **Scope:** This procedure applies to pharmacists, pharmacy technicians, and Pharmacy personnel.
3. **Definitions:**

**Medicaid Program:** A partnership between the federal and state government to provide health care services to the indigent and disabled. The Medicaid program pays for medical care including prescription drugs for those who cannot afford it. To qualify as a Medicaid beneficiary, an individual must meet federal low-income standards.

1. **Procedure:** To participate in the Medicaid program, a pharmacy must meet certain participation standards, such as:

* Only fill prescriptions compliant with state and federal law.
* Automatic refills of prescriptions are not allowed.
* Confirmation of medication receipt by beneficiary is required; electronic signatures permitted if signatures are retrievable.
* Observe strict quantity limits on prescription and non-prescription drugs and medical/ surgical supplies.
* Must comply with generic substitution requirements.
* Must comply with prior authorization programs.
* Must comply with step therapy program to ensure clinically appropriate but cost-effective use of prescribed drugs.
* Comply with frequency, quantity, and duration programs.
* Must be enrolled in the Medicare program to participate in the Medicaid program.
* Payment will not be made for experimental drugs or drugs used for cosmetic or other similar purposes, i.e., hair growth, infertility.

1. **References:**

* CMS website
* Pharmacy Law Desk Reference
* Pharmacy Malpractice: Law and Regulations
* Pharmaceutical Law

1. **Attachments:** N/A

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## 6.04 Health Plan Compliance Program

1. **Purpose:** This procedure describes the importance of the Pharmacy compliance program.
2. **Scope:** This procedure applies to pharmacists, pharmacy technicians, and Pharmacy personnel.
3. **Definitions:**

**Compliance:** Complying with state and federal laws, regulations, and Pharmacy policies and procedures; also includes proper billing of provided equipment and services. Compliance creates values, reliability, honesty, and integrity with personnel.

1. **Safety Requirements:** N/A
2. **Procedure:** Besides complying with pharmacy practice-related state and federal laws, rules, and regulations, the major component of the Pharmacy's compliance program is the identification of risks associated with coding and billing. Inappropriate billing practices include the following:

* Billing items or services not performed.
* Submitting claims for equipment, medical supplies and services that are not reasonable and necessary.
* Duplicate billing.
* Billing non-covered services.
* Misuse of Pharmacy's Provider Identification Number.
* Billing individual services when those services should be bundled under one billing code.
* Up-coding a provided service.

1. **References:**

* NABP website
* CMS website
* Pharmacy Law Desk Reference.

1. **Attachments:** N/A

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## 6.05 Usual and Customary Charges

* + - 1. **Purpose**: This Policy addresses the requirements when a Pharmacy bills for a prescription.
      2. **Scope**: This procedure applies to pharmacists, pharmacy technicians, and Pharmacy personnel.
      3. **Definitions**: The terms “Usual and Customary” or “U&C” means the lowest price the Pharmacy would charge to a cash-paying customer with no insurance at that location for an identical prescription on that day. This price must include any applicable discounts, promotions, or other offers to attract customers.
      4. **Policy**: Providers must bill the program for covered services with only the provider’s usual and customary charge to the general public, including any special pricing (for example, $4 generic programs), for the covered service. The provider’s usual and customary charge includes any dispensing fee that the provider may charge to the general public. Usual and customary charges are verified during on-site audits.
      5. **References**:
* CMS website
* Pharmacy Law Desk Reference
* Pharmacy Malpractice: Law and Regulations
* Pharmaceutical Law

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# 7.0 Quality Assurance

## 7.01 Adverse Drug Events

1. **Purpose:** This procedure describes the guidelines for Adverse Drug Event Reporting.
2. **Scope:** This procedure applies to all pharmacists or other Pharmacy personnel who are informed or notified that a dispensed medication has caused the patient an Adverse Drug Event (ADE) and or Reaction (ADR). Upon being notified of an Adverse Event (AE), the Pharmacy personnel must immediately report the event using the process outlined in this procedure.
3. **Definitions:**

**Adverse Event Drug Report:** A submitted report that documents ADE information provided to Pharmacy personnel by a patient and/ or a physician.

**Adverse Drug Event (ADE):**  Injuries resulting from medication use.

**Adverse Drug Reaction (ADR):** An unintended effect of the drug when used correctly for treatment (non-preventable ADE). For example, a red skin rash that may occur after taking a new medication.

**MedWatch:** The FDA's safety information and adverse event reporting program. It provides important and timely medical product information to health care professionals, including information on prescription and over-the-counter drugs, biologics, medical devices, and special nutritional products. Health care professionals and consumers can also report serious problems they suspect are related to certain FDA-regulated products. A MedWatch form is used to report adverse events.

**Drug Company ADE Reporting:**  Some contracted drug manufacturers require the Pharmacy to report ADE information to them in a specified manner and timeframe. It is the responsibility of the Clinical reviewing personnel to be aware of this requirement when evaluating ADE information.

**Adverse Event Severity Grade:**  A number assigned to the severity of the adverse event. The grading is from 1-5 (1 being a mild adverse event, and 5 the most severe: death related to an adverse event).

1. **Safety Requirements:** N/A
2. **Procedure:**

**General**

1. The Food and Drug Administration (FDA) approves a drug for marketing after determining that the drug's benefits of use outweigh the risks for the condition that the drug will treat. But even with a rigorous evaluation process, some safety problems surface only after a drug has been on the market and has been used in a broader population. After products approved by the FDA are on the market, the agency continues to monitor them for problems.
2. ADE Initial Review: Adverse drug events (ADE) reported to Pharmacy personnel must be submitted for review by a licensed pharmacist upon receipt.

* The pharmacist will review the ADE information and determine if the patient’s physician must be contacted or if other immediate corrective action or instruction to the patient is necessary.
* The pharmacist shall determine if the ADE is reportable. If it is reportable, the Pharmacy will initiate and fill out an ADE Form (See Section 13.0, [FM-03](#FM03)) as described in Section 7.03.
* The report may be made in hard copy or electronically within 24 hours of receipt of an ADE.

1. Training: New Pharmacy personnel are informed about the ADE process during new personnel orientation. Training to this full procedure is required for all Pharmacy personnel.

* Training to the ADE process/ procedure is the responsibility of the Pharmacist-in-Charge (PIC).
* Training should be documented as per the Pharmacy Training Policy.
* Training shall occur on an annual basis.

1. Submitting an ADE: Fill out all pertinent sections of the ADE Form:

* Adverse Drug Event Description: In the ADE description box, fully describe the ADE information with sufficient detail for a clinical assessment. This includes dates, names, and pertinent details of the ADE.
* Describe the patient’s symptoms and vital signs (if known).
* Note treatment administered consequent to the reaction, if any.
* Attach all associated documents related to the event, for example: prescription copy, label copy, drug formula sheet, or other documents.

**ADE Review and Reporting**

* 1. ADEs must be reviewed and, where applicable, reported to the Manufacturer or FDA within 24 hours or one business day.
  2. Pharmacists shall review all drug medication ADEs.
  3. Pharmacists will identify the ADE Severity Grade using CTCAE information for severity.

5 Severity Grades:

|  |  |
| --- | --- |
| Grade 1 | Mild adverse event |
| Grade 2 | Moderate adverse event |
| Grade 3 | Severe adverse event |
| Grade 4 | Life-threatening or disabling adverse event |
| Grade 5 | Death related to an adverse event |

* 1. Pharmacists will review and process the ADE and determine when and if a patient follow-up is required, a physician follow-up is required, or when to report a serious ADE to FDA.
  2. If reporting to the drug manufacturer is required, the pharmacist will provide ADE information from the ADE Form or use a manufacturer-provided ADE reporting form.
  3. FDA Reporting: ADEs reported to FDA will use the MedWatch Adverse Event Reporting Program Form #3500. Download the 3500 Form from the FDA website or link.
     + Fill out the required information or facts. For questions on filling out the form, call the 800 phone number listed below.
     + Fax the completed document to FDA using the fax number listed below.
     + MedWatch -https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm
     + Regular Mail: Use postage-paid, pre-addressed [FDA Form 3500](http://www.fda.gov/MedWatch/report.htm)
     + Fax: 800-FDA-0178 Phone: 800-332-1088
  4. All ADE communication must be sent using a "secure system" for protection of Patient Health Information (PHI). This means using a secure email, fax, or phone systems.
  5. The PIC is responsible for ensuring a review of all completed ADEs, making sure the correct reporting criteria was selected, identifying when follow-up is required, and communicating this to the pharmacist and/ or performing the follow-up themselves.
  6. ADE files are maintained in either electronic or hard copy form and on file as control and confidential records in the Pharmacy department for a period of 10 years.

1. **References:**

* [MedWatch Online Reporting](https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home)
* [FM-03 Adverse Drug Event Reporting Form](#FM03)

1. **Attachments:** N/A

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| Prepared by/Date: | Approved by/Date: |

## 7.02 Customer Complaints and Quality Related Events

1. **Purpose:** This procedure outlines the process for investigating Customer Complaints or Quality Related Events (QRE) received by the Pharmacy from internal or external sources.
2. **Scope:** This procedure applies to all Pharmacy personnel involved in receiving or investigating a complaint or quality related event. This includes, but is not limited to, information gathering, review of returned products, root cause analysis, corrective and preventative action, and investigation closure.
3. **Definitions:**

**Customer Complaint:**  An official statement submitted by an internal or external personnel or customer via phone call, fax, email, in person, or other means, regarding a suspected or identified problem with a product, medication, a pharmacy, service, or other. Examples of complaints:

* Medication errors
* Product complaints
* Service complaints
* Near-miss events

**Quality Related Event (QRE):**  A quality issue discovered internally or externally that may or may not be related to a prescription medication. A QRE can be related to a safety problem, customer service event, or other quality related event.

**Complaint/ QRE Timeline:**  The total number of days a complaint or QRE investigation will take until closure.

**CAPA:**  Corrective and Preventive Action, the measures taken to correct a problem and prevent a future reoccurrence. CAPA is a pharmacy "best practice" for continuous quality improvement.

**Complaint Reporting System:**  The established system used to report, document, and track complaint/ QRE information. This can be a secure electronic system/ database and or a hard copy Customer Complaint form. The reporting system used must have limited access for "protected health information” (PHI).

**Continuous Quality Improvement (CQI):**  A system used to identify and evaluate complaints/ QRE's for improvement of process, address training/ retraining, revise procedures or policies, maintain quality products, and support good customer service and continued quality patient care. CQI is a pharmacy "best practice."

**Protected Health Information (PHI):**  Information that is protected under HIPAA regulations (Section 4.13 HIPAA Policy) and must maintain confidentiality to the complaint investigation and viewed by only those directly involved in the investigation and with a “need to know.”

1. **Safety Requirements:** During a Complaint/QRE investigation, if a safety issue is identified, the investigators shall include the safety issue in the investigation report.
2. **Procedure:**

**Receiving a Complaint or Quality Related Event**

* 1. Upon receipt of a complaint or QRE by Pharmacy personnel, they shall document the information on a Complaint Form or the Pharmacy’s complaint reporting system.
  2. Complaint Information: The employee taking the complaint information must make all attempts to obtain the following information from the person submitting a complaint/ QRE:
* Names, addresses, and phone numbers of person affected
* The postal and e-mail address and phone number
* Name, address, and phone number of doctor or hospital if emergency treatment was provided
* Drug name and dosage, product codes, or identifying marks on the label or container
* Name and address of store where product was purchased and date of purchase
* Name and address of company on the product label
* Other applicable information for the complaint type
  1. Complaint/QRE Review: The received Complaint/ QRE information will be reviewed by the Pharmacist-in-Charge (PIC) and evaluated for possible quick resolution. The PIC will determine if and when a dispensed medication or product requires return to the Pharmacy for further inspection/ evaluation.
* If the complaint/ QRE is determined to be an Adverse Drug Event, the Pharmacy will follow the process described in SOP 7.01 - Adverse Drug Events.
* If the complaint/ QRE is determined to impact other Pharmacy stocked medication/ drugs/ products, the PIC will immediately segregate these from use for dispensing until such a time as the investigation is complete and resolved.
  1. Investigation: The investigation may require that the PIC research records pertaining to the event, such as prescription records, inventory records, pictures, or other types of records.
* The PIC may need to make follow-up contact with the patient/ customer as part of the investigation. This information will be documented in the complaint file.
* When all investigation information is complete and a root cause of the problem identified, the PIC is responsible for communicating a resolution to the patient/ customer. This information will be documented in the complaint file.
* The PIC will determine if any regulatory agency reporting is required for confirmed Pharmacy errors.
* The PIC will ensure all corrective actions resulting from a complaint/ QRE investigation are carried out and completed. Examples of this are:
  + Personnel retraining
  + Procedure revisions
  + Process improvement/ change
* When all corrective actions are complete, this information will be documented in the complaint file, and the file shall be considered closed out.
  1. Complaint/ QRE Trend Reports/ Charts: Quarterly, the PIC shall compile and trend complaint/ QRE information for review with operations management and the PIC personnel. The complaint/ QRE data shall be sorted by month, severity, and complaint or QRE type for ease of information review. The intent of this trend data review is to bring awareness of the types of complaints/ QREs occurring, to address repeated events, discuss further corrective actions, and review and flag complaints/ QREs that are outstanding for closure and/ or exceeding the complaint/ QRE timeline. The date of the quarterly review and signature of those in attendance will be noted on the annual review records.
  2. Complaint/ QRE Reports Annual Review: Annually, the PIC will summarize the twelve months of complaint/ QRE information into one annual trend report. This information will be reviewed with appropriate Pharmacy personnel at end of year for awareness of the overall types of complaints/ QREs received and to discuss areas for improvement, such as:
     + Equipment
     + Training or personnel needs
     + Major process changes

The date of the annual review and signature of those in attendance will be noted on the annual review records.

* 1. Complaint/QRE Document Retention: All Complaint/ QRE records and trend review reports will be maintained by the PIC (in hard copy or electronically) in a readily retrievable manner for at least 5 years for copying and inspection.

1. **References:**

* [SOP 7.01 – Adverse Drug Events](#page221)
* [FM-04 Complaint or Quality Related Event Report](#FM04)

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## 7.03 Error Reports

1. **Purpose:** This procedure describes the Pharmacy’s guidelines for Error Reporting.
2. **Scope:** This procedure applies to all pharmacists, Pharmacy personnel, and Quality Assurance notified of an Adverse Drug Event (ADE), Adverse Drug Reaction (ADR), or an error that has occurred, and which has been investigated and confirmed. Confirmed error shall be documented and reported as described in this procedure.
3. **Definitions:**

**Adverse Event Drug Report:** A submitted report that documents ADE information provided to Pharmacy personnel by a patient and/ or a physician.

**Adverse Drug Reaction (ADR):** An unintended effect of the drug, when used correctly for treatment (a non-preventable ADE). For example, a red skin rash that may occur after taking a new medication.

**MedWatch:** The FDA's safety information and adverse event reporting program. It provides important and timely medical product information to health care professionals, including information on prescription and over-the-counter drugs, biologics, medical devices, and special nutritional products. Health care professionals and consumers can also report serious problems they suspect are related to certain FDA-regulated products. A MedWatch form is used by the Pharmacy to report adverse events.

**Medication Error:** Any act or omission in the dispensing process that may cause or lead to patient harm. A Medication Error, as defined in this procedure, does not include any act or omission that is “corrected prior to furnishing the drug” to the patient or patient’s agent.

1. **Safety Requirements:** N/A
2. **Procedure:**
   1. Customer Complaints or Quality Event Reports: All customer complaints or internal quality related events shall be reported to the Quality Assurance Department by Pharmacy personnel. Customer complaints or quality related events shall be investigated for root cause, and corrective actions will be taken by Quality Assurance in cooperation with Pharmacy personnel. The complaint files will be retained as described in SOP 8.01 – Records and Retention and SOP 8.02 - Record Retention - Error Reports.

* Severe, Life-threatening, or Death ADEs shall be reported to FDA by Clinical Affairs using the MedWatch Form 3500 and following FDA reporting requirements. Reference SOP 7.01 - Adverse Drug Events for the reporting process.
* Where required by state Board of Pharmacy regulations, the Pharmacist-in-Charge (PIC) shall notify the state board of medication errors, ADE, or ADR information.
  1. Internal Quality Audit Reports: QA shall perform periodic Internal Quality Audits on a quarterly basis. The internal audit monitors the Pharmacy facility’s compliance with procedures, state or federal regulations, and accreditation requirements and identifies areas for continuous quality improvement. Audited sites are issued an Audit Report that documents compliance and non-compliance areas. For non-compliance areas, the PIC is responsible for correcting the action within a specified timeline. QA shall track corrective actions until completion. For “outstanding non-compliance areas” that are not corrected, QA shall report this to Pharmacy senior management during regular QA audit reviews. In addition, during these reviews, QA will provide trend audit information. These reports will be retained as described in SOP 8.01 – Record and Retention and SOP 8.02 - Record Retention - Error Reports.

3.0 Verified Medication Errors made in the Pharmacy shall be reported by the PIC to QA using the Quality Event Reporting process (Policy 1.16 - Quality Program). The PIC shall provide details of how the error occurred and the names of all personnel involved and work with QA on an appropriate corrective action or retraining process. As needed other departments may be included in the error review process, including Human Resources, Training department, or other departments. As needed, QA shall provide a copy of a completed Quality Related Event Report to any department involved in the review. These reports will be retained as described in SOP 8.01 – Record and Retention and SOP 8.02 – Record Retention - Error Reports.

4.0 Quality Performance Indicators:The Pharmacy uses the following metrics:

* Complaint Trend Reports: Customer complaint trend reports are provided quarterly to senior management for their awareness of errors or quality related events.
* Operational Review Meetings: Quality information is shared with senior management for review of data, plans for high-risk situations, non-compliance areas or other quality- or operations-related information. These reviews are maintained by quality assurance.
* Internal Audit Reports, or audit trends, are provided to senior management for awareness, support, and approval of quality plans to address non-compliance areas.
* Annual Review Reports: The Quality Officer reviews the overall status of the Quality System with the Compliance Committee. This review includes areas that impact product quality. These reviews are filed by quality assurance.

1. **References:**

* [Policy 1.16 - Quality Program](file:///C:\Users\Laura_2\Downloads\phcy-1.16-quality-program-policy.docx)
* [SOP 7.01 - Adverse Drug Events](#page221)
* [SOP 8.01 - Records and Retention](#page238)
* [SOP 8.02 – Record Retention - Error Reports](#page239)

1. **Attachments:** N/A

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## 7.04 Managed Care - Medicaid, Medicare Audits

1. **Purpose:** This procedure describes the Pharmacy process that allows its third-party payors to verify Pharmacy records to ensure compliance with contracts or regulatory requirements. This procedure outlines managed care audits for Medicaid and Medicare.
2. **Scope:** This procedure applies to all audits both internal and external for Medicaid and Medicare regulation compliance. This procedure applies to all Pharmacy personnel involved with support of audit activity, record maintenance, and regulatory knowledge and compliance. It is the responsibility of the Pharmacist-in-Charge (PIC) to be aware of and knowledgeable in current regulations regarding Medicaid and Medicare for compliance. It is the responsibility of the Pharmacy third party audit specialist to keep all personnel informed of new third party and Medicaid/ Medicare compliance rules/ regulation changes.
3. **Definitions:**

**Credentialing:** A process that payors use to establish the qualifications of pharmacists and/ or pharmacies to assess their background and legitimacy. Credentialing of downstream entities is a requirement of Medicare Part D Plans.

**Desk Audit:** A process that payers use to request information or documentation about a pharmacy or specific pharmacy claims to determine that payment is warranted.

**On-site Audit:** A payer audit that is performed on the pharmacy’s premises. The payer may conduct the audit with its own staff or may subcontract the audit function to an outside organization to perform on behalf of the payer.

**Internal Audit:** A review and verification of a process by trained Pharmacy personnel of records or processes to verify compliance with Pharmacy policy, procedures, or state or federal regulations.

1. **Safety Requirements:** N/A
2. **Procedure:**

**On Site Audit**

1. Contract language may include the right for the payer to visit a Pharmacy, company headquarters and/ or the individual pharmacy locations to inspect records related to the Pharmacy’s service obligations under the contract.
2. The Pharmacy requires advance written notice of any on-site audit to make accommodations to ensure that the audit does not interrupt the Pharmacy’s normal business.
3. The Pharmacy will provide a dedicated workstation/ desk for the auditor. A Pharmacy employee will assist the auditor during the audit to help facilitate the process.
4. All on-site audits are documented and tracked by a Pharmacy audit specialist who works directly with the auditor assigned by the payer. The audit specialist tracks the audit to ensure all documentation is sufficient, any additional documentation is provided post-audit, and any appeals are filed if necessary.
5. The on-site auditor is given access only to prescriptions and other information that are specific to claims for which that payer has paid.
6. Purchase information, such as warehouse invoices, may be provided to the auditor; however, any “pricing information is considered proprietary” and must be “blacked out” prior to submitting. The Pharmacy audit specialist is responsible for ensuring this is done for all impacted documents.
7. If the Pharmacy personnel or Pharmacy third party audit specialist has any question as to whether the information being requested is “allowable” under terms of the agreement, they will immediately contact the Managed Care department for review and approval.

**Desk Audit**

1. Contract language may include the right for the payer to request that the Pharmacy submit documentation via fax or other HIPAA compliant communication to the payer instead of an on-site visit.
2. Desk audits are coordinated and responded to by either Pharmacy personnel or the Pharmacy audit specialist.
3. All desk audits are documented and tracked by the Pharmacy audit specialist who works directly with the auditor assigned by the payer. The audit specialist tracks the audit to ensure all documentation is sufficient, any additional documentation is provided post-audit, and any appeals are filed if necessary.
4. Purchase information such as warehouse invoices may be provided; however, any “pricing information is considered proprietary” and should be “blacked out” prior to submitting. The Pharmacy audit specialist is responsible for ensuring this is done for all impacted documents.
5. If Pharmacy personnel or the Pharmacy third party audit specialist has any question as to whether the information being requested is allowable under terms of the agreement, they will immediately contact the Managed Care department for review and approval.

**Credentialing**

1. Payer agreements may require that the Pharmacy provide annual credentialing information to ensure ongoing compliance with regulatory requirements.
2. The Pharmacy third party contract administrator will complete all credentialing requests on behalf of the individual stores.
3. Credentialing information is reviewed for accuracy by the Managed Care department prior to submission.
4. Credentialing information is reviewed and signed by a Pharmacy executive with signature authority prior to submission to the payer.

**Internal Compliance Audits**

1. Each Pharmacy shall be audited on a regular basis or a minimum of twice per year by trained internal auditors.
2. The audit shall be unannounced to simulate agency audits and will be completed in one day.
3. The intent of internal audits is to ensure compliance with internal policy and procedures, compliance with current regulations, follow-up on non-compliance corrective actions, and as part of continuous quality improvement.
4. Auditors shall follow an audit plan, including:

* Review of the facility’s compliance with third party audits and status
* Third party information review
* Use of audit checklists to include Medicaid and Medicare document and process review
* Review of current statutes and or regulations

1. Before beginning the audit, the auditor shall review the audit process with the PIC, including:

* Use of checklists
* Document review and verification, or other methods of information verification
* Length of time for the audit
* Communication during the audit

If possible, identify one person assigned to answer audit related questions if this is not the PIC.

1. At the end of the audit, the auditor shall have a brief close out meeting with the PIC to review the results of the audit and/ or request further information or verification if needed. The auditor shall inform the PIC that a formal audit report will be issued within 2 weeks and will include instructions for correcting non-compliance areas.
2. The auditor will issue the audit report and track corrective action response, plan, and timelines until compliance is achieved. The audit reports shall be maintained on file by the auditing department. Internal Audit Reports are considered “confidential and for internal use only documents.”
3. As part of the Pharmacy’s internal management review process, annually the auditing department will provide Pharmacy management with an overall summary and status of each audit site and/ or internal trend information.
4. **References:** N/A
5. **Attachments:** N/A

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## 7.05 Product Recall

1. **Purpose:** This procedure describes the actions the Pharmacy shall take upon being notified of a Drug Recall or a Market Withdrawal. The recall or market withdrawal may originate from the drug manufacturer or wholesaler upon advice from an expert advisory committee or from information received from a regulatory agency (FDA).
2. **Scope:** This procedure applies to all drug products in inventory, staged for dispensing, or dispensed to patients. The Pharmacy Manager is responsible for taking immediate action to quarantine recalled or market withdrawn drugs or products upon notification.
3. **Definitions:**

**Drug Recall:** A drug recall is a situation where a drug product that has been distributed is found to be potentially harmful and must be pulled from stock and returned to a supplier. Usually, a recall is associated with a defective or contaminated product. Recalls can be either voluntary by the manufacturer or, rarely, mandated by FDA. Specific information about drug recalls is issued by FDA.

**Market Withdrawal:**  Drugs that are withdrawn from the market because the drug itself is potentially harmful to extent that the risks outweigh the benefits. Unlike recalls that may involve specific lots of a drug, a withdrawal involves a drug being completely taken off the market. Withdrawals, like recalls, can be either voluntary or mandated by the (FDA).

**Recall Classifications:** As defined per FDA.gov website.

**Class I Recall:** A situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death.

**Class II Recall:** A situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

**Class III Recall:**  A situation in which use of or exposure to a violative product is not likely to cause adverse health consequences.

**Medical Device Safety Alert:**  Issued by FDA in situations where a medical device may present an unreasonable risk of substantial harm. In some cases, these situations also are considered recalls.

1. **Safety Requirements:** Recalled or market withdrawn drug products will be segregated according to the notification instructions. If disposal is required, the proper safety handling or disposal methods will be followed in compliance with Pharmacy, city, or state regulations or practice. If the notification requires return of the drug product to the wholesaler and/ or drug manufacturer, documentation is required for accurate accounting of what was returned.
2. **Procedure:**

**Notification and Plan of Action**

1. The wholesaler or other notifying body will inform the Pharmacy directly via email or written letter when there is a Recall or Market Withdrawal for a drug product.
2. The communication shall contain the requirements for the specific lot or other pertinent drug product information.
3. Immediately upon notification, it is the responsibility of each pharmacist or Pharmacy Manager to immediately check Pharmacy inventory. All identified recalled or market withdrawn drug products shall be removed, segregated, and labeled to prevent use.
4. If there is no drug product in inventory stock, the pharmacist will sign the printed notification with "None in Stock" and sign/ date and file the notification.
5. As needed Senior Management, Quality, Legal, Marketing, or other Operational Departments may be involved in research of dispensed prescription records of the recalled or withdrawn drug product to identify all patients who may have received the drug or specific lots. These departments may also assist the Pharmacy with a plan of action for patient communication.
6. Patient communication shall include the proper steps for returning the medication or the proper disposal procedure and product credit information.
7. The Recall/ Withdrawal process will not be terminated until such a time as all impacted drug products are accounted for, all attempts have been made to retrieve, segregate, and isolate recalled or withdrawn medications, and disposal or returns are complete.
8. Recalled or Market Withdrawn product information such as identified inventory quantity, patient return quantity, or other applicable information shall be fully tracked, documented, and filed as part of Pharmacy control records by the pharmacist with support from the Quality Assurance Department. As needed, this information may be provided to the notifying body or agency.
9. **References:**

* [www.fda.gov/Safety/Recalls/default.htm](http://www.fda.gov/Safety/Recalls/default.htm)

1. **Attachments:** N/A

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# 8.0 Record Retention

## 8.01 Records and Retention

1. **Purpose:** This procedure describes record retention requirements followed by the Pharmacy for any records relating to Board of Pharmacy inspections and Pharmacy records.
2. **Scope:** This procedure applies to all Pharmacy personnel responsible for recordkeeping and record retention that complies with state and federal regulations. The pharmacist is responsible for knowledge of state Board of Pharmacy record retention requirements.
3. **Definitions:** N/A
4. **Safety Requirements:** N/A
5. **Procedure:**

**Recordkeeping and Retention**

* 1. Prescription Record shall be maintained by the Pharmacy as described in applicable state Board of Pharmacy retention requirements.
  2. The Pharmacist-in-Charge (PIC) will be responsible for recordkeeping of all Pharmacy records, ensuring they meet the retention period described in state or federal regulations, and are readily available for inspections.
  3. The PIC is responsible for record maintenance of all state, federal, or internal Audit or Inspection documents or reports and ensuring these records are readily available as needed.
  4. Record Retention Period: Records shall be retained for a period of time as described in state Board of Pharmacy regulations for the record retention period. A typical retention period is a minimum of 5 years from date signed.[[1]](#footnote-1)
  5. Retained Records shall be made available upon request for inspection by the Board or other authorized officers of the law.

1. **References:** N/A
2. **Attachments:** N/A

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## 8.02 Record Retention - Error Reports

1. **Purpose:** This procedure describes the record retention requirements for Error Reports at the Pharmacy.
2. **Scope:** This procedure applies to all Pharmacy personnel responsible for record maintenance and retention of Pharmacy error reports.
3. **Definitions:**

**Medication Error Reports:** Also known as Quality Event Reports. Reports that document the details of any act or omission in the dispensing process that may cause or lead to patient harm.

**MedWatch Report Form 3500:** The form used to report to FDA regarding safety information and adverse event information. It provides important and timely medical product information to health care professionals, including information on prescription and over-the-counter drugs, biologics, medical devices, and special nutritional products. Health care professionals and consumers can also report serious problems they suspect are related to certain FDA-regulated products. A MedWatch form is used by the Pharmacy to report adverse events.

**Customer Complaints or Quality Event Reports:**  All customer complaints or internal quality related events shall be reported to the Quality Assurance Department by Pharmacy personnel. Customer complaints or quality related events are investigated for root cause and corrective action by Quality Assurance in cooperation with Pharmacy personnel. This complaint information is documented on a Complaint Report form. These complaint files are maintained by QA.

1. **Procedure:**
   1. All reports listed in this procedure shall be retained either electronically using a secure database/ system and/ or hard copy file. The records shall be easily retrievable and maintained by Quality Assurance. As needed, the pharmacist may retain copies of these reports in the Pharmacy.
   2. Medication Error Reports: The record retention requirement for Medication Error Reports is 2 years from date of investigation completion.
   3. **MedWatch Report Form 3500: The record retention requirement is 2 years from date of submission to FDA.**
   4. Customer Complaints or Quality Event Reports:The record retention requirement for Complaint Records is 2 years from date of investigation completion.
2. **References:** N/A
3. **Attachments:** N/A

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## 8.03 Electronic Record Retention

1. **Purpose:** This procedure describes the Pharmacy’s requirements for electronic record retention.
2. **Scope:** This procedure applies to all Pharmacy personnel responsible for electronic record retention and compliance with state or federal regulations.
3. **Definitions:**

**Electronic Record:** A record created, signed, transmitted, and received in an electronic format in the Pharmacy.

1. **Safety Requirements:** N/A
2. **Procedure:**

**Electronic Recordkeeping**

1. If a prescription is created, signed, transmitted, and received electronically, all records related to that prescription must be retained electronically.
2. Records must be maintained electronically for 5 years[[2]](#footnote-2) from the date of their creation or receipt. This record retention requirement shall not pre-empt any longer period of retention that may be required now or in the future by any other federal or state law or regulation applicable to practitioners, pharmacists, or pharmacies.
3. Records regarding controlled substances prescriptions must be readily retrievable from all other records. Electronic records must be easily readable or easily rendered into a format that a person can read.
4. Electronic records must be made available for inspection upon request.
5. If a service provider ceases to provide an electronic prescription application or an electronic Pharmacy application or if the Pharmacy registrant ceases to use an application service provider, the application service provider must transfer any records subject to this part to the registrant in a format that the registrant's applications are capable of retrieving, displaying, and printing in a readable format.
6. If a registrant changes application providers, the registrant must ensure that any electronic records are migrated to the new application or are stored in a format that can be retrieved, displayed, and printed in a readable format.
7. If the Pharmacy transfers its electronic prescription files to another registrant, both registrants must ensure that the records are migrated to the new application or are stored in a format that can be retrieved, displayed, and printed in a readable format.
8. Digitally signed prescription records must be transferred or migrated with the digital signature.
9. **References:**

* [Title 21 CFR Part 1311 Subpart C-Electronic Prescriptions](http://www.deadiversion.usdoj.gov/21cfr/cfr/1311/subpart_c100.htm)

1. **Attachments:**  N/A

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## 8.04 Controlled Substance - Records Retention

1. **Purpose:** This procedure describes the Pharmacy’s record retention requirements for any Pharmacy Controlled Substance, records, reports, or forms.
2. **Scope:** This procedure applies to all Pharmacy personnel responsible for record retention of controlled substance records and compliance with state and federal regulations.
3. **Definitions:**

**Controlled Substance Records:** For this procedure, include the following:

* Executed and unexecuted official order forms: DEA Form 222 or the electronic equivalent
* Power of Attorney authorization to sign order forms (See Section 13.0, FM-8)
* Receipts and/ or invoices for Schedules III, IV, and V controlled substances
* All inventory records of controlled substances, including the initial and biennial inventories, dated as of beginning or close of business
* Records of controlled substances distributed (i.e., sales to other registrants, returns to vendors, distributions to reverse distributors)
* Records of controlled substances dispensed (i.e., prescriptions, Schedule V logbook)
* [Reports of Theft or Significant Loss (DEA Form 106)](http://www.deadiversion.usdoj.gov/21cfr_reports/theft/index.html), if applicable
* [Inventory of Drugs Surrendered for Disposal (DEA Form 41)](http://www.deadiversion.usdoj.gov/21cfr_reports/surrend/index.html), if applicable
* Records of transfers of controlled substances between pharmacies
* DEA registration certificate
* Self-certification certificate and logbook (or electronic equivalent) as required under the Combat Methamphetamine Epidemic Act of 2005
* Controlled Substance Program Monitoring records

1. **Safety Requirements:** N/A
2. **Procedure:**

**General Requirements**

* 1. The Pharmacy must maintain complete and accurate records on a current basis for each controlled substance purchased, received, stored, distributed, dispensed, or otherwise disposed of. These records are required to provide accountability of all controlled substances from the manufacturing process through the Pharmacy and to the ultimate user. The closed system reduces the potential for diversion of controlled substances.
  2. All required records concerning controlled substances must be maintained for at least 2 years for inspection and copying by duly authorized DEA officials.
  3. Records and inventories of Schedule II controlled substances must be maintained separately from all other records of the registrant. All records and inventories of Schedules III, IV, and V controlled substances must be maintained either separately from all other records or in such a form that the information required is readily retrievable from the ordinary business records.

**Retrievable Records**

* 1. Readily retrievable records are defined as:
* Records kept by automatic data processing systems or other electronic or mechanized recordkeeping systems in such a manner that they can be separated out from all other records in a reasonable time.
* Records kept in such a manner that certain items are asterisked, redlined, or in some other manner visually identifiable apart from other items appearing on the records.
  1. Central Recordkeeping: A registrant desiring to maintain shipping and financial records (but not executed official order forms) at a central location rather than the registered location must submit written notification of his/ her intention by registered or certified mail, return receipt requested, in triplicate, to the Special Agent in Charge of the local DEA Diversion Field Office in which the registrant is located (Appendix K). Unless the registrant is informed by the DEA that the permission to keep central records is denied, the registrant may begin maintaining central records 14 days after DEA receives this notification. Central recordkeeping requirements are described in 21 CFR 1304.04. Central recordkeeping permits are no longer issued by the DEA.
  2. Prescription Records: Pharmacies have two options for filing prescription records under the C.F.R. If there is a conflict between federal and state requirements for filing prescriptions, DEA recognizes that the Pharmacy must choose a filing system that would comply with both federal and state law. All prescription records must be readily retrievable for DEA inspection. Controlled substance prescriptions must be filed in one of the following ways:
     + Paper Prescriptions Records Option 1 (Three separate files):
* A file for Schedule II controlled substances dispensed
* A file for Schedules III, IV and V controlled substances dispensed
* A file for all non-controlled drugs dispensed
* Paper Prescriptions Records Option 2 (Two separate files):
* A file for all Schedule II controlled substances dispensed
* A file for all other drugs dispensed (non-controlled and those in Schedules III, IV, and V). If this method is used, a prescription for a Schedule III, IV, or V drug must be made readily retrievable by use of a red "C" stamp not less than one inch high. If the Pharmacy has an electronic recordkeeping system for prescriptions which permits identification by prescription number and retrieval of original documents by prescriber’s name, patient’s name, drug dispensed, and date filled, the requirement to mark the hard copy with a red “C” is waived.
* Electronic Prescription Records
* If a prescription is created, signed, transmitted, and received electronically, all records related to that prescription must be retained electronically.
* Electronic records must be maintained electronically for two years from the date of their creation or receipt. However, this record retention requirement shall not pre-empt any longer period of retention which may be required now or in the future, by any other federal or state law or regulation applicable to pharmacists or pharmacies.
* Records regarding controlled substances must be readily retrievable from all other records. Electronic records must be easily readable or easily rendered into a format that a person can read.
  1. Records of electronic prescriptions for controlled substances shall be maintained in an application that meets the requirements of [21 CFR 1311](http://www.deadiversion.usdoj.gov/21cfr/cfr/2111cfrt.htm). The computers on which the records are maintained may be located at another location, but the records must be readily retrievable at the registered location if requested by DEA or other law enforcement agent. The electronic application must be capable of printing out or transferring the records in a format that is readily understandable to an Administration or other law enforcement agent at the registered location. Electronic copies of prescription records must be sortable by prescriber name, patient name, drug dispensed, and date filled.

1. **References:**

* US Dept. of Justice, Drug Enforcement Administration Office of Diversion Control-Pharmacist Manual Section I-VIII
* [SOP 5.03 - Controlled Substance Prescription Monitoring Program](#page150)
* [SOP 5.04 - DEA Form 222 Ordering/ Processing/ Receiving](#page154)

1. **Attachments:** N/A

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| Prepared by/Date: | Approved by/Date: |

## 8.05 Record Retention - Invoices and Wholesale Receipts

1. **Purpose:** This procedure describes the record retention requirements for Invoices and Wholesaler receipts at the Pharmacy.
2. **Scope:** This procedure applies to all Pharmacy personnel responsible for record maintenance and retention of Pharmacy invoices and wholesale receipts.
3. **Definitions:** N/A
4. **Safety Requirements:** N/A
5. **Procedure:**
6. **Invoice Records:** For Pharmacy purchase requisition orders of Pharmacy materials or drugs from established contracts with vendors, the Pharmacy will have each order received:
   * Inspected against the invoice record and verified for accuracy.
   * Verified by the pharmacy technician, who shall stamp the invoice with the date received and initial the invoice record.
   * Forwarded to the Pharmacy Manager or PIC for review and record retention.
   * In the event there is a discrepancy in the order, inform the PIC or Pharmacy Manager who will contact the vendor to address the discrepancy.
7. **Wholesaler Receipts/ Records:** Upon receipt of a wholesaler’s order, the pharmacy technician will:
   * **V**erify all contents against the invoice.
   * If contents in the order are found acceptable, the technician will stamp the invoice with the date received and initial the invoice.
   * Forward the invoice document to the Pharmacy Manager or PIC for review and record retention.
   * In the event there is a discrepancy in the order, inform the PIC or Pharmacy Manager, who will contact the vendor to address the discrepancy.
8. **Recordkeeping*:*** The Pharmacy shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs. These records shall include the following information:
   * 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.
   * The identity and quantity of the drugs received and distributed or disposed of.
   * The dates of receipt and distribution or other disposition of the drugs.

Inventories and records shall be made available for inspection and photocopying by authorized federal, state, or local law enforcement agency officials for a period of 3 years after the date of their creation.

1. **Record Retention Period:** Records described in this section kept at the Pharmacy site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within 2 working days of a request by an authorized official of a federal, state, or local law enforcement agency.

Inventories and records shall be made available for inspection and photocopying by authorized federal, state, or local law enforcement agency officials for a period of 3 years after the date of their creation.

1. **References:** N/A
2. **Attachment:** N/A

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## 8.06 Retaining Patient Medication History

1. **Purpose:** This procedure describes the various equipment and patient records that must be maintained by the Pharmacy according to state and federal law.
2. **Scope:** This procedure applies to pharmacists, pharmacy technicians, and pharmacy personnel.
3. **Definitions:**

**Maintenance of Pharmacy Records:**  Pertaining to equipment and pharmacy/ patient computerized systems used in the practice of pharmacy. Extremely important to patient safety, the practice of pharmacy, and compliance with state and federal laws.

1. **Safety Requirements:** N/A
2. **Procedure:**  Examples of records required to be maintained by the Pharmacy include:

* Patient record system.
* Dispensing records for prescription orders.
* Security/ confidentiality records and policies and procedures to safeguard protected health information (PHI) such as the patient's name, address, DOB, gender, list of prescription orders dispensed for each patient, etc.
* Pharmacy computer system maintenance according to manufacturer recommendations.
* Maintenance of other equipment used in the practice of pharmacy, like automatic counting machines, according to manufacturer recommendations.
* List of all prescription orders dispensed by the Pharmacy for the preceding \_\_\_ years.
* Prescription files.
* Prescription drug inventories as required by state and federal law, such as the biennial controlled substance inventory required by the Controlled Substances Act.
* Drug orders/ receipts from wholesalers or manufacturers as well as drug disposition records.
* Current state and federal regulations and statutes relating to the practice of pharmacy.
* Records of all state/ federal inspections of the Pharmacy, letters of warning, etc.
* Records of personnel on duty in the Pharmacy.
* Pharmacy personnel job descriptions.
* Quality assurance records.
* Policies and procedures for processing prescriptions.
* Records that Pharmacy personnel read and understood the Pharmacy policies and procedures.
* Records of immunizations to include the patient receiving the immunization, who administered the immunization, the vaccine administered, etc.
* Any collaborative protocols with practitioners.

1. **References:** N/A
2. **Attachments:** N/A

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# 9.0 Safety

## 9.01 Bloodborne Pathogen Exposure Control Panel

1. **Purpose:** This procedure describes the standard precautions for bloodborne pathogen exposure and control plan for Pharmacy personnel.

The Pharmacy is committed to providing a safe and healthy work environment for its personnel. In pursuit of this goal, the exposure control plan (ECP) described in this procedure is provided to eliminate or minimize occupational exposure to bloodborne pathogens in accordance with OSHA Standard [29 CFR1910.1030](https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_id=10051&p_table=STANDARDS) “Occupational Exposure to Bloodborne Pathogens.”

1. **Scope:** This procedure applies to all personnel.
2. **Definitions:**

**Bloodborne Pathogens:** A microorganism present in human blood and other bodily fluids that can cause disease. Bloodborne pathogens include the hepatitis B virus, hepatitis C virus, and human immunodeficiency virus (HIV). These pathogens may be transmitted through the exchange of blood or other potentially infectious materials, including cerebrospinal fluid, synovial fluid, pleural fluid, amniotic fluid, pericardial fluid, peritoneal fluid, semen, vaginal secretions, or any body fluid contaminated with blood.

1. **Safety Requirements:** All safety precautions should be followed.
2. **Procedure:**

**Exposure and Control Plan Requirements**

* 1. Determination of Employee Exposure: It is the responsibility of the Pharmacist-in-Charge (PIC) to outline and identify employee exposure risks, based on the job description and tasks.
  2. Methods of Exposure Control: It is the responsibility of the PIC to identify and implement the following methods for exposure control including:
     + Use of universal precautions
     + Engineering and work practice controls
     + Personal protective equipment (PPE)
     + Housekeeping
     + Hepatitis B vaccination
     + Post-exposure evaluation and follow-up procedures
     + Communication of hazards to personnel and training
     + Record-keeping
     + Procedures for evaluating circumstances regarding exposure incidents
  3. Training**:** ThePIC is responsible for implementation of this exposure control plan and performing initial training for all impacted Pharmacy personnel. The PIC is responsible for ensuring that all impacted Pharmacy personnel are trained to this procedure upon hire and annually. Training should be documented.
  4. Personal Protective Equipment (PPE): The Pharmacy must provide appropriate and necessary PPE, engineering controls (sharps containers), labels, and red bags as required for exposure control in the Pharmacy work environment. The pharmacist must ensure these supplies are available at the work location.

**Methods of Implementation and Control**

* 1. Universal or Standard Precautions: All personnel must follow universal/ standard precautions in the Pharmacy. Universal/ standard precautions require that personnel use PPE to prevent direct contact with a patient’s blood or bodily fluids.
  2. Engineering Controls: Pharmacy work areas are required to have controls that have been demonstrated to significantly reduce an occupational hazard. One example of an engineering control for bloodborne pathogens in the Pharmacy is the use of sharps containers for safe disposal of sharps contaminated with blood or body fluids.
  3. Work Practice Controls: Work practice controls are implemented controls to change the way in which a task is performed to reduce the likelihood of exposure of bloodborne pathogens. The following are common work practice controls used in the Pharmacy:
     + Hand Washing– Contaminated hands should be washed with soap and water as soon as possible. There must be hand washing facilities that are readily accessible to personnel. All Pharmacy personnel shall wash their hands frequently. There should also be appropriate antiseptic hand cleanser in the work areas.
     + Contaminated Sharps– Contaminated needles, syringes or other contaminated sharps are not to be bent, broken, recapped, or removed. Contaminated sharps must be placed into a puncture resistant, leak-proof container displaying a biohazard label.
     + Food, Drink, and Personal Care Activities– Eating, drinking, smoking, applying cosmetics or lip balm, and handling contact lenses are prohibited in a work area where there is a reasonable likelihood of occupational exposure to bloodborne pathogens. Food and drink must not be stored in refrigerators, freezers, shelves and cabinets or on countertops or bench tops where blood or other potentially infectious materials are present.
     + Splash Protection – All procedures involving blood or other potentially infectious materials must be performed in such a manner as to minimize splashing, spraying, spattering, or the creation of droplets of these substances.
     + Pipetting – Mouth pipetting/ suctioning of blood or other potentially infectious materials is not allowed.
     + Specimen Containers– Specimens of blood or other potentially infectious materials are to be placed in a leak-proof container that displays a biohazard label during collection, handling, processing, storage, transport, or shipping. If the specimen could puncture or if outside contamination of the primary container occurs, the primary container must be placed within a second labeled, leak-proof container.
  4. Personal Protective Equipment: PPE are specialized clothing and equipment worn in the Pharmacy to protect against hazards such as contamination from blood or other potentially infectious materials.  The following are required types of PPE for the Pharmacy:
     + Gloves– Gloves are to be worn when it can reasonably be anticipated that Pharmacy personnel may have hand contact with blood, other potentially infectious materials, or mucous membranes or when handling or touching contaminated items or surfaces. Disposable gloves, such as surgical or examination gloves, must be replaced as soon as practical when contaminated or as soon as feasible when they are torn, punctured, or their ability to function as a barrier is compromised.
     + Masks, Eye Protection and Face Shields– Masks in combination with eye protection devices such as goggles or glasses with solid side shields or chin-length face shields are to be worn whenever splashes, spray, spatter, or droplets of blood or other potentially infectious materials may be generated and eye, nose, or mouth contamination can be reasonably anticipated.
     + Gowns, Aprons, and Other Protective Body Clothing– Appropriate protective clothing, such as gowns, aprons, lab coats, clinic jackets, or similar outer garments, are to be worn in occupational exposure situations. The type and characteristics will depend on the tasks and degree of exposure anticipated.
     + Universal Biohazard Sign– The universal biohazard sign must be used to alert personnel that containers may contain infectious materials.  Secondary containers used for manually transporting specimens/ waste must display the biohazard sign. The primary specimen container and accompanying tags and/ or labels must be free of any contamination.
     + Contaminated Equipment– Contaminated equipment must be cleaned if contaminated with blood or other potentially infectious materials using an EPA-approved disinfectant detergent or an appropriate dilution of bleach and water.
     + Housekeeping– The Pharmacy must be maintained in a clean and sanitary condition. Follow SOP 11.04 - General Housekeeping.  All equipment and work surfaces must be cleaned and decontaminated with an appropriate disinfectant after completion of procedures or immediately after spills.
     + Clean-up of Spills – Spills may occur when containers of potentially infectious materials are dropped or when an injured person drips blood on the floor. To clean a spill:
       - Limit access to area
       - Use an appropriate type of “Pharmacy spill kit”
       - Wear appropriate PPE
       - Use paper towels soaked with a suitable disinfectant to clean the spill
       - Allow solution to stand for appropriate amount of time to adequately disinfect
       - Place all contaminated materials and PPE into a plastic bag and tie
     + Waste Disposal: Dispose of waste material into an appropriately labeled biohazard waste container. Follow SOP 5.13 - Disposing of Biohazard Waste.
  5. Exposure Incident: In the event of a bloodborne pathogen exposure, immediately perform first aid and inform a supervisor or manager and seek further medical attention or evaluation.
     + The incident should be documented to include routes of exposure and how the exposure occurred.
     + The PIC should review and investigate all circumstances surrounding any exposure incident to determine:
       - Whether engineering controls were in use
       - What work practices were followed
       - What equipment or devices were used or involved in the incident
       - Whether PPE was used
       - The location where the incident occurred
       - What procedures were being performed when incident occurred
       - The employee training
       - Other pertinent information

This review should be documented and maintained on file.

* + - As needed based on incident information, procedures may be revised or process changes may be addressed. Required training for changes or awareness will be performed and documented.

1. **References:**

* [29 CFR 1910.1030 - OSHA-Occupational Exposure to Bloodborne Pathogens](https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_id=10051&p_table=STANDARDS)
* [SOP 11.04 - General Housekeeping](#page279)
* [SOP 5.13 - Disposing of Biohazard Waste](#page181)

1. **Attachments:** N/A

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## 9.02 Cleaning Chemical Spills

1. **Purpose:** This procedure describes the process for cleaning up chemical spills that occur in the Pharmacy.
2. **Scope:** This procedure applies to all Pharmacy personnel.
3. **Definitions:**

**Chemical Spill:** An accident or the unintentional release of one or more hazardous substances that can harm human health or the environment.

**MSDS (Material Safety Data Sheet):** A written document that outlines information and procedures for handling and working with chemicals.

1. **Safety Requirements:** All Pharmacy safety policy and procedures shall be followed.
2. **Procedure:**

**Cleaning Chemical Spills**

* 1. The Pharmacy must properly stock and maintain clearly labeled and suitable spill kits. All Pharmacy personnel must be trained on safety procedures.
  2. Upon identifying a chemical spill, Pharmacy personnel must immediately alert their supervisor or manager in the area. Notify the Pharmacist-in-Charge (PIC), who may evaluate the situation and elect to evacuate the area as necessary.
     + The PIC shall also identify trained personnel for chemical spill cleanup.
     + Trained personnel shall reference the MSDS sheet for the spilled material or the Pharmacy spill response plan.
  3. Call 911 if immediate medical attention is needed
  4. Flammable Material Spills: If the spill involves a flammable material, immediately turn off any source of ignition in the Pharmacy such as Bunsen burners or any other equipment that uses heat or an open flame or has electrical current.
  5. Gowning for Spill Clean-Up: Trained cleanup personnel must wear the personal protective equipment (PPE) appropriate to the hazards. PPE should be easily located in the Pharmacy. PPE include: face shield/ goggles, lab coat/ apron, nitrile gloves, and any other PPE listed in the MSDS.
  6. Spill Size:
     + A minor spill (less than 1 gallon or 4 liters) of a known material should be cleaned up immediately by trained Pharmacy personnel.
     + A moderate size spill (more than 1 gallon or 4 liters) of a known material should be cleaned up immediately by trained Pharmacy personnel.
     + Larger spills of unknown materials (more than 5 gallons) that may result in fire or explosion or spills that are immediately dangerous to life and health or where injury has occurred should be treated as emergencies. Evacuate the immediate area of the spill and call 911 for assistance.

In the event that a chemical spill has caused an employee to suffer a corrosive chemical exposure to the eyes or body, carefully assist the injured person to an eyewash, shower, or combination unit, until medical assistance arrives.

* 1. Spills and Drains:For minor and moderate size spills, contain the spill (consult MSDS for proper absorbent materials to use, such as paper towels, sand, vermiculite, or other such materials). Immediately protect all floor drains with absorbent material to prevent an environmental release.
  2. Containing the Spill: Use the proper absorbent materials to surround the spill to begin to absorb.

**Disposal of Cleaning Material after Cleanup:**

* 1. When spill materials have been absorbed, place materials into an appropriate container (i.e. plastic bag, trash can with lid, or other container per MSDS).
  2. Dispose of as per MSDS instructions.

**Decontamination of Area after Cleanup**

* 1. As standard Pharmacy practice, after a chemical spill is cleaned up, decontaminate the area with a mild detergent or approved cleaner and water before Pharmacy work resumes.

1. **References:** [US. Dept. of Labor: OSHA Safety Data Sheet Information](https://www.osha.gov/Publications/OSHA3514.html)

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## 9.03 Patient Injury

1. **Purpose:** This procedure describes the Pharmacy requirements for immediate reporting of patient injury claims that may be reported to a Pharmacist-in-Charge (PIC) or Pharmacy personnel.
2. **Scope:** This procedure applies to all personnel.
3. **Definitions:**

**Complaint Reporting System:**  The reporting process used to report, document, and track complaint/ quality related event information can be a secure electronic system/ database and/ or a hard copy Customer Complaint form. The reporting system used must have limited access to Electronic Health Information (ePHI) and individually-identifiable health information (IIHI).

1. **Safety Requirements:** N/A
2. **Procedure:**

**Receiving a Patient Injury Claim**

* 1. Pharmacy personnel who receive communication from a patient or customer regarding a Pharmacy error or an injury claim has the responsibility to report the information using SOP 7.02 - Customer Complaints or Quality Related Events.
  2. This reporting process requires documentation of all information relating to the customer/ patient complaint or event and/ or injury claim, including:
* Names, addresses, and phone numbers of the individual affected
* The postal and e-mail address and phone number
* Name, address, and phone number of doctor or hospital if emergency treatment was provided
* Drug name and dosage, product codes, or identifying marks on the label or container
* Name and address of the pharmacy where the product was purchased and date of purchase
* Name and address of the company on the product label
* Other applicable information for the complaint type
  1. The PIC should inform the patient/ customer of the Pharmacy complaint process and communicate with them as needed.
  2. Complaint/ QRE Review:The received Complaint/ QRE information will be reviewed by the PIC and evaluated for possible quick resolution.
  3. Investigation: The investigation may require researching records pertaining to the event, such as hard copy prescription(s), inventory records, or other types of records.
* The PIC may need to make follow-up contact with the patient/ customer as part of the investigation. This communication should be documented in the complaint file.
* When all investigation information is complete and a root cause of the problem identified, the PIC is responsible for communicating a resolution to the patient/ customer. This information will be documented in the complaint file.
* Please refer to Attachment 1 of this procedure for Pharmacy Precautionary Measures, which are best practice strategies for minimizing dispensing errors in the Pharmacy.

1. **References:**

* [SOP 7.02 - Customer Complaints and Quality Related Events](#page225)

1. **Attachment:**

* Attachment 1 - **Pharmacy Precautionary Measures**

**Attachment 1 – Pharmacy Precautionary Measures**

**Note:** To the Policy Maker only. Delete prior to publication.*This is a list of suggested strategies the pharmacists and Pharmacy personnel may adopt in order to reduce the risk of causing a patient harm by means of medication error.*

1. Ensure correct entry of the prescription.

2. Confirm that the prescription is correct and complete.

3. Beware of look-alike, sound-alike drugs.

4. Be careful with zeroes and abbreviations.

5. Organize the workplace.

6. Reduce distractions when possible.

7. Focus on reducing stress and balancing heavy workloads.

8. Take the time to store drugs properly.

9. Thoroughly check all prescriptions.

10. Always provide thorough patient counseling.

11. Best Practices during Patient Counseling:

* Open the container and show the actual medication to the patient during counseling rather than delivering it to the patient in a sealed bag. Completing this process will provide an opportunity for the patient to see the medication and ask questions if it looks different from what they have been taking.
* Counseling should also include instructions on how to take the medication and appropriate route of administration. Many dispensing errors are attributed to misunderstood directions for use. Educating patients about safe and effective use of their medication promotes patient involvement in their health care, which will likely reduce medication errors.

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## 9.04 Safe Handling and Lifting

1. **Purpose:** This procedure describes safe handling and lifting methods and requirements.
2. **Scope:** This procedure applies to all personnel.
3. **Definitions:** N/A
4. **Safety Requirements:** One of the biggest causes of back injuries at work is lifting or handling objects incorrectly. Learning and following the correct method for lifting and handling heavy loads can help to prevent injury and avoid back pain.
5. **Procedure:**

**Safe Handling and Lifting**

1. Manual handling involves any activity in the Pharmacy that requires the use of force exerted by a person to lift, lower, push, pull, carry or otherwise move or hold an object. Some Pharmacy tasks that involve manual handling are carrying boxes and retrieving and carrying heavy containers.
2. The following are suggested guidelines to use and follow in the Pharmacy for proper safe handling:

* Store and place materials that need to be manually lifted and transported at about mid-thigh to mid-chest.
* Minimize bending and reaching by placing heavy objects on shelves, tables, or racks at about mid-thigh to mid-chest.
* Break down loads into smaller units/ packages as needed to reduce the weight. Place materials in containers without handles into containers with good handles.
* Ask suppliers to package their materials in containers with proper handles.
* Rotate tasks so personnel are not exposed to the same activity for too long.
* Work in teams for heavy lifting tasks.

1. Lifting: Plan the lift before beginning:

* Determine where the load will be placed.
* Use appropriate handling aids where possible.
* Determine whether help is needed to move the load.
* Remove obstructions, such as discarded wrapping materials in the path where you will be walking.
* For long lifts, such as from floor to shoulder height, consider resting the load mid-way on a table or bench to change your grip on it.

1. Keep the load close to your waistfor as long as possible while lifting. The distance of the load from the spine at waist height is an important factor in the overall load on the spine and back muscles. Keep the heaviest side of the load next to the body. If closely approaching the load is not possible, try to slide it towards the body before trying to lift it.
2. Stand in a Stable Position:Your feet should be apart with one leg slightly forward to maintain balance (alongside the load if it's on the ground). Be prepared to move your feet during the lift to maintain a stable posture. Wearing over-tight clothing or unsuitable footwear, such as heels or flip flops, may make this difficult.
3. Holding the Load: Where possible, hug the load close to the body. This may be a better option than gripping it tightly with the hands only. Keep your elbows close to your body and keep the load as close to your body as possible.
4. Do not bend your back when lifting. A slight bending of the back, hips, and knees at the start of the lift is preferable to either fully flexing the back (stooping) or fully flexing the hips and knees – in other words, fully squatting.
5. Do not flex back any further while lifting. This can happen if legs begin to straighten before starting to raise the load.
6. Do not twist when lifting. Avoid twisting the back or leaning sideways, especially while the back is bent. Keep your shoulders level and facing the same direction as the hips. Turning by moving your feet is better than twisting and lifting at the same time.
7. Keep your head up when handling the load. Look ahead, not down at the load, once it has been held securely.
8. Move Smoothly: Do not jerk or grab the load as this can make it harder to keep control and increase the risk of injury.
9. Know your limits. Do not handle or lift more than you can easily manage. There is a difference between what you can lift and what you can lift safely. If you are in doubt about lifting an item in the Pharmacy, ask for help or assistance.
10. Putting the Load Down: Lower the load down and then adjust. If you need to position the load precisely, put it down first then slide it into the desired position.
11. **References:**

* <http://www.osha.gov>

1. **Attachments:** N/A

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# 10.0 Security

## 10.01 Authorized Entry

1. **Purpose:** This procedure describes the rules for authorized entry at the Pharmacy to ensure safety and security.
2. **Scope:** This procedure applies to all Pharmacy personnel responsible for complying with state or federal regulations for authorized pharmacy entry.
3. **Definitions:** N/A
4. **Safety Requirements:** N/A
5. **Procedure:**
   1. A pharmacist employed by the Pharmacy shall ensure that the Pharmacy is physically secure while the pharmacist is on duty.
   2. A pharmacist shall ensure that the Pharmacy area and any additional storage area for drugs that requires restricted access only be accessed by a pharmacist and be locked when a pharmacist is not present, except in an extreme emergency.
   3. A pharmacist is the only person permitted to unlock the Pharmacy area or any additional storage area for drugs restricted to access only by a pharmacist, except in an extreme emergency.
   4. Pharmacy interns, graduate interns, pharmacy technicians, pharmacy technician trainees, support personnel, and other designated personnel shall NOT be permitted in the Pharmacy area unless a pharmacist is on duty, except in an extreme emergency.
   5. The prescription area of the Pharmacy may not be open without a licensed pharmacist on duty at all times.
   6. A pharmacist shall follow the guidelines in SOP 10.03 - Key Control Procedure.
6. **References:**

* [SOP 10.03 - Key Control Procedure](#page264)

1. **Attachments:** N/A

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## 10.02 Burglary Procedure

1. **Purpose:** This procedure outlines the process to be followed by Pharmacy personnel after a burglary event.
2. **Scope:** This procedure applies to all Pharmacy personnel.
3. **Definitions:**

**Burglary:** The unlawful entering into any property with intent to commit a crime. In most jurisdictions, no forced entry is required to meet the definition of burglary. No property has to be removed. However, most often we think of burglary as a forced entry to commit theft.

1. **Safety Requirements:** All company safety policy and procedures shall be followed during a burglary event. Do not place yourself in an unsafe situation. As soon as possible after the event, contact law enforcement and Pharmacy senior management for investigation.
2. **Procedure:**
   1. Burglary Facts
      * Pharmacies have always been an attractive target for burglars.
      * Burglaries against pharmacies are increasing at an alarming rate.
      * Preventing burglaries is difficult, but not impossible. The object is to make a pharmacy less attractive to a potential thief so he/ she/ they move along to an easier target.
   2. Make the Pharmacy a Less Attractive Target
      * Arrange stock shelves so that the most targeted drugs are not visible from windows.
      * Rearrange stock shelves periodically so that the most targeted drugs are not always in the same location.
      * Pharmacy personnel should never discuss company inventory controls with anyone.
      * All stores must have an installed Alarm System and a Video Surveillance system.
      * Interior lights will be left on in strategic locations after hours, making it difficult for an intruder to hide once inside.
   3. Video Surveillance and Alarm Systems
      * The Pharmacy shall maintain video security surveillance. Video surveillance should be capable of remote viewing, have available recording for several days’ time, and be able to be downloaded to a USB drive.
      * Each store Pharmacist-in-Charge (PIC) must be trained on the use and operation of this system.
      * Each store is required to have a professionally installed alarm system. Each PIC is responsible for the use and operation of the alarm system and the confidential store ID code.
      * False Alarms: In the event of a FALSE ALARM, please contact the appropriate security company and provide them the confidential store ID Code. This code must be maintained confidential and communicated to only those with a need to know.
   4. Safety Awareness and Confidentiality
      * Pharmacy personnel must maintain safety awareness and watch for suspicious behavior(s) from customers.
      * Management and Pharmacy personnel should refrain from discussing store procedures, inventory controls, cash handling, store layouts, security systems, etc. with any outsider (including family), other than law enforcement personnel and/ or vendors with a legitimate interest in a particular system.
      * The Pharmacy shall restrict access, keys, or combinations to as few personnel as is feasible.
      * The Pharmacy will deposit checks and cash nightly to keep minimal amounts of cash on hand at any one time. NO cash will be left in cash registers overnight.
   5. Discovering a Burglary
      * The person discovering a pharmacy burglary, must immediately CALL THE POLICE (911) – even if the alarm has been triggered. If the PIC or Pharmacy Manager has been contacted at home by the security company, they must respond to the store to assist law enforcement with their investigation. If law enforcement has not arrived, wait for them before conducting your own investigation and/ or placing yourself in an unsafe situation.
      * If necessary and safe, lock the doors. Prevent anyone from entering. When law enforcement arrives, greet them and assist in assessing whether or not the premises are secure.
      * Preserve the crime scene for the law enforcement investigators. Do not touch anything the burglar may have touched and block off any areas to protect evidence they may have left behind.
      * If necessary, post signs at store entries that the “store opening will be delayed.”
      * If there has been damage to the property, call credentialed contractors for repairs as soon as possible to protect property on the premises from further damage or loss.
      * At this point, turn the matter over to the law enforcement officials. Cooperate fully!
      * Refer all inquiries (media, etc.) to the responding law enforcement officials.
      * Do not discuss items taken with anyone other than law enforcement officials.
      * The PIC or Pharmacy Manager shall call the alarm company to reset or repair the alarm system if necessary.
      * When safe or as soon as possible, the PIC or Pharmacy Manager shall contact Pharmacy senior management to inform them of the burglary event and status.
      * As needed, senior management will file a claim for the event with the insurance company and obtain instructions on the claim process.
      * Documentation: When safe or as soon as possible, the PIC or Pharmacy Manager shall fill out any required reports for the Security, insurance company, police, or other types of documents related to the burglary event. The PIC or Pharmacy Manager shall keep a copy of each form filled out and these will be maintained at the site.
      * As soon as possible, the PIC or Pharmacy Manager shall obtain a copy of the Law Enforcement’s official written report. This will be maintained on site.
3. **References:** N/A
4. **Attachments:** N/A

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## 10.03 Key Control Procedure

1. **Purpose:** This procedure describes the process for controlling Pharmacy keys issued to Pharmacy personnel to ensure safety and security.
2. **Scope:** This procedure applies to all Pharmacy personnel responsible for issuing Pharmacy keys and/ or receiving issued keys to secure locations in the Pharmacy.
3. **Definitions:** N/A
4. **Safety Requirements:** This procedure applies to all areas of the Pharmacy that require access with the use of keys to doors, locks, safe combinations, or other controlled and secured access.
5. **Procedure:**

**General Requirements**

* 1. A pharmacist employed by the Pharmacy shall ensure that the Pharmacy is physically secure while the pharmacist is on duty.
  2. A pharmacist shall ensure that the Pharmacy are, and any additional storage area for drugs that is restricted to access only by a pharmacist is locked when a pharmacist is not present, except in an extreme emergency.
  3. A pharmacist is the only person permitted to unlock the Pharmacy area or any additional storage area for drugs restricted to access only by a pharmacist, except in an extreme emergency.
  4. Pharmacy interns, graduate interns, pharmacy technicians, pharmacy technician trainees, support personnel, and other designated personnel shall be permitted in the Pharmacy area only when a pharmacist is on duty, except in an extreme emergency.
  5. The prescription area of the Pharmacy may not be open without a licensed pharmacist on duty at all times.
  6. A pharmacist shall secure prescription medication inside the locked Pharmacy, except when using an automated storage and distribution system.
  7. The Pharmacy Manager or the Pharmacist-in-Charge (PIC) shall maintain a list of issued keys to authorized pharmacy personnel that includes the name and date issued and the key number or other information. Upon the termination of any pharmacy personnel, all assigned keys will be accounted for and retrieved/ returned.

**Key and Lock Control**

* 1. Security Key Control Officers: A Pharmacy Manager or PIC shall be the responsible “security key control officers” and maintain key and lock control in the Pharmacy. This requires:
* Maintaining a recordkeeping system that cross-references keys used in the Pharmacy, alphabetically or numerically, to facilitate quick identification of the key needed for a particular lock, door, or other secure area of the Pharmacy.
* Maintains accurate inventories of padlocks in use, master keys for cabinets, key blanks, and all keys currently in use.
* Maintains, for the historical record, a collection of reference material on locking devices and systems, including devices and systems previously used in the Pharmacy. This includes safe combinations/ codes for security surveillance systems or other devices.
* Training Pharmacy personnel on key control procedure. The security key control officer is responsible for all administrative duties, including recordkeeping concerning keys and locks.
* The security key control officer shall enforce procedures for protecting the integrity of all safe combinations.
* The security key control officer shall maintain all preventive maintenance records for keys/ locks/ locked storage cabinets or other devices.
  1. Pharmacy keys shall be strictly controlled. These controls include:
* Maintaining Pharmacy keys in a restricted key cabinet in a secure area of the Pharmacy, and issuing them only to authorized Pharmacy personnel.
* Maintaining a second set of Pharmacy keys in a controlled area of the Pharmacy that is known only to the Pharmacy Manager or the PIC.
* In the event of an emergency that necessitates entry into the Pharmacy by anyone other than authorized Pharmacy personnel, the highest-ranking Manager on Duty may authorize immediate entry to the Pharmacy. The Manager shall then document the reasons for entry and sign the authorization.
  1. Records: All records for key control and or other related records described in this procedure shall be maintained on file by the security key control officer in a readily retrievable manner.

1. **References:** N/A
2. **Attachments:** N/A

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## 10.04 Parking Lot Security

1. **Purpose:** This procedure describes the Pharmacy's parking lot security measures to ensure a secure environment for all customers and patients of the Pharmacy.
2. **Scope:** This procedure applies to Pharmacy personnel responsible for parking lot security.
3. **Definitions:**

**Security Company:** A contracted or outside service hired to provide security personnel and services for monitoring Pharmacy parking lot or other areas.

**Digital Video Surveillance:** Security monitoring using professionally installed security cameras in key areas and connected to a digital video recording device.

1. **Safety Requirements:** N/A
2. **Procedure:**

**Use of Security Company**

* 1. Pharmacy may elect to use the services of a security company for ongoing area security.
  2. Pharmacy Building and Grounds Lighting: All entrances and Pharmacy parking lots are illuminated at night.
  3. Pharmacy Building and Grounds Security: A security company will provide security services after close of Pharmacy business hours.
* Security personnel will work from: 7 p.m. to 5 a.m.
* The security personnel are responsible for patrolling the Pharmacy parking lot areas regularly throughout the shift.
* Security rounds or patrolling will take place at different times and be scheduled each day.
* The security company will provide Pharmacy routine security reports. These reports shall be maintained in the Pharmacy.

**Digital Video Surveillance**

* 1. The Pharmacy may elect to use a digital video surveillance system for ongoing area security.
* Security cameras will be installed by a professional company in critical areas of the Pharmacy.
* The system shall be set up to record for either 24/7 or for hours when the Pharmacy is closed. The pharmacist must be trained to use this system; training shall be documented.

1. **References:** N/A

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## 10.05 Robbery Procedure

1. **Purpose:** This procedure outlines the process to be followed by Pharmacy personnel during and after a robbery event.
2. **Scope:** This procedure applies to all Pharmacy personnel.
3. **Definitions:**

**Robbery:** The theft or attempted theft of property by use of force or threat of use of force.

1. **Safety Requirements:** All company safety policies and procedures shall be followed during a robbery event. Do not place yourself in an unsafe situation. As soon as possible after the event, contact law enforcement and Pharmacy senior management for investigation.
2. **Procedure:**
   1. Make the Pharmacy a Less Attractive Target
      * Arrange stock shelves so that the most targeted drugs are not visible from windows.
      * Rearrange stock shelves periodically so that the most targeted drugs are not always in the same location.
      * Pharmacy personnel should never discuss company inventory controls with anyone.
      * The Pharmacy must have an installed Alarm system and a Video Surveillance system.
      * Interior lights will be left on in strategic locations after hours making it difficult for an intruder to hide once inside.
   2. Video Surveillance and Alarm Systems
      * The Pharmacy shall maintain video security surveillance. Video surveillance should be capable of remote viewing, have available recording for several days’ time, and be able to be downloaded to a USB drive.
      * The Pharmacist-in-Charge (PIC) must be trained on the use and operation of this system.
      * The Pharmacy is required to have a professionally installed alarm system. The PIC is responsible for the use and operation of the alarm system and the confidential store ID code.
      * False Alarms: In the event of a FALSE ALARM, please contact the appropriate Security Company and provide them the confidential store ID Code. This code must be maintained confidential and communicated to only those with a need to know.
   3. Safety Awareness and Confidentiality

* Pharmacy personnel must maintain safety awareness and watch for suspicious behavior(s) from customers.
* Pharmacy personnel should refrain from discussing store procedures, inventory controls, cash handling, store layouts, security systems, etc. with any outsider (including family), other than law enforcement personnel and/ or vendors with a legitimate interest in a particular system.
* The Pharmacy shall restrict access, keys, or combinations to as few personnel as is feasible.
* The Pharmacy will deposit checks and cash nightly to keep minimal amounts of cash on hand at any one time. NO cash will be left in cash registers overnight.
  1. During a Robbery
* Try to stay CALM - The objective is to get the robber out of the store as quickly as possible.
* Listen carefully. Not only in order to obey commands, but to hear a name used or something else said that can be used in the investigation.
* Do exactly as you are told, no more and no less. DO NOT RESIST! Take a step back. Place your hands in front of you with palms held outward. Turn your body sideways (reduces target area).
* Use caution; being careful is not cowardice.
* Alert the robber to any event or action you know is going to happen that may startle or upset the robber, i.e., someone is due to arrive soon.
* Do not make any sudden or quick movements. When necessary to move or reach to comply with the robbers demands, tell the robber what you are going to do and why.
* If applicable to store: Activate “panic button” or “toe kick” alarms only when you do it secretly. Take no chances.
* Passively try to keep any note or written instructions the robber may have given you if you can. Turn this over to the police later.
* Be observant; make a conscious effort to get a good description of the robber, BUT avoid making direct eye contact. The perception is that eye contact promotes recognition.
* Give the robber adequate time to leave. Avoid the urge to give chase!
* Note the direction of travel when the robber leaves. Try to get a description of any vehicle used in the getaway – if you can do so without compromising your personal safety. Example: Make, model, color, license number, distinguishing features (decals, dents, bumper stickers, hubcaps, etc.).
  1. After the Robber Has Left
* CALL THE POLICE (911) – even if the alarm has been triggered.
* Alert the dispatcher if there have been injuries so emergency assistance can be dispatched.
* Lock the doors from the inside.
* Do not touch anything the robbers may have touched and block off any areas where the robber(s) was to protect evidence they may have left behind.
* Provide basic first aid as needed for injured personnel or customers until the paramedics arrive.
* Ask any witnesses to provide their name, address, and phone number so police can follow up.
* Pharmacy personnel involved in the robbery event shall document their own recollection of the robbery details as soon as possible.
* When law enforcement arrives, go outside to greet them to show that the premises are secure.
* Turn the matter over to the law enforcement officials and cooperate fully! Provide any Pharmacy personnel documentation of the robbery event and any witness names/ list.
* As soon as possible, the facility PIC or Pharmacy Manager shall obtain a copy of the Law Enforcement’s official written report. Copies of completed documents shall be maintained at the site.
* Refer any inquiries from outsiders (media, etc.) to the responding law enforcement agency.
* Do not discuss items or amounts taken with anyone other than law enforcement.
* When safe or as soon as possible, the PIC or Pharmacy Manager shall contact Pharmacy senior management to inform them of the robbery event and status.
* As needed, senior management will file a claimfor the eventwith the insurance company and obtain instructions on the claim process.
* Documentation: When safe or as soon as possible, the PIC or Pharmacy Manager shall fill out any required reports for the Security, insurance company, police, or other types of documents related to the robbery event. The PIC or Pharmacy Manager shall keep a copy of each form filled out and these will be maintained at the site.

1. **References:** N/A
2. **Attachments:** N/A

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## 10.06 Employee and Facility Security

1. **Purpose:** This policy is to reduce the risk of harm or injury to personnel, customers, and Pharmacy property and to clearly articulate the Pharmacy’s policy that the personal safety of personnel and customers is paramount and should be safeguarded at all times.
2. **Scope:** This policy applies to all personnel.
3. **Definitions:** N/A
4. **Policy:** The Pharmacy desires to provide a safe and secure workplace for its personnel and customers. The safety and security of personnel and customers is paramount and surpasses the Pharmacy’s desire to protect Pharmacy property. If an unauthorized individual is observed on Pharmacy premises, personnel should immediately notify their supervisor or, in the personnel’s judgment, law enforcement. Should a potentially hazardous situation arise and a decision needs to be made between protecting Pharmacy property/ production and protecting the safety of Pharmacy personnel, customers, and vendors, the decision should always be made in favor of protecting the safety of individuals.

**Weapons**

Possession of weapons on Pharmacy property is generally prohibited. An individual is considered to be in possession of a weapon if it is being carried on his/ her person or in any container belonging to or being used by that person. Violations of this policy will be subject to disciplinary action, up to and including termination. Exceptions to this policy must be approved by the Director of the Pharmacy. The Pharmacy has the right to search any areas on Pharmacy premises for weapons.

**Robberies**

In the event of a robbery during Pharmacy work hours, personnel must contact law enforcement as quickly as possible and should not attempt to apprehend or subdue a robber or a trespasser. Employees should cooperate with intruders by relinquishing personal and Pharmacy property upon request and place their personal safety and the safety of customers and vendors first.

**Visitors**

To provide for the safety and security of the personnel and facilities at the Pharmacy, only authorized visitors are allowed in the workplace. Restricting unauthorized visitors helps maintain safety standards, protects against theft, ensures security of equipment, protects confidential information, safeguards personnel welfare, and avoids potential distractions and disturbances. Personnel are responsible for the conduct and safety of their visitors. However, because of safety and security reasons, family and friends of personnel are not allowed behind the counter of the Pharmacy at any time.

**Workplace Violence**

Violence by personnel or anyone else against personnel or management will not be tolerated. The purpose of this policy is to minimize the potential risk of personal injuries to personnel at work and to reduce the possibility of damage to Pharmacy property in the event someone, for whatever reason, may be unhappy with a Pharmacy decision or action by Pharmacy personnel or a member of management.

If you receive or overhear any threatening communications from personnel or an outside third party, report it to your manager at once. Do not engage in either physical or verbal confrontation with a potentially violent individual. If you encounter an individual who is threatening immediate harm to personnel or visitors to our premises, contact an emergency agency (such as 911) immediately.

All reports of work-related threats will be kept confidential to the extent possible, investigated, and documented. Personnel are expected to report and participate in an investigation of any suspected or actual cases of workplace violence and will not be subjected to disciplinary consequences for such reports or cooperation.

Violations of this policy, including your failure to report or fully cooperate in the Pharmacy's investigation, may result in disciplinary action, up to and including discharge.

**Building Security**

Locks, lockers, safes, and alarm systems are in place for your protection and the Pharmacy’s protection. Keep your personal property in your locker. The Pharmacy will not be responsible for personnel’s lost or stolen property. The Pharmacy will not be responsible for damage to personnel vehicles on Pharmacy property. Personnel must safeguard building keys, passwords, and alarm codes. Personnel who are responsible for closing the Pharmacy must take appropriate actions to ensure that the Pharmacy is secured, controlled substances are properly stored, alarms are set, and doors are locked. Failure to do so may result in disciplinary action, up to and including termination from employment.

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# 11.0 Facility

## 11.01 Alarm-Security Requirement

1. **Purpose:** This procedure describes the precautionary measures taken at the Pharmacy to provide a safe and secure environment.
2. **Scope:** This procedure applies to all Pharmacy personnel responsible for securing the Pharmacy area and work environment. The Pharmacist-in-Charge (PIC) is responsible for complying with state or federal regulations for security of the Pharmacy facility.
3. **Definitions:** N/A
4. **Safety Requirements:** All Pharmacy safety policies and procedures shall be followed to maintain a safe work environment. No one should be placed in an unsafe situation. As needed, contact law enforcement (911) and senior management for assistance.
5. **Procedure:**

**Physical Security**

* 1. The pharmacist shall ensure that all areas around the prescription area and safe are well-lit during closed hours.
  2. The pharmacist shall assign an authorized person to check all doors and windows before the close of each day. Make sure every access point is locked.
     + Check areas where there may be customers, such as bathrooms, closets in waiting or retail areas, behind shelving, and consultation areas.
  3. Register Closeout: There shall be no cash left in the register after closing hours.
  4. The pharmacist is responsible for activating the alarm before leaving the Pharmacy.
  5. The pharmacist is responsible for ensuring that video surveillance systems are turned on and working prior to leaving the Pharmacy.
  6. The pharmacist shall ensure that any ‘night lighting’ for all areas of the Pharmacy are turned on and working prior to leaving the Pharmacy.
     + Rear of building
     + Employee exits
     + Side doors
     + Pharmacy windows
     + Storage areas
  7. It is good practice to bolt the safe to the floor. It is good practice to ensure that high value drugs are properly secured against theft.

**Alarm System**

* 1. A Pharmacy alarm system shall cover all areas of the Pharmacy and ring locally and off-site.
  2. If the alarm system has motion detectors, they shall be placed in appropriate locations within the Pharmacy, including office and storage areas. Motion detectors should be free from anything that may prevent their effectiveness.
  3. The alarm system should be linked to a cell phone back-up for lines that carry the alarm signals or another type of line security. There should also be a battery back-up system in the event of power outages.
  4. The alarm system is tested at a minimum of semi-annually (every six months).
  5. The Director of Pharmacy should be kept informed of occupancies or vacancies of adjacent and/ or overhead offices or building space to monitor and prevent access to the Pharmacy facility.

**Emergency Response**

* 1. Police response is critical. Pharmacists shall maintain a good relationship with the appropriate law enforcement agencies, including showing them around the Pharmacy premises.
  2. The pharmacist shall ensure that emergency phone numbers (for example: 911, utility companies, alarm company, management, personnel, and Internet provider) are posted in key locations within the Pharmacy, and that Pharmacy personnel are trained in emergency procedures.
  3. During a robbery or burglary, Pharmacy personnel should not push a silent alarm unless it is known how the police department will respond. Response with “guns drawn” can create a hostage situation. For robbery procedure, reference SOP 10.05. For burglary procedure, reference SOP 10.02.

1. **References:**

* [SOP 10.02 - Burglary Procedure](#page261)
* [SOP 10.05 - Robbery Procedure](#page268)
* Pharmacist Mutual Ins. Co. – Risk Management Assessment

1. **Attachments:** N/A

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## 11.02 Displaying Licenses

1. **Purpose:** This procedure describes the guidelines for displaying licenses in the Pharmacy.
2. **Scope:** This procedure applies to all licensed personnel.
3. **Definitions:**

**License:** A permit from an authority to own or use something, do a particular thing, or carry on a trade. For example, this would include licenses for individuals (pharmacists, pharmacy interns, pharmacy externs, preceptors, and pharmacy technicians, etc.) and permits or registrations for the Pharmacy (Pharmacy permit, DEA registration, state licenses, etc.).

1. **Safety Requirements:** N/A
2. **Procedure:**

**Displaying Licenses in the Pharmacy**

* 1. Pharmacist, Intern, and Extern Licenses: All pharmacists, interns, and externs shall publicly display their current licenses to practice in the Pharmacy where they are easily viewable by the public. The pharmacist-in-charge (PIC) is responsible for ensuring licenses are adequately posted and current.
  2. Pharmacist Renewal: A pharmacist shall publicly display a license renewal certificate in the pharmacist’s primary place of practice.
  3. Pharmacy Technician License: All pharmacy technicians shall publicly display their current pharmacy technician licenses or a certified copy of their licenses in the Pharmacy where they are easily viewable by the public. The PIC is responsible for ensuring pharmacy technician licenses are adequately posted and current.
  4. Pharmacy Business Permit: All business licenses required by the state, county, or city shall be publicly displayed. It is the responsibility of the PIC to ensure a business license is current at all times.
  5. Pharmacy DEA and State Narcotic Licenses: Licenses shall be on public display in the Pharmacy where they are easily viewable by the public. It is the responsibility of the PIC to ensure a narcotic license is current at all times.

1. **References:** N/A
2. **Attachments:** N/A

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## 11.03 Pharmacy Facilities

1. **Purpose:** This procedure describes the Pharmacy facility requirements.
2. **Scope:** This procedure applies to the Pharmacist-in-Charge (PIC) and Pharmacy management responsible for ensuring the Pharmacy facility meets state and local laws and ordinances.
3. **Definitions:** N/A
4. **Procedure:**

**Facility General Requirements**

* 1. The Pharmacy facilities must be constructed according to state and local laws and ordinances and must be of adequate size.
* Adequate size means that the space in the Pharmacy department allow for:
  + A confidential patient consultation area
  + Patient pick-up and cash register area
  + Medication preparation areas
  + A restroom facility
  + Storage areas for:
    - Prescription drugs and prescription devices
    - Controlled substances
    - Syringes and needles
    - Pseudoephedrine and other precursors
    - Items that have specific environmental storage requirements, such as refrigeration
    - All other inventory that is required to be maintained behind the prescription department counter
  1. Patient Consultation Area: There shall be adequate space within the Pharmacy to allow for a separate or segregated space for the pharmacist to hold patient medication consultations that allows for privacy from others.
  2. General Housekeeping: Walls, ceilings, windows, floors, shelves, and equipment must be clean at all times and in good repair and order.
* As part of general good housekeeping and good safety practices, all countertops, shelves, aisles, and open spaces must be dust-free and kept free of clutter.
  1. Trash Containers: There must be adequate trash containers located in strategic locations throughout the Pharmacy and must be emptied periodically as needed during the day. Trash containing individually-identifiable health information (IIHI) must be shredded or disposed of in a sealed container whose contents will be shredded. (See SOP 4.14 - Security of Health Information). Biohazard waste must be disposed of in a secure container marked “Biohazard.” (See SOP 5.13 – Disposing Biohazard Waste).
  2. Restrooms: The Pharmacy must provide toilet facilities either within the Pharmacy area or within a reasonable walking distance from the Pharmacy area.
* Restrooms must be maintained in a sanitary condition and in good repair. As part of standard Pharmacy housekeeping, the restrooms must be cleaned on a regular schedule.
* Good hygiene posters for proper hand washing must be posted in the restroom area.
  1. Personal Hygiene: All Pharmacy personnel must keep themselves and their apparel clean while working in the Pharmacy areas. This includes clean work uniforms, lab coats or scrubs, and periodically washing hands, changing soiled gloves, and changing other hygiene items.
  2. No animals, except for service animals for Pharmacy personnel, are allowed in the Pharmacy.
  3. Pest Control:The Pharmacy must be kept free of insects or rodents. There shall be a licensed pest control company for use by the Pharmacy as needed. The phone number for the pest company must be easily available for Pharmacy personnel use.
  4. Sinks: There must be a sink with hot and cold running water (other than a sink in a toilet or restroom facility) that is located within the Pharmacy area for use in preparing drug products.
  5. Drug Inventory: The Pharmacy shall maintain a sufficient supply of stock drugs, chemicals, and medications to meet the normal demands of the customer base the Pharmacy serves.
* The inventory products must meet all standards of strength and purity as established by the official compendiums.
* Pharmacy practices and procedures shall ensure that all effort is made to maintain inventory stock free of contamination and appropriately stored per manufacturers’ requirements.
* Procedures must be in place for periodic inventory to identify and remove expired or soon to expire drugs, medications, or products to prevent dispensing products that are past expiration, damaged or deteriorated, improperly labeled, in a defective container, do not comply with federal law, or other.
  1. SOPs: All Pharmacy Standard Operating Procedures (SOPs) must be made available to all Pharmacy personnel.

1. **References:**

* [SOP 4.14 – Security of Health Information](#page134)
* [SOP 5.13 – Disposing of Biohazard Waste](#page181)

1. **Attachments:** N/A

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## 11.04 General Housekeeping

1. **Purpose:** This procedure describes the general housekeeping requirements to be followed by all personnel.
2. **Scope:** This procedure applies to all Pharmacy personnel responsible for performing and verifying housekeeping duties and responsibilities.
3. **Definitions:**

**Housekeeping:** Activities performed in the Pharmacy that assure the cleanliness of areas, floors, and equipment, the elimination of clutter that could cause potential accidents, the removal of trash, reduction of dust/ debris, prevention of potential for contamination, and making the work place neat, comfortable, and pleasant.

1. **Safety Requirements:** N/A
2. **Procedure:**

**General Requirements**

1. The Pharmacy will be maintained in a continuing state of cleanliness that enhances the image of the Pharmacy and the Pharmacy profession.
2. Each member of the Pharmacy personnel may be assigned an area of responsibility to maintain in a neat, clean, and orderly manner. This may involve cleaning, dusting, or other activity on a routine basis as described in this procedure.
3. Pharmacy personnel who identify a safety issue or hazard must immediately inform the PIC, who will take action to investigate or remove the hazard. (See SOP 9.01 and SOP 9.02).
4. Cleaning or maintenance of Pharmacy equipment shall be documented and performed on a periodic basis as required for compliance with state or other regulatory requirements.
5. The Pharmacy shall provide all cleaning materials or supplies for maintaining clean work areas.
6. Alcohol cleaning wipes should be used for counter surface cleaning.

**Cleaning of Pharmacy Areas**

1. Store Lobby Area: The lobby should be cleaned daily. This includes disposing of trash, vacuuming carpet, cleaning hard floor areas, changing soiled floor mats, and straightening general materials in the area.
2. The Sales Counter Area should be clean and orderly at all times and cleaned daily.
3. The Patient Consult Area should be clean and orderly at all times and cleaned daily.
4. Restroom/ Toilet Facilities should be cleaned daily by either Pharmacy personnel or a contracted janitorial service. There must be adequate supplies that are replenished as needed.
5. Main Pharmacy Dispensing Areas: Pharmacy personnel shall use alcohol cleaning wipes for cleaning of all counter surfaces and shelves to remove dust or debris. All spills must be cleaned up immediately.
6. Main Pharmacy Floor Areas:

* Sweep, vacuum, and mop all Pharmacy floor areas.
* Floor sweeping and mopping must be documented on a cleaning log that includes date cleaned, cleaned by, and the type of cleaning agent used.

1. Equipment: All equipment and utensils utilized during the course of a workday are to be cleaned thoroughly immediately after use. This includes cleaning all tablet counting trays and spatulas as necessary throughout the day and washing them with soap and water at least once daily. The automatic counting machines for tablets and capsules must be free of accumulation of tablet dust and cleaned with warm water and soap at least once daily. Equipment cleaning must be documented on the equipment cleaning/ maintenance.
2. Shelving: All Pharmacy shelving shall be wiped clean of dust or debris as needed using alcohol wipes. Removal of stock materials should be performed prior to cleaning. Upon completion of cleaning, if needed, use a clean dry wipe to dry and then return the stock materials to the exact location.
3. Regular Trash Removal: Daily, all trash dispensers within the Pharmacy should be emptied and garbage bags should be disposed into the proper collection bins. Trash disposal may occur more frequently during the day as warranted.
4. Materials to Be Shredded: All materials containing individually identifiable health information (IIHI) must be shredded or disposed of in a sealed container whose contents will be shredded. These materials should not be disposed of with the regular trash.
5. Hazardous Waste Bins: All Pharmacy hazardous waste bins will be scheduled for periodic pickup by a certified hazardous waste disposal company. Documentation for this process shall be maintained on file in the Pharmacy.
6. Pests: If any pest or pest problems are observed in any Pharmacy area, immediately inform the PIC for scheduling with a certified pest control company to take actions to eliminate the problem. Documentation for this process should be maintained on file in the Pharmacy.
7. Personnel working in each area of the Pharmacy should recognize and correct any deficiencies in the above cleaning requirements resulting from normal operations and standard practice (i.e., cleaning up breakage or spillage of medications).
8. **References:**

* [SOP 9.01 - Bloodborne Pathogen Exposure Control Panel](#page249)
* [SOP 9.02 - Cleaning Chemical Spills](#page253)

1. **Attachments:** N/A

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## 11.05 Required Equipment

1. **Purpose:** This procedure describes the Pharmacy facility equipment that must be kept within the Pharmacy.
2. **Scope:** This procedure applies to all Pharmacy personnel. The Pharmacist-in-Charge (PIC) is responsible for ensuring adherence to this procedure.
3. **Definitions:**

**Required Equipment:**  The equipment required by state pharmacy regulations to be present in the Pharmacy and required to obtain a state pharmacy license.

1. **Safety Requirements:**  N/A
2. **Procedure:** The Pharmacy must maintain the following equipment:

* A current copy (either hard copy or electronic) of all state and federal law relating to the practice of pharmacy and the legal distribution of drugs.
* Current clinical references in pharmacology, toxicology, drug interactions, and proper drug usage.
* A refrigerator and freezer to be used only for storage of medications and that has the capability of maintaining temperatures as stipulated in the United States Pharmacopeia-National Formulary (USP-NF) or the manufacturer’s labeling.
* A sink with hot and cold running water.
* An effective security system, while the Pharmacy is open, for effective control against theft or diversion of drugs/ devices.
* An effective security system when the Pharmacy is closed with either a suitable physical barrier or an electronic barrier.
* Any other item or equipment required by state pharmacy law.

1. **References:** N/A
2. **Attachment:** N/A

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## 11.06 Personnel Parking

1. **Purpose:** This procedure describes the personnel parking guidelines to be followed by all Pharmacy personnel. These guidelines are intended for the benefit, safety, and convenience of the pharmacy personnel.
2. **Scope:** This procedure applies to all Pharmacy personnel.
3. **Definitions:** N/A
4. **Safety Requirements:** N/A
5. **Procedure:**
   1. General parking is allowed in the designated area of the Pharmacy parking lot during open store hours.
   2. Pharmacy personnel parking is allowed in the designated area of the Pharmacy or public parking lot during the open store hours. Personnel should park in the spaces that are farthest from the front door to allow customers to have easy access.
   3. All Pharmacy personnel cars shall be parked in a single parking space marked by two lines.
   4. Parking is prohibited in entrance areas, exit roads, in the shipping/ receiving area, fire lanes, in front of parking ramps, pedestrian ramps/ walkways, handicap spaces, in diagonally-striped spaces, or other location where signage prohibits parking.
   5. Drivers are required to follow instructions on public safety and posted signage.
   6. Parking policy violations may result in ticketing, towing at the vehicle owner's expense, or revocation of parking privileges.
   7. The Pharmacy assumes no liability for loss or damage to vehicles or their contents while parked in the Pharmacy or public parking lots or to vehicles that are towed.
6. **References:** N/A
7. **Attachment:** N/A

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## 11.07 Holiday Party and Gift Giving

1. **Purpose:** This procedure describes the guidelines on holiday parties and gift policies.
2. **Scope:** This procedure applies to all personnel.
3. **Definitions:** N/A
4. **Safety Requirements:** N/A
5. **Procedure:**

**Company Sponsored Parties**

* 1. Holiday parties are an opportunity to get together in an informal way to celebrate. It is a way for the Pharmacy to thank personnel for their efforts and commitment to the Pharmacy.
  2. Personnel attendance at a Pharmacy holiday party is not a requirement – attendance at such events is voluntary.
  3. A holiday party is an “out-of-work” event, but, technically, it is a work-related activity; all personnel should be aware of Pharmacy policies, such as Code of Conduct, Harassment, or other policies that apply to holiday parties.
  4. Personnel should not drink excessively or be involved in altercations, harassment, taking of drugs, or other similar or unwanted behavior.
  5. Management should set a good example and have a watchful eye for inappropriate behavior.
  6. The holiday party will be held in an appropriate venue in a centralized location of adequate size to accommodate all personnel. A local hotel or restaurant are good options.
  7. Alcohol Consumption Limits: Prior to the holiday party, management will provide further information in this area; for example, management may provide “alcohol vouchers” or set times when alcohol will be served. In the event that an individual does have too much to drink, the Pharmacy shall provide a “safe ride” option.
  8. Internal Office Parties: Personnel are discouraged from having inter-department office parties where there may be the perceived opportunity for discrimination.
  9. Company Sponsored In-House Celebrations: On occasion, the Pharmacy may provide an “all personnel” celebration event, for example, meeting a sales goal, meeting an accreditation goal, or other Pharmacy milestones. A Pharmacy communication shall be sent to all personnel in advance of the event with specific information on the celebration event.

**Gift Policy**

* 1. To avoid a conflict of interest, the appearance of a conflict of interest, or the need for personnel to examine the ethics of acceptance, the Pharmacy and its personnel do not accept gifts from vendors, suppliers, customers, potential personnel, potential vendors or suppliers, or any other individual or organization, under any circumstances.
  2. The Code of Conduct policy requires that all personnel demonstrate our commitment to treating all people and organizations with whom we come into contact or conduct business impartially and with the highest standards of ethics and conduct.
  3. All personnel must abide by the following no-gift policy requirements:
* No gifts of any kind, that are offered by vendors, potential vendors, suppliers, customers, potential personnel, potential vendors and suppliers, or any other individual or organization, no matter the value, will be accepted by any personnel, at any time, on or off the work premises. By “gift,” the Pharmacy means any item including pens, hats, t-shirts, mugs, calendars, bags, key chains, portfolios, or other items, as well as items of greater value.
* This includes supplier-provided food, beverages, meals, or entertainment, such as sporting events, any business courtesy, product discounts, or any other benefit if the benefit is not extended to all personnel.
  1. Gift Policy Exceptions:
     + Gifts, such as t-shirts, pens, and trade show bags, that personnel obtain as members of the public at events, such as conferences, training events, seminars, and trade shows, that are offered equally to all members of the public attending the event. This includes attendance, food and beverages at events, exhibitor trade show floor locations, press events, and parties funded by conference or event sponsors.
     + Cards, thank you notes, certificates, or other written forms of thanks and recognition.
     + Food, beverages, and moderately priced meals or tickets to local events that are supplied by and also attended by current customers, partners, and vendors or suppliers in the interest of building positive business relationships. This moderately priced entertainment is provided as part of a “working” meeting or session to benefit and advance positive working relationships and Pharmacy interests. These activities are expected to be reciprocated by the Pharmacy in turn.
  2. Informing Vendors: Personnel shall inform vendors, potential vendors, and others of this no-gift policy and the reasons why the Pharmacy has adopted the policy. Personnel will request that vendors respect our policy and not purchase and deliver any gift for our personnel, a department, an office or the Pharmacy, at any time, for any reason.
     + In the event that personnel or a department receives a gift:
* If feasible, the gift is returned to the vendor.
* If not feasible to return the gift, the gift shall be donated to a designated charity.
* Plants or flowers will be displayed in the lobby or at another central location where all personnel may enjoy.
* Gifts of food that may arrive during the holidays or other times of the year will be provided to the entire personnel even if addressed to a single employee.
* Under no circumstances may personnel take a food gift home; food gifts must be shared with and distributed to all personnel with email notice during work hours in central worksite locations.
  1. Internal Personnel Gift Giving: Personnel are discouraged from giving inter-department gifts from one employee to another or one department to another during work hours, where there may be the perceived opportunity for discrimination.

1. **References:** 
   * [Policy 3.18 - Code of Conduct](#page80)
2. **Attachments:** N/A

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| Prepared by/Date: | Approved by/Date: |

## 11.08 Lost and Found Procedure

1. **Purpose:** This procedure describes the Pharmacy lost and found guidelines.
2. **Scope:** This procedure applies to all Pharmacy personnel.
3. **Definitions:**

**Lost Items:** Items that may have been lost at the Pharmacy or building.

**Found Items:** Items that have been found at the Pharmacy or building.

1. **Safety Requirements:** N/A
2. **Procedure:**
   1. An item that may have been lost in either the Pharmacy or building and found by an employee or other person shall be returned to the Pharmacist-in-Charge or to the most senior manager for that facility.
   2. Lost and Found items will be kept in a dedicated, secure, and restricted location of the Pharmacy or other building.
   3. Upon receiving a lost/ found item, the pharmacist or manager shall document the find on a Lost and Found log. The information should contain a minimum of the following information:

* Date found
* Location found
* Who found it
* Number of items found
* A brief description of the found item(s)
  1. All efforts shall be made to identify the owner if possible. If not possible, the item(s) shall be placed into a plastic bag and placed in the secure location.

5.0 Only the pharmacist or manager may return a lost/ found item to a customer/ patient after first asking a few item identification questions and receiving an acceptable response. Some examples of questions are:

* What date did you lose the item?
* Where did you lose the item?
* What color is the item?
* Can you fully describe the lost item?

1. **References:** N/A
2. **Attachments:** N/A

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| Prepared by/Date: | Approved by/Date: |

## 11.09 Solicitation Procedure

1. **Purpose:** This procedure describes the solicitation policy for Pharmacy personnel.
2. **Scope:** This procedure applies to all Pharmacy personnel and non-personnel.
3. **Definitions:**

**Solicitation/ Solicit:** To ask for something, such as money or help from people, companies, etc., or to promote, distribute, or ask for donations.

1. **Safety Requirements:** N/A
2. **Procedure:**
   1. Pharmacy personnel may not solicit for any purpose nor distribute literature or materials within Pharmacy buildings or property during the employee’s working time or the working time of any personnel being solicited or approached. “Working time” shall not include break periods, meal times, and other non-work periods during the day.
   2. Personnel may not distribute literature or materials within the working areas of the Pharmacy at any time.
   3. Non-personnel may not solicit, canvas, or distribute materials or literature for any purpose within Pharmacy buildings or on Pharmacy property at any time.
   4. Personnel may not solicit other personnel or distribute literature or materials in areas of the Pharmacy at any time.
3. **References:** N/A
4. **Attachments:** N/A

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| Prepared by/Date: | Approved by/Date: |

## 11.10 Store Appearance

1. **Purpose:** This procedure describes the requirements for the Pharmacy store appearance. The Pharmacy shall maintain a professional appearance with a high standard of good housekeeping and safety at all times.
2. **Scope:** This procedure applies to the Pharmacist-in-Charge and Pharmacy personnel responsible for ensuring the Pharmacy facility meets state and federal regulations for Pharmacy areas, appearance, size, and housekeeping.
3. **Definitions:** N/A
4. **Safety Requirements:** N/A
5. **Procedure:**
   1. Pharmacy areas must comply with state and local laws and ordinances or other regulations for:
      * Adequate size
      * Minimum area
      * Actual area for stocking drugs
      * Compounding (if applicable) and dispensing activity
      * Cash register counter space
      * Office area
      * Patient consult areas
      * Controlled substance area
   2. Pharmacy Personnel: All personnel must keep themselves and their apparel clean while in the Pharmacy area and wear clearly legible name tags.
   3. Patient Consult Area: There shall be a separate or segregated space for pharmacists to hold patient or customer medication consultations that allow for privacy.
   4. General Housekeeping: Store entry, lobby, retail areas, walls, ceilings, windows, floors, shelves, and equipment must be clean at all times and in good repair and order.

* As part of general good housekeeping and good safety practices, counters, shelves, aisles, and open spaces must be kept free of clutter.
  1. Restrooms: The Pharmacy must provide toilet facilities that are maintained in a sanitary condition and in good repair.

1. **References:**

* [SOP 11.03 - Pharmacy Facilities](#page277)
* [SOP 11.04 - General Housekeeping](#page279)

1. **Attachments:** N/A

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| Prepared by/Date: | Approved by/Date: |

## 11.11 Staff Meetings

1. **Purpose:** This procedure describes requirements for Pharmacy personnel meetings.
2. **Scope:** This procedure applies to the Pharmacist-in-Charge (PIC) and all Pharmacy personnel.
3. **Definitions:** N/A
4. **Safety Requirements:** N/A
5. **Procedure:**
   1. The Pharmacy should conduct monthly meetings. These meetings are intended to provide an open forum to communicate Pharmacy-related information between the PIC and the Pharmacy personnel.
   2. The PIC or Director of Pharmacy will schedule and hold the meeting; all Pharmacy personnel are required to attend.
   3. In the event that someone is not able to attend, the information reviewed at the meeting shall be provided to that person on their next scheduled work day.
   4. The meeting will have an agenda, personnel in attendance must be documented, and the meeting minutes shall be on file in the Pharmacy. Monthly meeting minutes must be made readily available upon request during inspections.
   5. Monthly meetings are intended for review of the following information or other critical Pharmacy information not listed below:

* Policy and Procedure review
* Operational problems or Quality Assurance information
* Pharmacy, operational, or personnel changes
* Regulatory Agency Information
* Controlled Substance Problems
* Human Resource information
* Drug Recalls or other drug information
* Safety Information
* Information Technology (IT) upgrades/ training
* Best Practice Information
* Errors and Preventative Measures

1. **References:** N/A
2. **Attachments:** N/A

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| Prepared by/Date: | Approved by/Date: |

## 11.12 Pharmacy Work Environment

1. **Purpose:** This procedure describes the Pharmacy work environment.
2. **Scope:** This procedure applies to all Pharmacy personnel.
3. **Definitions:** N/A
4. **Procedure:**

**Pharmacy Work Environment**

1. The Pharmacy must be maintained in a secure manner during non-working hours.
2. The Pharmacy shall be of adequate size to meet state and local laws or regulations.
3. The Pharmacy shall have a segregated patient consulting area to provide customer privacy.
4. The Pharmacy must follow routine housekeeping procedures.
5. Trash receptacles must be emptied as needed.
6. A pest control system must be maintained in the Pharmacy.
7. Clean and sanitary restrooms must be made available.
8. Pharmacy personnel are required to wear clean clothing and maintain personal hygiene habits on the job or as required by procedures.
9. There shall be adequately stocked drugs or inventory as needed for the customer or patients the Pharmacy serves.
10. There shall be adequate ventilation, lighting, sinks, counter space, and separate personnel eating areas.
11. The Pharmacy must provide standard operating procedures that are available for all personnel.
12. The Pharmacy must provide all personnel with a safe working environment.
13. **References:**

* [SOP 11.03 - Pharmacy Facilities](#page277)

1. **Attachments:** N/A

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| Prepared by/Date: | Approved by/Date: |

# 12.0 Supply Chain

## 12.01 Purchasing Bags, Vials, Labels

1. **Purpose:**  This procedure describes how and when to purchase bags, vials, and labels.
2. **Scope:**  This procedure applies to all Pharmacy personnel.
3. **Definitions:** N/A
4. **Safety Requirements:** N/A
5. **Procedure:**

* Notify the person in charge of ordering (the PIC or the designated technician) when there is only one box of a supply remaining.
* Check supplies and place orders every other weekend or as needed.

1. **References:**  N/A
2. **Attachments:** N/A

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| Prepared by/Date: | Approved by/Date: |

## 12.02 Pedigrees

1. **Purpose:** This procedure describes the process to comply with various state and federal laws when receiving legend drug shipments from manufacturers/ wholesalers.
2. **Scope:** This procedure applies to all Pharmacy personnel who will be involved in the receipt of drug shipments from manufacturers/ wholesalers.
3. **Definitions:**

**Pedigree:** A record in hard copy or electronic form containing information regarding each transaction resulting in a change of ownership of a legend drug from sale by a manufacturer through acquisition and sale by one or more wholesalers, manufacturers or pharmacies until a final sale to a pharmacy or other person furnishing, administering or dispensing the legend drug.

**Authentication:** To affirmatively verify upon receipt of a legend drug(s) that each transaction listed on the pedigree document actually occurred**.**

**Certification:** To confirm under penalty of perjury that all the information contained in the pedigree document is true and accurate.

**Product Identifier:** A standardized graphic that is both human and machine-readable, that conforms to standards developed by a well-recognized international standards organization and contains the numeric drug identifier, the lot number, and expiration date of the legend drug.

1. **Safety Requirements:** N/A
2. **Procedure:** Manufacturers/wholesalers must comply with both state and federal law concerning the sale/ receipt of legend drugs. Detailed information about the sale/ receipt of these legend drugs must be transmitted from the manufacturer/ wholesaler to the Pharmacy. The Pharmacy shall not accept ownership of drug products unless the manufacturer/ wholesaler provides the required data elements. The legend drug(s) being sold by the wholesaler/ manufacturer must be authenticated upon receipt in the Pharmacy by verifying the following information contained in the pedigree or other document shipped with the legend drugs:

* Drug(s) source, i.e.name and address of the wholesaler/ manufacturer that sold the drug(s) to the Pharmacy as well as any previous owners of the legend drug(s), state license number(s), and federal manufacturer registration number
* Drug(s) trade/ generic name and amount
* Drug(s) dosage form and strength
* Lot numbers of the drug(s)
* Expiration dates
* Shipping information
* Invoice number, a shipping document number, or another number uniquely identifying the transaction
* Certification/ verification of product identifier
* Transaction history
* Transaction information
* Standard drug numeric identifier
* Wholesaler must be authorized trading partner of the manufacturer

The pharmacy can return saleable/ non-saleable drug products to its trading partner (seller) without providing a transaction history/ information received from the previous owner. In the event of a recall, the Pharmacy shall provide the applicable transaction history/ information history statements.

1. **References:**

* Various state pedigree laws
* [Drug Supply Chain Security Act](http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/default.htm)

1. **Attachments:** N/A

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| Prepared by/Date: | Approved by/Date: |

## 12.03 Drug Supply Chain Security Act (DSCSA)

1. **Purpose**: The purpose of this procedure is to comply with the federal Drug Supply Chain Security Act (DSCSA) of 2013. By assuring integrity of pharmaceutical products, Pharmacy must order from authorized suppliers, receive and send proper transaction information, quarantine suspect or illegitimate products, and proper notifications if required. This policy includes the requirements as of March 1, 2016, and will need to be updated on November 27, 2020 to add the new DSCSA requirements that come into effect on that date.
2. **Scope**: This procedure applies to all Pharmacy personnel who will be involved in the receipt of purchase orders.
3. **Definitions**:
   1. **Authorized Trading Partners**: Entities such as manufacturers, repackagers, wholesale distributors, third party logistic providers, and other dispensers that pharmacy has documented to be properly licensed or registered as set forth in Section (IV)(1.0) that transfers direct ownership or possession of a product.
   2. **Dispenser:** A retail pharmacy, hospital pharmacy, a group of chain pharmacies under common ownership and control that do not act as a wholesale distributor, or any other person authorized by law to dispense and administer prescription drugs, and the affiliated warehouses or distribution centers of such entities under common ownership and control that do not act as a wholesale distributor.
      * Dispenser does not include a person who dispenses products to be used in animals.
   3. **Illegitimate Product**: A product for which there is credible evidence that it:
      * Is potentially counterfeit, diverted, or stolen;
      * Is potentially intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;
      * Is potentially the subject of a fraudulent transaction; or
      * Appears otherwise unfit for distribution.
   4. **Product Identifier:** A standardized graphic that includes, in both human and machine readable data carrier that conforms to the standards developed by a widely recognized international standards development organization and will include:
      * Standardized numerical identifier;
      * Lot number; and
      * Expiration date of the product.
   5. **Suspect Product:** A product for which there is reason to believe that it:
      * Is counterfeit, diverted, or stolen;
      * Is intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;
      * Is the subject of a fraudulent transaction; or
      * Appears otherwise unfit for distribution.
   6. **Transaction History:** A statement, in paper or electronic form, including the transaction information for each prior transaction going back to the manufacturer of the product.
   7. **Transaction Information:** Information about the product including:
      * The proprietary or established name(s)
      * Strength and dosage form
      * National Drug Code number
      * Container size
      * Number of containers
      * Lot number
      * Date of transaction
      * Date of shipment (if more than 24 hours after date of transaction)
      * Business name and address of person from who ownership is being transferred
      * Business name and address of person to who ownership is being transferred
   8. **Transaction Statement:** A statement, in paper or electronic form, that states the entity transferring ownership in a transaction:
      * Is authorized under the DSCSA;
      * Received the product from a person that is authorized;
      * Received transaction information and a transaction statement from the prior owner of the product;
      * Did not knowingly ship a suspect or illegitimate product;
      * Had systems and processes in place to comply with verification requirements;
      * Did not knowingly provide false transaction information; and
      * Did not knowingly alter the transaction history.
   9. **T3:** Transaction History, Transaction Information, and Transaction Statement.
4. **Procedure**:

Beginning March 1, 2016 (extended by FDA from July 1, 2015) dispensers must maintain T3 with respect to each transaction.

* 1. **Authorized Trading Partners**
     1. The Pharmacy shall only trade products with Authorized Trading Partners. Pharmacy will determine whether trading partners are “authorized” by using one of the following resources:
* Manufacturer and Repackagers:
  + *Valid Registration with FDA* – Pharmacy may check using the FDA website “Drug Establishments Current Registration Site” at <http://www.accessdata.fda.gov/scripts/cder/drls/>
* Wholesale Distributors and Third-Party Logistics Providers:
  + *Valid State License or Federal License* (if state does not issue) – Pharmacy may verify state licensure by requesting a copy of the license from the wholesale distributor or third-party logistics provider. The Pharmacy may use the FDA website as a resource to verify licensure, “Verify Wholesale Drug Distributor Licenses” at <http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm281446.htm>.
  + *Reported License to FDA -* To verify the wholesale distributor or third-party logistics provider has reported to the FDA, the Pharmacy may search the FDA’s website “Wholesale Distributor and Third-Party Logistics Providers Reporting” at <http://www.accessdata.fda.gov/scripts/cder/wdd3plreporting/index.cfm>
* Dispenser:
  + *Valid State License* – the Pharmacy should verify using the state database or request a copy of the license from the dispenser.
    1. Pharmacy personnel shall be trained to verify and document each trading partner’s proof of authorization.
    2. The Pharmacy shall, at least once a year, verify each trading partner to determine they qualify as an Authorized Trading Partner:
* Creating a list of all drug suppliers for the pharmacy;
* Maintaining documentation of authorized trading partner’s licenses or registrations;
* Conducting verification through public databases; and
* Auditing trading partners randomly to ensure authorization is maintained.
  + 1. If a trading partner is deemed not-authorized, transactions shall be immediately suspended.
  1. **Product Tracing**
     1. The Pharmacy shall only accept ownership of product from an Authorized Trading Partner if provided with the T3 before or at the time of the transaction.
     2. If the Pharmacy transfers ownership of a product (not including dispensing to a patient or returns) shall provide the subsequent owner with the T3.
* Exception: T3 is not required for sales to another dispenser to fulfill a specific patient need.
  + 1. The Pharmacy must capture Transaction Information (including lot level information, if provided), Transaction History, and Transaction Statements.
* The Pharmacy may enter into written agreement with a third party, such as a wholesale distributor, who confidentially maintains the T3 on behalf of the dispenser. The Pharmacy shall maintain a copy of such a written agreement.
  1. **Product Verification**
     1. Suspect Products
* The Pharmacy must determine if the product is a Suspect Product or identify if the FDA has made a determination that a product is suspect. All products must be inspected on receipt.
* Potential methods of identifying a Suspect Product include:
  + Be alert to product offers at very low prices or are “too good to be true”;
  + Closely examine the package and transport container for signs of:
    - being comprised (e.g., opened, broken seal, damaged, repaired, or altered),
    - being changed since it was last received for an unexplained reason,
    - product inserts missing or don’t correspond with the product,
    - shipping addresses, postmarks, or other materials indicating the product came from an unknown foreign entity or source;
  + Closely examine the label on the package or on the individual retail unit for:
    - missing information (e.g., lot number, NDC, strength),
    - altered product information (e.g., smudged print, print difficult to read),
    - misspelled words,
    - label has bubbled at surface,
    - no Rx symbol,
    - little or no English provided (i.e., in a foreign language) or lot information in a foreign language,
    - product name differs from FDA-approved drug, or is the product name for a foreign-version of the drug,
    - product transported in case or tote when not expected to be,
    - lot numbers and expiration dates on product do not match the outer container.
* Any product deemed to be a Suspect Product must be immediately quarantined pending direction from pharmacy management, vendor, or governing authority.
* Any product received without documentation or from an unauthorized trading partner must be immediately quarantined.
* The Pharmacy shall conduct an investigation with the trading partners to determine whether the product is an illegitimate product. The Pharmacy will validate any application transaction history and transaction information in possession.
* If the Pharmacy determines the suspect product is an illegitimate product, the Pharmacy will notify the FDA promptly.
  + 1. If the Pharmacy determines a product is an illegitimate product:
* The Pharmacy shall attempt to assist trading partners in disposing of the illegitimate product not in the possession of the Pharmacy. The Pharmacy shall retain a sample of the product for examination by the manufacturer, FDA, or other Federal or State official upon request.
* The Pharmacy shall notify the FDA and all immediate trading partners within 24 hours using Form FDA 3911.
  + 1. If the FDA or Authorized Trading Partner determines a product is an illegitimate product, the Pharmacy must identify all Illegitimate Products subject to this notification in possession or control of the Pharmacy and perform any duties in Sections 3.1 and 3.2.
    2. The Pharmacy shall maintain records of the disposition of Illegitimate Products.
  1. **Records**
     1. All T3 and other records created through this SOP must be maintained for six (6) years.
     2. The Pharmacy will provide the applicable T3 within 2 business days if the FDA or other appropriate Federal or State official requests the information in the event of a recall or investigation of a suspect or illegitimate product. The Pharmacy does not need to provide the lot number, initial transaction date, or initial shipment date from the manufacturer unless such information was included in the T3 provided to the Pharmacy.

1. **References/ Resources**:

21 U.S.C. § 360eee.

[FDA, DSCSA Implementation: Product Tracing Requirements for Dispensers – Compliance Policy (Revised) (Oct. 2015)](http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM453225.pdf)

[FDA, Draft Guidance, Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification (June 2014)](http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM400470.pdf)

[FDA, Drug Establishments Current Registration Site](http://www.accessdata.fda.gov/scripts/cder/drls/default.cfm)

[FDA, Verify Wholesale Drug Distributor Licenses](http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm281446.htm)

[FDA, Form 3911](http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM513940.pdf)

[FDA, Form 3911 Instructions](http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM513942.pdf)

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| Prepared by/Date: | Approved by/Date: |

# 13.0 Forms

## FM-01 Acknowledgement of Policies

I hereby acknowledge that I have received a copy of the Pharmacy Policies. I have read the Policies, fully understand them, and also understand that I can ask my supervisor or another manager for further information on any subject contained in the Policies at any time. I am fully aware of my obligations at all times to comply with the responsibilities that are imposed on me as a condition of employment, including compliance with the Pharmacy’s policies, practices, and procedures.

I further understand that the contents of the Policies are presented as a matter of information only. While the Pharmacy believes in the plans, policies, and procedures described in the Policies, they are not intended nor should they be construed as a contract of employment, and they do not modify my at-will employment status.

I understand and agree that my employment with the Pharmacy is “at will,” meaning that either the Pharmacy or I may terminate the employment relationship at any time, for any reason or no reason, with or without notice or cause.

I understand and agree that the provisions of these policies supersede all prior written or verbal policies regarding my employment. I understand these provisions are subject to change or revocation at any time without notice at the sole discretion of the Pharmacy. I understand and agree that no individual manager or supervisor of the Pharmacy, except the Pharmacy owner, has any authority to enter into any agreement contrary to these provisions. Any agreement contrary to the provisions of this Handbook must be signed by the Pharmacy owner, including but not limited to any modifications of my at-will employment status.

I understand and acknowledge that there have been no oral or written representations made promising or guaranteeing my continued employment.

I understand and acknowledge that I am responsible for ensuring that the Pharmacy’s rules and procedures are complied with and that I am responsible for maintaining a cohesive, effective, and safe working environment. I acknowledge that I am responsible for immediately reporting any unsafe condition to my supervisor.

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Print Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

## FM-02 Pharmacy Change Form

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| **Pharmacy**  **Change Form** |

**Section 1:**Change Request - **Initiator**

|  |  |
| --- | --- |
| Initiator name: | Date: |
| Document Name: | Document Number: |
| Current Revision: | New Revision: |
| Was initiation of the SOP or Policy change approved by the Pharmacy owner?Yes\_­­­­­ No\_  Pharmacy owner name: Date of initiation approval: | |
| **Reason for Change or New Procedure:** Briefly describe the reason and justification for the change or new procedure. | |

**Section 2:** Document Control (DC) - List all reviewers required to evaluate the impact to quality, cost, product, operations, other procedure or document impact, benefits or negatives of proposed change. The Pharmacy owner must be included in the review.

|  |  |  |  |
| --- | --- | --- | --- |
| Reviewers: | Comments: | Approve | Reject |
|  |  |  |  |
|  |  |  |  |
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**Section 3:** Training - Work with the Pharmacy owner to identify training requirements, potential impacts on personnel, develop training material, and create training schedule.

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| --- |
| Training Requirements: |

**Section 4:**Pharmacy Owner Approval - Obtain signed approval to indicate that all requirements for Change Control are complete.

|  |
| --- |
| Document Control: Date: |

**Section 5:**Change Status

|  |
| --- |
| □ Approved – Comments: □ Master Index Updated |
| □ Rejected / Reason: |
|  |

## FM-03 Adverse Drug Event (ADE) Reporting Form

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Adverse Event Report** | | | | | | |
| **Part 1** | | | | **Date Received:** | | |
| Pharmacy Location: | | | | | | |
| Rx Number: | | | | Date Filled: | | |
| **Part 2** - **Patient Information** | | | | | | |
| Name: | | | | Phone: | | |
| Age: | | DOB: | | | Gender: | |
| Address: | City: | | | State: | | Zip: |
| **Part 3** - **Provider Information** | | | | | | |
| Doctor Name: | | | | Phone: | | |
| Address: | City: | | | State: | | Zip: |
| **Part 4** - **Product Information** | | | | | | |
| Product Name: | | | | Form: | | Strength: |
| Qty Dispensed: | | | | Manufacturer: | | |
| NDC #: | | Lot #: | | | Expiration Date: | |
| Directions for Use: | | | | | | |
|  | | | | | | |
| **Part 4 - ADE Information** | | | | | | |
| Date of Onset: | | | | Stop Date: | | |
| Therapy Start Date: | | | | Therapy Stop Date: | | |
| Diagnosis: | | | | | | |
| **Description of ADE** - describe event with detail and attach all associated documents: | | | | | | |
|  | | | | | | |
| **Part 5 - Clinical Evaluation** | | | Performed By: | | | Date: |
| Severity Grade: | | | | | | |
| Is this reportable to MFG: | | | | Date Sent: | | |
| Is this reportable to FDA: | | | | Date Sent: | | |
| Required Follow Up Instructions: | | | | | | |
|  | | | | | | |

## FM-04 Complaint or Quality Related Event (QRE) Report

|  |  |
| --- | --- |
| Complaint or Quality Related Event Report | |
| Complaint/ QRE Received By: | |
| Incident Location: | Date/Time: |
| Complainant Name: | |
| Address: | |
| Phone No: | Email: |
| Dr. or Hospital Name: | |
| Medication or Drug Information: | |
| **Nature of Complaint or Event** | |
| ***Description of Complaint/ Event:*** | |
| **Response to Complaint or Event** | |
| Initial Complaint Reviewed By: | Resolution Rendered: |
| Need for Further Review/ Follow Up:  Yes\_\_ No\_\_ | Follow Up By: |
| ***Investigation Summary Information:*** | |
| Corrective Action: | |
| Closure Date: | By: |

## FM-05 Inadvertent Disclosure Letter

[COMPANY LETTERHEAD]

(Insert Date)

Dear \*:

We are contacting you because we have learned of an inadvertent disclosure incident that occurred on [*specific or approximate date*] and that may have involved some of your personal information.

We sincerely apologize that [*Describe what happened, the date it happened, and the date it was discovered. Also describe what type of information was breached, such as full name, Social Security number, date of birth, home address, account number, diagnosis, disability code, or other types of information.*]

Our company takes this inadvertent disclosure very seriously, and when we were notified of this incident, we launched a full investigation. [*Describe what you are doing to investigate the breach. For example: “We mobilized our Incident Response Team which investigated the source and cause of the breach in addition to the potential damages caused by the breach.”*]

[*Describe what you are doing to mitigate harm to the affected individuals. For example: “We have notified law enforcement and have advised the three major U.S. credit bureaus about this incident. We have also given them a general report alerting them to the fact that the incident occurred. However, we have not notified them about the presence of specific information in the breach.” OR if a RX was given to the wrong individual, how you issued a recall, or if you are having someone retrieve the Rx and destroying it, etc.*]

To ensure that this type of incident doesn’t occur again, we have conducted additional training for our employees and have implemented additional procedures in our [*patient verification, shipping, etc. whichever department caused the breach].*

Again, we apologize for any distress this situation has caused you, and we are here to assist you in any way. For more information or to ask questions, contact us *at [insert toll-free telephone number, e-mail address, Web site, and/or postal address].*

Best regards,

*[Signature]*

*[TITLE]*

## FM-06 HIPAA Notice of Privacy Practices and Acknowledgement

**NOTICE OF PRIVACY PRACTICES**

Your Information. Your Rights. Our Responsibilities.

This notice describes how medical information about you may be used and disclosed and how you can get access to this information. Please review it carefully.

Your Rights

You have the right to:

* Get a copy of your paper or electronic medical record
* Correct your paper or electronic medical record
* Request confidential communication
* Ask us to limit the information we share
* Get a list of those with whom we’ve shared your information
* Get a copy of this privacy notice
* Choose someone to act for you
* File a complaint if you believe your privacy rights have been violated

**Your Choices**

You have some choices in the way that we use and share information as we:

* Tell family and friends about your condition
* Provide disaster relief
* Include you in a hospital directory
* Provide mental health care
* Market our services and sell your information
* Raise funds

**Our Uses and Disclosures**

We may use and share your information as we:

|  |
| --- |
| * Treat you * Run our organization * Bill for your services * Help with public health and safety issues * Do research * Comply with the law * Respond to organ and tissue donation requests * Work with a medical examiner or funeral director * Address workers’ compensation, law enforcement, and other government requests * Respond to lawsuits and legal actions |

**Your Rights**

**When it comes to your health information, you have certain rights.** This section explains your rights and some of our responsibilities to help you.

**Get an electronic or paper copy of your medical record**

* You can ask to see or get an electronic or paper copy of your medical record and other health information we have about you. Ask us how to do this.
* We will provide a copy or a summary of your health information, usually within 30 days of your request. We may charge a reasonable, cost-based fee.

**Ask us to correct your medical record**

* You can ask us to correct health information about you that you think is incorrect or incomplete. Ask us how to do this.
* We may say “no” to your request, but we will tell you why in writing within 60 days.

**Request confidential communications**

* You can ask us to contact you in a specific way (for example, home or office phone) or to send mail to a different address.
* We will say “yes” to all reasonable requests.

**Ask us to limit what we use or share**

* You can ask us not to use or share certain health information for treatment, payment, or our operations. We are not required to agree to your request, and we may say “no” if it would affect your care.
* If you pay for a service or health care item out-of-pocket in full, you can ask us not to share that information for the purpose of payment or our operations with your health insurer. We will say “yes” unless a law requires us to share that information.

**Get a list of those with whom we have shared information**

* You can ask for a list (accounting) of the times we’ve shared your health information for six years prior to the date you ask, who we shared it with, and why.
* We will include all the disclosures except for those about treatment, payment, and health care operations, and certain other disclosures (such as any you asked us to make). We’ll provide one accounting a year for free but will charge a reasonable, cost-based fee if you ask for another one within 12 months.

**Get a copy of this privacy notice**

You can ask for a paper copy of this notice at any time, even if you have agreed to receive the notice electronically. We will provide you with a paper copy promptly.

**Choose someone to act for you**

* If you have given someone medical power of attorney or if someone is your legal guardian, that person can exercise your rights and make choices about your health information.
* We will make sure the person has this authority and can act for you before we take any action.

**File a complaint if you feel your rights are violated**

* You can complain if you feel we have violated your rights by contacting us using the information on page 1.
* You can file a complaint with the U.S. Department of Health and Human Services Office for Civil Rights by sending a letter to 200 Independence Avenue, S.W., Washington, D.C. 20201, calling 1-877-696-6775, or visiting **www.hhs.gov/ocr/privacy/hipaa/complaints/.**
* We will not retaliate against you for filing a complaint.

**Your Choices**

**For certain health information, you can tell us your choices about what we share.** If you have a clear preference for how we share your information in the situations described below, talk to us. Tell us what you want us to do, and we will follow your instructions.

In these cases, you have both the right and choice to tell us to:

* Share information with your family, close friends, or others involved in your care
* Share information in a disaster relief situation
* Include your information in a hospital directory

*If you are not able to tell us your preference, for example if you are unconscious, we may go ahead and share your information if we believe it is in your best interest. We may also share your information when needed to lessen a serious and imminent threat to health or safety.*

In these cases we never share your information unless you give us written permission:

* Marketing purposes
* Sale of your information
* Most sharing of psychotherapy notes

In the case of fundraising:

* We may contact you for fundraising efforts, but you can tell us not to contact you again.

**Our Uses and Disclosures**

**How do we typically use or share your health information?**

We typically use or share your health information in the following ways.

**Treat you**

We can use your health information and share it with other professionals who are treating you.

*Example: A doctor treating you for an injury asks another doctor about your overall health condition.*

**Run our organization**

We can use and share your health information to run our practice, improve your care, and contact you when necessary.

*Example: We use health information about you to manage your treatment and services.*

**Bill for your services**

We can use and share your health information to bill and get payment from health plans or other entities.

*Example: We give information about you to your health insurance plan so it will pay for your services.*

How else can we use or share your health information?

We are allowed or required to share your information in other ways – usually in ways that contribute to the public good, such as public health and research. We have to meet many conditions in the law before we can share your information for these purposes. For more information see: [www.hhs.gov/ocr/privacy/hipaa/understanding/consumers/index.html](http://www.hhs.gov/ocr/privacy/hipaa/understanding/consumers/index.html).

**Help with public health and safety issues**

We can share health information about you for certain situations such as:

* Preventing disease
* Helping with product recalls
* Reporting adverse reactions to medications
* Reporting suspected abuse, neglect, or domestic violence
* Preventing or reducing a serious threat to anyone’s health or safety

**Do research**

We can use or share your information for health research.

**Comply with the law**

We will share information about you if state or federal laws require it, including with the Department of Health and Human Services if it wants to see that we’re complying with federal privacy law.

**Respond to organ and tissue donation requests**

We can share health information about you with organ procurement organizations.

**Work with a medical examiner or funeral director**

We can share health information with a coroner, medical examiner, or funeral director when an individual dies.

**Address workers’ compensation, law enforcement, and other government requests**

We can use or share health information about you:

* For workers’ compensation claims
* For law enforcement purposes or with a law enforcement official
* With health oversight agencies for activities authorized by law
* For special government functions such as military, national security, and presidential protective services

**Respond to lawsuits and legal actions**

We can share health information about you in response to a court or administrative order, or in response to a subpoena.

**Our Responsibilities**

* We are required by law to maintain the privacy and security of your protected health information.
* We will let you know promptly if a breach occurs that may have compromised the privacy or security of your information.
* We must follow the duties and privacy practices described in this notice and give you a copy of it.
* We will not use or share your information other than as described here unless you tell us we can in writing. If you tell us we can, you may change your mind at any time. Let us know in writing if you change your mind.

For more information see: [www.hhs.gov/ocr/privacy/hipaa/understanding/consumers/noticepp.html](http://www.hhs.gov/ocr/privacy/hipaa/understanding/consumers/noticepp.html).

Changes to the Terms of this Notice

We can change the terms of this notice, and the changes will apply to all information we have about you. The new notice will be available upon request, in our office, and on our web site.

If you need any additional information about this Notice or wish to exercise any of your rights set forth in this Notice, please contact the Privacy Officer at the following address:

Telephone:

POLICY MAKER NOTE: The Privacy Rule requires you to describe any state or other laws that require greater limits on disclosures. For example, “We will never share any substance abuse treatment records without your written permission.” Insert this type of information here. If no laws with greater limits apply to your entity, no information needs to be added.

**ACKNOWLEDGEMENT OF RECEIPT OF NOTICE OF PRIVACY PRACTICES**\* You May Refuse to Sign This Acknowledgement\*

I, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, have received a copy of this office’s Notice of Privacy Practices.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Please Print Name

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date

**For Office Use Only**

We attempted to obtain written acknowledgement of receipt of our Notice of Privacy Practices, but acknowledgement could not be obtained because:

■ ☐ Individual refused to sign  
■ ☐ Communications barriers prohibited obtaining the acknowledgement ■

☐ An emergency situation prevented us from obtaining acknowledgement ■

☐ Other (Please Specify)

## FM-07 Business Associate Agreement

**BUSINESS ASSOCIATE AGREEMENT**

This Agreement is by and between \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (“Covered Entity”), whose address is \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, and \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, (“Business Associate”), whose address is \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

**Definitions**

The following terms used in this Agreement shall have the same meaning as those terms in the HIPAA Rules: Breach, Data Aggregation, Designated Record Set, Disclosure, Health Care Operations, Individual, Minimum Necessary, Notice of Privacy Practices, Protected Health Information, Required By Law, Secretary, Security Incident, Subcontractor, Unsecured Protected Health Information, and Use.

**Business Associate**. “Business Associate” shall generally have the same meaning as the term “business associate” at 45 CFR 160.103, and in reference to the party to this agreement, shall mean [Insert Name of Business Associate].

**Covered Entity**. “Covered Entity” shall generally have the same meaning as the term “covered entity” at 45 CFR 160.103, and in reference to the party to this agreement, shall mean [Insert Name of Covered Entity].

**HIPAA Rules**. “HIPAA Rules” shall mean the Privacy, Security, Breach Notification, and Enforcement Rules at 45 CFR Part 160 and Part 164.

**Obligations and Activities of Business Associate**

**Business Associate agrees to**:

(a) Not use or disclose protected health information other than as permitted or required by the Agreement or as required by law;

(b) Use appropriate safeguards and comply with Subpart C of 45 CFR Part 164 with respect to electronic protected health information to prevent use or disclosure of protected health information other than as provided for by the Agreement;

(c) Report to Covered Entity any use or disclosure of protected health information not provided for by the Agreement of which it becomes aware, including breaches of unsecured protected health information as required at 45 CFR 164.410, and any security incident of which it becomes aware;

(d) In accordance with 45 CFR 164.502(e)(1)(ii) and 164.308(b)(2), if applicable, ensure that any subcontractors that create, receive, maintain, or transmit protected health information on behalf of Business Associate agree to the same restrictions, conditions, and requirements that apply to Business Associate with respect to such information;

(e) Make available protected health information in a designated record set to the [Choose either “Covered Entity” or “Individual or the Individual’s Designee”] as necessary to satisfy Covered Entity’s obligations under 45 CFR 164.524;

(f) Make any amendment(s) to protected health information in a designated record set as directed or agreed to by Covered Entity pursuant to 45 CFR 164.526, or take other measures as necessary to satisfy Covered Entity’s obligations under 45 CFR 164.526;

(g) Maintain and make available the information required to provide an accounting of disclosures to the [Choose either “Covered Entity” or “Individual”] as necessary to satisfy Covered Entity’s obligations under 45 CFR 164.528;

(h) To the extent Business Associate is to carry out one or more of Covered Entity's obligation(s) under Subpart E of 45 CFR Part 164, comply with the requirements of Subpart E that apply to Covered Entity in the performance of such obligation(s); and

(i) Make its internal practices, books, and records available to the Secretary for purposes of determining compliance with the HIPAA Rules.

**Permitted Uses and Disclosures by Business Associate**

(a) Business Associate may only use or disclose protected health information:

*[Option 1 – Provide a specific list of permissible purposes.]*

*[Option 2 – Reference an underlying service agreement, such as “as necessary to perform the services set forth in Service Agreement.”]*

[In addition to other permissible purposes, the parties should specify whether Business Associate is authorized to use protected health information to de-identify the information in accordance with 45 CFR 164.514(a)-(c). The parties also may wish to specify the manner in which Business Associate will de-identify the information and the permitted uses and disclosures by Business Associate of the de-identified information.]

(b) Business Associate may use or disclose protected health information as required by law.

(c) Business Associate agrees to make uses and disclosures and requests for protected health information consistent with Covered Entity’s minimum necessary policies and procedures.

(d) Business Associate may not use or disclose protected health information in a manner that would violate Subpart E of 45 CFR Part 164 if done by Covered Entity.

**Term and Termination**

(a) Term. The Term of this Agreement shall be effective as of [Insert effective date], and shall terminate on [Insert termination date or event] or on the date Covered Entity terminates for cause as authorized in paragraph (b) of this Section, whichever is sooner.

(b) Termination for Cause. Business Associate authorizes termination of this Agreement by Covered Entity, if Covered Entity determines Business Associate has violated a material term of the Agreement and Business Associate has not cured the breach or ended the violation within the time specified by Covered Entity.

(c) Obligations of Business Associate upon Termination.

Upon termination of this Agreement for any reason, Business Associate shall return to Covered Entity all protected health information received from Covered Entity, or created, maintained, or received by Business Associate on behalf of Covered Entity that Business Associate still maintains in any form. Business Associate shall retain no copies of the protected health information.

(d) Survival. The obligations of Business Associate under this Section shall survive the termination of this Agreement.

**Miscellaneous**

(a) Regulatory References. A reference in this Agreement to a section in the HIPAA Rules means the section as in effect or as amended.

(b) Amendment. The Parties agree to take such action as is necessary to amend this Agreement from time to time as is necessary for compliance with the requirements of the HIPAA Rules and any other applicable law.

(c) Interpretation. Any ambiguity in this Agreement shall be interpreted to permit compliance with the HIPAA Rules.

DATED this \_\_\_\_\_ day of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, 20\_\_\_\_.

COVERED ENTITY: BUSINESS ASSOCIATE:

By: By:

Its: Its:

## FM-08 Power of Attorney for DEA 222/ EOS & Revocation

**Power of Attorney for DEA Forms 222 and Electronic Orders**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (Name of registrant)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(Address of registrant)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(DEA registration number)

I, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(name of person granting power), the undersigned, who is authorized to sign the current application for registration of the above named registrant under the Controlled Substances Act or Controlled Substances Import and Export Act, have made, constituted, and appointed, and by these presents, do make, constitute, and appoint \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(name of attorney-in-fact), my true and lawful attorney for me in my name, place, and stead, to execute applications for books of official order forms and to sign such order forms in requisition for schedule I and II controlled substances, in accordance with Section 308 of the Controlled Substances Act (21 U.S.C. 828) and part 1305 of Title 21 of the Code of Federal Regulations.  I hereby ratify and confirm all that said attorney shall lawfully do or cause to be done by virtue hereof.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(Signature of person granting power)

I, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(name of attorney-in-fact), hereby affirm that I am the person named herein as attorney-in-fact and that the signature affixed hereto is my signature.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(Signature of attorney-in-fact)

Witnesses:

1. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

2. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signed and dated on the \_\_\_ day of \_\_\_\_\_\_\_\_\_\_\_\_in the year\_\_\_\_ at \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, \_\_\_\_\_\_\_.

**Notice of Revocation**

The foregoing power of attorney is hereby revoked by the undersigned, who is authorized to sign the current application for registration of the above-named registrant under the Controlled Substances Act.  Written notice of this revocation has been given to the attorney-in-fact \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ this same day.

(Signature of person revoking power)

Witnesses:

1. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

2. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signed and dated on the \_\_\_ day of \_\_\_\_\_\_\_\_\_\_\_\_in the year\_\_\_\_ at\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, \_\_\_\_\_\_\_\_\_\_\_\_.

## FM-09 Family and Medical Leave (FMLA) Request Form

|  |  |  |  |
| --- | --- | --- | --- |
| **Family and Medical Leave Act (FMLA) Request Form** | | | |
| **To be completed by employee** | | | |
| Employee’s Name | | Department | Phone Number |
| Job Title | | | Employee ID |
| Initial Application Home Phone #: | | | |
| *Reason for Leave of Absence*  Own illness (not work related) Care for ill parent/spouse/child Other (specify)  Pregnancy disability Care for newborn/adopted child (Date of Birth/Placement) | | *Answer all:*  Do you have company medical insurance? Do you have company dental insurance?  **Yes No**  **YesNo**  Are you currently on another leave? Have you or will you be filling a Disability insurance claim? | |
| Requested start date | Anticipated end date | Requested intermittent or reduced work schedule | |
| ***An FMLA leave of absence is a leave without pay. Paid leave (using accrued sick time or vacation hours) shall be substituted for the unpaid leave in accordance with the Family Medical Leave Act Policy.*** | | | |
| I understand that I am required to use accrued paid time off until leave concludes or accrued balance is depleted. Below is an estimate of paid time off available in my account. Hours | | Date Begins (mm/dd/yy) | Date Ends (mm/dd/yy) |
|  | Accrued sick leave |  |  |
|  | Accrued vacation leave |  |  |
| *Employee’s Signature* | | *Date* | |

I understand that I am required to complete a FMLA Leave Certification of Health Care Provider form and submit the form to Human Resources before my leave commences. I understand that if my leave is approved, my time away from work will be charged against my 12 week leave maximum under FMLA. Upon approval of this requested leave, I am required to utilize all paid time available to me prior to going into an unpaid leave status. In the event that I go into an unpaid status while on leave, I understand that I must contact Human Resources to make arrangements to pay my portion of health insurance premiums.

I request the following forms for my FMLA leave of absence:

1. ***Certification of Health Care Provider: This form is to be completed by either my health care provider (if this leave is for my own serious health condition) or by my family member’s health care provider (if this leave is for the serious health condition of a spouse, parent, or child). My physician must complete this entire form. Failure to complete this form may delay or prevent my leave approval.***
2. Continuation of Benefits While on FMLA Leave: This is an agreement between my employer and myself to continue my benefits while on FMLA leave and a financial arrangement for my portion of health care premiums.
3. Notification of FMLA Status (Approval/Denial): This is to notify me that my employer is designating the leave as FMLA leave and to inform me in writing of the specific expectations and obligations required by my employer under FMLA.
4. Request to Return From FMLA Leave: I should fill out the top portion of the form, notifying Human Resources of the date of my return. For my own serious health condition, the bottom portion of the form (fitness-for-duty certification) should be filled out by my Health Care Provider and returned to Human Resources on the day I return to work from FMLA leave.

I understand that the Certification of Health Care Provider form should be returned to Human Resources within 15 days. If I am not able to return the form within the allowed timeframe, I will contact Human Resources for assistance.

If this information is not received in the required timeframe, my leave will be considered unauthorized.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Employee Signature Print Name

## FM-10 Sample Nondiscrimination and Language Service Notification

Under Section 1557 of the Affordable Care Act (ACA), covered entities are required to post notices of nondiscrimination and taglines that alert individuals with limited English proficiency (LEP) to the availability of language assistance services. The translated resources below are available for use by covered entities.

**Sample Notice of Nondiscrimination**

*[Pharmacy Name]* complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. *[Pharmacy Name]* does not exclude people or treat them differently because of race, color, national origin, age, disability, or sex.

*[Pharmacy Name]*:

• Provides free aids and services to people with disabilities to communicate effectively with us, such as:

○ Qualified sign language interpreters

○ Written information in other formats (large print, audio, accessible electronic formats, other formats)

• Provides free language services to people whose primary language is not English, such as:

○ Qualified interpreters

○ Information written in other languages

If you need these services, contact *[Name of Civil Rights Coordinator]*

If you believe that *[Pharmacy Name]* has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with: *[Name and Title of Civil Rights Coordinator], [Mailing Address], [Telephone number], [TTY number—if Pharmacy has one], [Fax], [Email].* You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, *[Name and Title of Civil Rights Coordinator]* is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services

200 Independence Avenue, SW

Room 509F, HHH Building

Washington, D.C. 20201

1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>.

**Sample Statement of Nondiscrimination**

*[Pharmacy Name]* complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex.

**Taglines Informing Individuals with LEP of Language Assistance Services**

[In English, Spanish, Chinese, Vietnamese, Korean, Tagalog, Russian, Haitian Creole, French, Polish, Portuguese, Italian, German, and Japanese]

HHS Hotline: 1-877-696-6775

ATTENTION: If you speak English, language assistance services, free of charge, are available to you. Call 1-xxx-xxx-xxxx.

ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1-xxx-xxx-xxxx.

注意：如果您使用繁體中文，您可以免費獲得語言援助服務。請致電 1-xxx-xxx-xxxx。

CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1-xxx-xxx-xxxx.

주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1-xxx-xxx-xxxx 번으로 전화해 주십시오.

PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nang walang bayad. Tumawag sa 1-xxx-xxx-xxxx.

ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 1-xxx-xxx-xxxx.

ATANSYON: Si w pale Kreyòl Ayisyen, gen sèvis èd pou lang ki disponib gratis pou ou. Rele 1-xxx-xxx-xxxx.

ATTENTION : Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 1-xxx-xxx-xxxx.

UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer 1-xxx-xxx-xxxx.

ATENÇÃO: Se fala português, encontram-se disponíveis serviços linguísticos, grátis. Ligue para 1-xxx-xxx-xxxx.

ATTENZIONE: In caso la lingua parlata sia l'italiano, sono disponibili servizi di assistenza linguistica gratuiti. Chiamare il numero 1-xxx-xxx-xxxx.

ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 1-xxx-xxx-xxxx.

注意事項：日本語を話される場合、無料の言語支援をご利用いただけます。1-xxx-xxx-xxxx まで、お電話にてご連絡ください。

1. For state specific record retention requirements, please review question #5 in the Bula Medicaid for Pharmacies module at https://in.bulalaw.com/ModuleReport/Detail/97?Questions=5&States= [↑](#footnote-ref-1)
2. For state specific record retention requirements, please review question #5 in the Bula Medicaid for Pharmacies module at https://in.bulalaw.com/ModuleReport/Detail/97?Questions=5&States= [↑](#footnote-ref-2)