

**List of Laguna Honda Hospital and Rehabilitation Center (LHH)
Hospital-wide/Department Policies and Procedures
Submitted to the Joint Conference Committee (JCC) for Approval on
July 14, 2020**

Hospital-wide Policies and Procedures

New Policies (page 3)

| <u>Policies</u> | <u>Comments</u> |
|---|---|
| 25-12 Drug Diversion Reporting and Response | Created to provide a standardized approach for identification, reporting, and investigation of any suspected drug diversion by LHH employees. |

Department: Pharmacy Services

Revised Policies (page 17)

| <u>Policies</u> | <u>Comments</u> |
|--|--|
| 01.01.00 General Service | Minor revisions; added that technicians must be licensed by the California State Board of Pharmacy (BOP). |
| 01.01.01 Accessibility To Medications | Minor revisions. |
| 01.01.02 Zero Tolerance For Employees Who Work Under The Influence | Minor revisions to match BOP regulations and limit reporting to BOP for pharmacy personnel only. |
| 01.02.00 Medication Order Records | Revised to clarify record storage dates; removed description of floor stock available in Omnicell, as this will be addressed in policy on Distribution of Medications. |
| 01.02.01 Orders for Medications and Standing Orders | Minor revisions. |
| 01.04.00 Medication Errors | Removed most of the content to refer to hospital-wide policy. |
| 01.04.01 Medication Error Quality Assurance Program (SB1339) | Clarifies that this policy refers specifically to errors in pharmacy practice for investigation and tracking. |
| 02.01.02 Disposition of Medications | Updated reference to hospital-wide and pharmacy policies with appropriate numbers. |
| 02.01.05 Pharmacy Computer Down Time | Revised and updated to be consistent with current practice and technology resources; added references for hospital-wide policy and DPH-wide policy for downtime. |
| 07.01.00 Sterile Product Preparation Handling and Disposal | Added minor updates and removed mention of CACI/hazardous drugs. |

New Hospital-wide Policies and Procedures

DRUG DIVERSION REPORTING AND RESPONSE

POLICY:

1. The prevention of drug diversion is essential to the safety of Laguna Honda Hospital and Rehabilitation Center (LHH) patients and is the individual responsibility of every LHH employee.
2. Employees are required to report known or suspected incidents of drug diversion by employees as soon as suspected.
3. Employees are required to report known or suspected incidents of drug diversion by patients and visitors as outlined in LHHPP 75-05 Illicit or Diverted Drugs and/or Paraphernalia Possession/Use by Residents or Visitors.
4. The Controlled Substance (CS) Oversight Governance includes a Diversion Prevention Committee and Diversion Prevention Core Team, Medication Error Reduction Committee (MERC) in coordination with Pharmacy and Therapeutics (P&T) and Nursing Executive Committee (NEC). Ad hoc members of the Committee may include but not limited to: Medical staff, Nursing, Pharmacy, Security, Human Resources, and Quality Management.
5. Follow the steps and ensure decisions are obtained through each step: 1) initial report, 2) preliminary patient safety assessment, 3) decision to investigate, 4) complete investigation, 5) decision on allegation, 6) employment action, if any, and 6) external reporting, if any. Refer to Appendix I.
6. All suspected incidents of drug diversion shall be thoroughly investigated by the necessary disciplines.
7. Any employee who reports suspected drug diversion honestly and in good faith shall be protected from retaliation.
8. Routine monitoring by audit and surveillance of controlled substance data by pharmacy and nursing shall be analyzed to identify trends and opportunities for potential improvement in the medication use process.
9. Routine monitoring of barcode medication administration data by nursing shall be analyzed to identify trends and opportunities for potential improvement in the medication administration process.

PURPOSE:

To provide a standardized approach for identification, reporting, and investigation of any suspected drug diversion by LHH employees.

DEFINITIONS:

- **Drug Diversion:** Intentionally and without proper authorization, using or taking possession of a medication that does not belong to the employee. Examples of drug diversion include, but are not limited to, the following:
 - Medication theft, including “waste” from patients or organization
 - Using or taking possession of a medication without a valid order or prescription
 - Forging or inappropriately modifying a prescription
- **Employee:** Any staff, allied health staff, healthcare trainee, student, volunteer, contract worker, or any other employee or individual who has received an appointment at LHH.
- **Controlled substance (CS):** Medications classified as Schedule I through V by the Federal Drug Enforcement Agency (DEA) and/or applicable state law.
- **CS Oversight Governance** consists of a multidisciplinary approach that promotes controlled substances monitoring and drug diversion prevention.
- **Drug Diversion Response Team:** A response team consisting of a coordinator and multidisciplinary team to investigate suspected drug diversion. Members shall include: Quality Management, Nursing, Pharmacy and the Manager and Director of the employee suspected of diversion.

PROCEDURE – Refer to Appendix I**A. Initial Report**

Initial reporting that may elicit suspicion of possible diversion may arise from:

- A witnessed incident reported to the employees Manager
 - If an employee is not comfortable notifying his/her/their Manager, an employee may contact Quality Management directly or do so anonymously at Quality Management line 415-759-3055.
- Evidence of drug tampering
- Subjective/objective behaviors that may indicate an impaired individual
- Suspicious activity identified during routine audit and/or surveillance of controlled substance monitoring data
- Self-disclosure
- Notification of suspected drug diversion from an external source, such as local law enforcement or a family member of a suspected drug diverter
- Positive urinary toxicology screen of patients for medication not on patient profile
- Use of naloxone for patient/resident change of condition

B. Immediate Safety and Potential Harm Assessment and Preliminary Investigation

1. Upon initial report eliciting suspicion of possible diversion, the Manager of the employee shall perform an “Immediate Safety and Potential Harm Assessment.”

Refer to Appendix II. Sometimes there are immediate signs and symptoms present. Other times, it is a pattern of behavior that may be a concern. Each situation should be assessed on a case-by-case basis.

- a. Refer to Appendix II Table 1, “Signs and Symptoms of Impairment and Problematic Substance Use” to assist in determining if there may be immediate risk to safety and potential for harm.
 - b. If the suspected individual(s) exhibiting objective and subjective symptoms of impairment related to problematic substance use is on duty and has the ability to cause patient harm, notify HR immediately and consult with Labor Relations for employment action.
2. After completing the safety assessment, the Manager shall notify the Drug Diversion Response Team Coordinator to begin the preliminary investigation to determine if there is evidence of possible drug diversion. This preliminary investigation may include but is not limited to: controlled substance monitoring data and reports; medication theft, including “waste” from patients or organization; using or taking possession of a medication without a valid order or prescription; or forging or inappropriately modifying a prescription
- a. Refer to Appendix II Table 2, “Patterns or Behaviors associated with Potential Diversion Risk” for criteria to guide the diversion investigation.
 - b. The Manager should not engage in any additional evidence collection or investigation without consulting with Quality Management. Except as directed by Quality Management and HR, the Manager shall not interview the individual suspected of drug diversion.
 - c. The Drug Diversion Response Team shall review the Manager’s preliminary investigation findings and collaboratively decide if further investigation is warranted.

C. Decision to Investigate

1. The Drug Diversion Response Team shall guide and support any additional investigations that are deemed necessary.
2. If a patient or a visitor is suspected of drug diversion, follow LHHPP 75-05 Illicit or Diverted Drugs and/or Paraphernalia Possession/Use by Residents or Visitors.

D. Complete the Investigation and Decision Regarding Allegations of Drug Diversion

1. Summarize the findings from the preliminary and detailed investigation into problem statements. Using data and policy reference when possible,

demonstrate the desired standard or employee expectation and why the suspected individual(s) may be an outlier.

2. Confirm the decision regarding allegations of drug diversion with the Director(s) and Drug Diversion Response Team.

E. Reporting to Human Resources and Labor Relations

1. Upon decision to confirm the allegation or consider the incident as a probable diversion, the Manager shall work with HR Labor Relations on Employment Actions, if any.
2. Alternative program to assist in the rehabilitation of impaired healthcare professionals may be offered.

F. Reporting to Law Enforcement and External Regulatory Bodies

1. In collaboration with the Quality Management Department, the following individuals shall report drug diversion by licensed or registered health care providers to the appropriate State licensing board:
 - a. The Chief Nursing Officer shall report drug diversion by nurses.
 - b. The Chief Pharmacy Officer shall report drug diversion by pharmacy staff.
 - c. The Chief Medical Officer shall report drug diversion by staff physicians
 - d. The applicable Manager or other Departmental leader shall report drug diversion by all other licensed or registered health care providers.
2. The Quality Management Department and the Drug Diversion Response Team shall evaluate all incidents of drug diversion to determine whether additional external reports should be made, such as reports to the California Department of Public Health (CDPH), local law enforcement, and Drug Enforcement Agency (DEA).
3. If any patient is harmed by drug diversion, steps consistent with LHHPP 22-01 Abuse and Neglect Prevention, Identification, Investigation, Protection, Reporting and Response shall be followed.

G. Audits and Data Surveillance

1. Routine monitoring by audit or data surveillance shall be analyzed to identify trends and opportunities for potential improvement in the medication use process.

ATTACHMENT:

Appendix I: Controlled Substance Diversion Investigation Flow

Appendix II: Immediate Safety and Potential Harm Assessment and Preliminary Investigation

REFERENCE:

1. Diversion Investigation Form
2. Nursing Policy J1.0 Medication Administration
3. LHHPP 22-01 Abuse and Neglect Prevention, Identification, Investigation, Protection, Reporting and Response
4. LHHPP 75-05 Illicit or Diverted Drugs and/or Paraphernalia Possession/Use by Residents or Visitors
5. Pharmacy Policy 02.02.00 Controlled Substances
6. Pharmacy Policy 09.00 Automated Dispensing Cabinets
7. Reducing Controlled Substances Diversion in Hospitals. California Hospital Association Medication Safety Committee, www.calhospital.org/medication-safety-committee, Accessed April 2, 2019.
8. Road Map to Controlled Substance Diversion Prevention. Minnesota Hospital Association, <https://www.mnhospitals.org/Portals/0/Documents/ptsafety/diversion/controlled-substance-diversion-prevention-roadmap.pdf>, Accessed April 2, 2019.
9. Institutional Policy Manual Drug Diversion Reporting and Response. Mayo Foundation for Medical Education and Research Original effective date: 06/01/2012. Available at <https://www.mnhospitals.org/Portals/0/Documents/ptsafety/diversion/drug-diversion-reporting-and-response.pdf>, Accessed April 1, 2019.
10. ASHP Guidelines on Preventing Diversion of Controlled Substances, <https://www.ashp.org/-/media/assets/policy-guidelines/docs/guidelines/preventing-diversion-of-controlled-substances.ashx>, Accessed April 5, 2019.
11. Canadian Centre for Occupational Health and Safety. Impairment at Work Fact Sheet, <https://www.ccohs.ca/oshanswers/hsprograms/impairment.html>, Accessed April 8, 2019.

Appendix I – Controlled Substance Diversion Investigation Flow

Controlled Substance Diversion Response



Initial Reporting

- Manager/Supervisor of employee identifies suspected diversion
- May be related to witnessed incident, subjective/objective behavior, routine audit findings, surveillance of controlled substance monitoring data from reports, self-disclosure, external source

Immediate Assessment

- Follow the “Immediate Safety Assessment and Investigation Worksheet”
- If the suspected individual(s) exhibit objective and subjective symptoms of impairment while on duty and has the potential to cause patient harm, notify the AOD and Director of the employee suspected of diversion

Investigation (Step 2 and 3)

- Under the guidance of the Director of the employee suspected of diversion, the Drug Diversion Response Team Coordinator shall assemble the team which includes: Quality, Nursing, Pharmacy, Director, Manager
- For initial baseline, use a minimum of past 30 days or 20 shifts. The team will determine if further investigation of another 30 days or 20 shifts is needed

Complete

- Summarize findings, including the Immediate Safety Assessment and Investigation Worksheet as well as report of behaviors that deviate from standard work, policy and procedures, and/or similar patterns of peers and work environment

Confirm Allegation

- In collaboration with the HR and Quality Management Departments, the Manager/Supervisor, Director and Response Team Coordinator shall determine the next steps, if applicable, which may include but is not limited to discipline and external reporting

Employment Action

- The Manager/Supervisor shall work with HR Labor Relations Department on employee actions and collaboratively confirm the allegation or consider as probable diversion.

External Reporting

- In collaboration with the Quality Management Department, confirmed drug diversion by LHH staff shall be reported to the appropriate State licensing boards
- The Quality Management Department and the Drug Diversion Response Team will evaluate if reporting to external reports should be made

Appendix II Immediate Safety and Potential Harm Assessment and Preliminary Investigation

Step 1: Immediate Safety and Potential Harm Assessment

- The following table can be used to help determine impairment in general. Each situation should be assessed on a case-by-case basis.
- Take steps to preserve any readily apparent evidence, such as medication vials or syringes, collect additional surveillance and witness statements.
- Consider if the employee is at risk for injury to self or others. After referring to Table 1: Signs and Symptoms of Impairment and Problematic Substance Use, additional considerations include but are not limited to:
 - Does the suspected individual(s) have the ability to cause patient harm?
 - Are they operating machinery?
 - Using sharp objects?
 - Exhibiting inappropriate cognitive ability and impaired judgment?
 - If yes, contact Director/AOD and notify HR immediately to consult with Labor Relations on Employment Actions.
 - If there is no immediate patient safety concern, the Manager may proceed to initiate a preliminary investigation

| Table 1. Worksheet to Identify Potential Diversion or Immediate Safety and Potential Harm Assessment | | 1. Name of Suspected Individual: 2. List All Subjective/Objective Criteria Found |
|---|--|---|
| Initial Reporting Source | <input type="checkbox"/> A witnessed incident <input type="checkbox"/> Evidence of drug tampering <input type="checkbox"/> Subjective/objective behaviors that may indicate an impaired individual <input type="checkbox"/> Suspicious activity identified during routine audit and/or surveillance of controlled substance monitoring data <input type="checkbox"/> Self-disclosure <input type="checkbox"/> Notification of suspected drug diversion from an external source, such as local law enforcement or a family member of a suspected drug diverter <input type="checkbox"/> Other | |

| | | |
|--|--|--|
| <p>Diversion Definition</p> | <ul style="list-style-type: none"> <input type="checkbox"/> Medication theft, including “waste” from patients or organization <input type="checkbox"/> Using or taking possession of a medication without a valid order or prescription <input type="checkbox"/> Forging or inappropriately modifying a prescription <input type="checkbox"/> Other | |
| <p>Potential Signs and Symptoms of Impairment</p> | | |
| <p>Subjective</p> | <ul style="list-style-type: none"> <input type="checkbox"/> Significant stress in personal life, family disharmony <input type="checkbox"/> Personality changes or erratic behavior (e.g. increased interpersonal conflicts; overreaction to criticism) <input type="checkbox"/> Mood fluctuations (e.g., swinging from being extremely fatigued to ‘perkiness’ in a short period of time) <input type="checkbox"/> Inappropriate verbal or emotional response <input type="checkbox"/> Irritability <input type="checkbox"/> Confusing or memory lapses <input type="checkbox"/> Inappropriate responses/behaviors <input type="checkbox"/> Isolation from colleagues <input type="checkbox"/> Lack of focus/concentration and forgetfulness <input type="checkbox"/> Lying and/or providing implausible excuses for behavior <input type="checkbox"/> Other | |
| <p>Objective</p> | <ul style="list-style-type: none"> <input type="checkbox"/> Deterioration in appearance and/or personal hygiene <input type="checkbox"/> Unexplained bruises <input type="checkbox"/> Sweating <input type="checkbox"/> Complaints of headaches <input type="checkbox"/> Tremors <input type="checkbox"/> Diarrhea and vomiting <input type="checkbox"/> Abdominal/muscle cramps <input type="checkbox"/> Restlessness <input type="checkbox"/> Frequent use of breath mints/gum or mouthwash <input type="checkbox"/> Odor of alcohol on breath <input type="checkbox"/> Slurred speech <input type="checkbox"/> Unsteady gait | |

| | | |
|--|--|--|
| | <input type="checkbox"/> Neglect of duty or failure to perform job duties properly or repeatedly performs in an unsafe manner or involvement in an incident(s) <input type="checkbox"/> Consistent tardiness, absenteeism, or reduced productivity or quality of work <input type="checkbox"/> Failing a drug or alcohol test (Board of Nursing/Pharmacy may require as condition of return to work) <input type="checkbox"/> Other | |
|--|--|--|

Step 2: Preliminary Investigation

- Evaluate trends using the criteria below
- Use 1 month or 20 shifts of data as baseline for audits and reports
- Document evaluations and findings using template provided by the Diversion Response Team Coordinator

| Table 2. Worksheet to Identify Patterns or Behaviors Associated with Potential Diversion Risk | | 1. Name of Suspected Individual: 2. List All Data Found |
|--|--|--|
| Patterns or Behaviors Associated with Potential Diversion Risk | | |
| Role | <input type="checkbox"/> Agency or contract staff <input type="checkbox"/> Night shift <input type="checkbox"/> Evening shift <input type="checkbox"/> Day shift <input type="checkbox"/> Other | |
| Suspicious Behaviors | <input type="checkbox"/> Significant stress in personal life <input type="checkbox"/> Tardiness, unscheduled absences and an excessive number of sick days used <input type="checkbox"/> Frequency disappearances from the work site and taking frequent or long trips to the bathroom or to the stockroom where drugs are kept <input type="checkbox"/> Arrives at work early, stays late, and is at work when not scheduled to be there | |

| | | |
|-----------------------------|--|--|
| | <input type="checkbox"/> Work performances alternates between periods of high and low productivity, may suffer from mistakes, poor judgment, and bad decisions <input type="checkbox"/> Moving to a position where there is less visibility or supervision <input type="checkbox"/> Extended breaks; sometimes without telling colleagues they are leaving <input type="checkbox"/> Forgetfulness <input type="checkbox"/> Errors in judgment <input type="checkbox"/> Deterioration in performance <input type="checkbox"/> Excessive number of incidents/mistakes <input type="checkbox"/> Non-compliance with policies <input type="checkbox"/> Other | |
| Storage and Security | <input type="checkbox"/> CS are stored in unapproved location and <input checked="" type="checkbox"/> CS access is not limited to authorized staff <input type="checkbox"/> Access is continued for terminated employees <input type="checkbox"/> Cabinets contain outdated stock <input type="checkbox"/> Other | |
| Procurement | <input type="checkbox"/> Unauthorized individuals are able to order Scheduled II to V <input type="checkbox"/> The ordering staff are the same persons who receive the CS. <input type="checkbox"/> CS receiving is not limited to licensed pharmacist or authorized receiving individual signs for CS delivery <input type="checkbox"/> Discrepancy between the receipt and the type or quantity of CS actually received are not reported promptly to the wholesaler or manufacturer <input type="checkbox"/> Other | |
| Prescribing | <input type="checkbox"/> CS are prescribed for him/herself or immediate family members <input type="checkbox"/> Uneven request for "one time" orders compared to other colleagues <input type="checkbox"/> Other | |

| | | |
|---|---|--|
| <p>Preparation and Dispensing</p> | <p><input type="checkbox"/> Evidence of tampering <input type="checkbox"/> Discrepancies in the count <input type="checkbox"/> Reconciliation is performed on ADM CS dispense transactions for temporary patients to ensure that the CS went to the actual patient and valid prescriber order exist <input type="checkbox"/> CS ADM overrides is used according to approved criteria <input type="checkbox"/> Other</p> | |
| <p>Medication Administration</p> | <p><input type="checkbox"/> <input type="checkbox"/> The individual retrieving CS from the ADM/locked storage area is not the person that administers the medication <input type="checkbox"/> Time of transaction patterns – extended duration between retrieval & admin, end of shift transactions <input type="checkbox"/> Removal of duplicate dose or discharged patients <input type="checkbox"/> Uneven administration to patient(s) in one area <input type="checkbox"/> Uneven pain scores compared w/ colleagues <input type="checkbox"/> Uneven # transactions & overrides based on unit <input type="checkbox"/> Unreconciled verbal order <input type="checkbox"/> No documentation of administration <input type="checkbox"/> Other</p> | |
| <p>Handling CS Wasting</p> | <p><input type="checkbox"/> Failure to follow procedures for wasting CS medication <input type="checkbox"/> Frequent wasting of entire doses <input type="checkbox"/> Unusual or high pattern of wastage or overrides, common “wasting partners”, holding of waste until oncoming shift <input type="checkbox"/> Expire CS are not quarantined for reverse distribution and documented <input type="checkbox"/> Other</p> | |
| <p>Monitoring of CS and process if</p> | <p><input type="checkbox"/> All transaction for Suspected User – Look for</p> <ul style="list-style-type: none"> • Discrepancies • Overrides | |

| | | |
|-------------------------------|---|--|
| diversion is suspected | <ul style="list-style-type: none">• Failure to waste<input type="checkbox"/> Unusual or high patterns compared to their peers in the same unit for high dose, quantity, frequency of overrides, or non-approved uses of overrides<input type="checkbox"/> Barcode medication administration scanning overrides<input type="checkbox"/> Other | |
|-------------------------------|---|--|

Revised Pharmacy Policies and Procedures

LAGUNA HONDA HOSPITAL
DEPARTMENT OF PHARMACEUTICAL SERVICES

01.01.00

POLICY AND PROCEDURE FOR PHARMACY SERVICE: GENERAL

Policy:

Laguna Honda Hospital will have on its premises a licensed pharmacy that will be responsible for: purchasing, storing, and preparing medications; monitoring the medication distribution system; and providing consultative service to the hospital medical and nursing staffs. In order to accomplish this, the pharmacy will have adequate personnel, adequate space, equipment, and supplies.

Purpose:

To ensure an adequate and prompt supply of medications to residents.

Procedures:

There are written policies and procedures for safe and effective distribution, control and use of medications.

I. Location and Licensing

- A. The hospital maintains a licensed pharmacy on its premises for the use of hospital in-patients only.
- B. The pharmacy is licensed by the State of California under numbers HPE 4323, the Sterile Compounding license is LSE 99090. The DEA license is AL7995751.

II. The pharmacy is responsible for rendering the required service in accordance with local, state, and federal laws and regulations; facility policies and procedures; community standards of practice; and professional standards of practice.

III. The pharmacy performs the following pharmaceutical services, including but not limited to:

- A. Determining the appropriate equipment and packaging to meet the medication needs of the residents and the facility.
- B. Accurately dispensing prescriptions based on authorized prescriber orders.
- C. Supplying only USP-NF approved medications, biologicals, and supplies, other than extemporaneously compounded medications or investigational drugs.
- D. Labeling all medications dispensed in accordance with state and federal requirements.
- E. Providing routine and timely pharmacy service six days per week and emergency pharmacy service 24 hours per day, seven days per week.
- F. Performing an initial medication use assessment for each new resident to ensure that the medication regimen meets the resident's needs.
- G. Maintaining a medication profile on each resident that includes all medications dispensed and information such as resident's age, diagnoses, condition, medication allergies, diet, and any other pertinent information.
- H. Reviewing the resident's profile prior to dispensing any medication.

- I. Screening each new medication order for an appropriate indication or diagnosis; for medication interactions based on the medication profile of the resident; for duplication of therapy with other drugs in the same therapeutic class ordered for the resident; and for appropriate drug dose, dosing interval, and route of administration, based on resident and other pertinent variables.
- J. Providing medication information and consultation to the facility's staff.
- K. Providing, maintaining, and replenishing an emergency medication supply in a sealed and properly labeled container in a timely manner.
- L. Assisting the physician in documenting the medical necessity for a "non-covered" or non-formulary medication ordered for a resident otherwise eligible for medication benefits through Medicare, Medicaid or other third-party programs.

IV. Hospital Formulary and Medication Purchasing

- A. There is a Hospital formulary that is approved by the Pharmacy and Therapeutics Committee. The pharmacy will initiate purchase orders according to the regulations of the City Purchasing Department in order to maintain an adequate supply of medications.
- B. Whenever a medication is not available and it is needed quickly, the pharmacy may order it directly from the manufacturer or wholesaler, or may borrow it from other City institutions.

V. Medication Storage

- A. Medications received from suppliers are checked against the invoices for correctness and then stored in the pharmacy following recommendations of the U.S. Pharmacopeia and National Formulary and regulations of the DEA.
- B. Doors to the pharmacy are kept locked at all times.
- C. Only the pharmacists have keys to the pharmacy. The pharmacy helper and technicians have electronic access to the pharmacy during working hours only.

VI. Medication Preparation

- A. Medications are prepared according to standard pharmaceutical practices and only by pharmacists or pharmacy technicians or pharmacy interns under the supervision of a pharmacist. Any repackaging of oral medications into blister packages will be done according to standard pharmaceutical practice. The beyond use date for non-sterile products repackaged into single unit or unit dose containers is one year or less, unless stability data or the manufacturer's labeling indicates otherwise.

VII. Consultative Services to the Hospital

- A. The pharmacists are available on the premises to provide needed consultative service during pharmacy hours and after hours by phone.

- B. In general, consultation is provided to physicians and nurses only; on request from physicians or nurses, consultation may be provided to residents.
- C. In order to provide this service, the pharmacy has an adequate reference library.
- D. Whenever necessary, the pharmacy may request consultation from outside sources.
- E. Pharmacists will serve on the Pharmacy and Therapeutics Committee of the Medical Staff and in the hospital Performance Improvement ~~Committee~~ and Patient Safety Committee, and in other advisory or consultative capacities.

VIII. Personnel

- A. All pharmacists and technicians employed at Laguna Honda Hospital are duly licensed by the State of California.
- B. The hospital will employ a sufficient number of pharmacists, technicians and clerks to properly carry out the needed work.

IX. Space, Equipment, and Supplies

- A. The pharmacy has an adequate amount of space to carry out its functions and to comply with California State Board of Pharmacy regulations.
- B. In order to carry out its functions the pharmacy has the necessary equipment recommended or required by the California State Board of Pharmacy and other State and Federal agencies.
- C. The pharmacy maintains a supply of medications and chemicals sufficient for the needs of the hospital.

Revision History 02/06, 04/07, 03/09, 7/09, 5/14,
8/15, 5/20

LAGUNA HONDA HOSPITAL
DEPARTMENT OF PHARMACEUTICAL SERVICES

01.01.01

POLICY AND PROCEDURE FOR ACCESSIBILITY TO MEDICATIONS

Policy:

Only authorized personnel will have access to medications and biologicals.

Purpose:

To safeguard medications and biologicals from unauthorized personnel.

Procedure:

- I. All medications and biologicals will be secured in locked areas. Only the following personnel will have access to the keys:
 - A. Pharmacists will have ~~keys~~ electronic access to the pharmacy and its storage areas at all times.
 - B. The Pharmacy helper and pharmacy technicians may have electronic access to the pharmacy during working hours only.
 - C. ~~On the Units, only designated staff~~ the registered nurse or LVN assigned to medication duty ~~licensed nurses will will~~ have access to ~~the~~ locked medication rooms. Only licensed staff will have access to medication cabinets and medication carts.
 - D. When the pharmacy is closed at night or weekends, the Unit nurse may obtain medications from the Nursing Supervisor who has access to the Emergency Medication Room. When a drug is not available from the Emergency Medication Room, the Nursing Supervisor will call ~~a~~ the on-call Pharmacist ~~from the Pharmacist Call Back Roster~~.
 - E. There will be 24 hour Pharmacy service. See policy 02.03.00 (Emergency and Supplemental Medication Supplies).
- II. Pharmacy staff shall not bring personal belongings (e.g. purses, backpacks) into drug storage areas.

Revision History: 02/06, 04/07, 05/09, 7/09, 35/20

LAGUNA HONDA HOSPITAL
DEPARTMENT OF PHARMACEUTICAL SERVICES

01.01.02

ZERO TOLERANCE FOR EMPLOYEES WHO WORK UNDER THE INFLUENCE OF DANGEROUS DRUGS OR ALCOHOL, AND/OR ENGAGED IN THE THEFT OR DIVERSION OF DANGEROUS DRUGS

Policy:

It is the policy of Laguna Honda that there will be zero tolerance for employees who work while under the influence of dangerous drugs or alcohol or are found to be engaged in the theft or diversion of dangerous drugs. Any pharmacy employee of Laguna Honda who violates this policy will be subject to corrective or disciplinary action, up to and including termination and will be reported to the State Board of Pharmacy within 14 days of the violation.

Purpose:

The purpose of this policy is to ensure that LHH protects patient safety by strictly prohibiting employees from working under the influence of dangerous drugs or alcohol.

Definitions:

"Impairment" as used in this Policy is defined as diminished ability of an individual to perform the essential functions of their job due to use of or dependency on dangerous drugs or alcohol.

Procedures:

1. Staff will notify their supervisor immediately when they suspect that a coworker may be impaired or working under the influence of a dangerous drug or alcohol.
2. Staff will notify their supervisor immediately when a co-worker is found through documentary evidence or self-admission to be involved in the theft or diversion of dangerous drugs.
3. The supervisor will investigate, consult Human Resources staff, and counsel affected staff, as appropriate.
4. The supervisor will also consult with their manager and, if necessary, appropriate agencies as required by law will be notified of suspected criminal action(s) and/or activity that may have compromised patient safety. The State Board of Pharmacy will be notified within 14 days of the receipt or development ~~of information regarding~~ any pharmacy employee found to be engaged in the theft, diversion or self-use of dangerous drugs. The State Board of Pharmacy will be notified within 14 days of any termination based on chemical, mental, or physical impairment of a licensed ~~individual-pharmacy staff member~~ to the extent it affects his/her ability to practice or any termination of a licensed pharmacy staff member ~~individual~~ based on theft, diversion, or self-use of dangerous drugs.

~~6.5.~~ California Business and Professions Code, Section 4327, makes it a misdemeanor for any person, who, while on duty, sells, dispenses, or compounds any drug while under the influence of any dangerous drug or alcoholic beverages. Such a misdemeanor is a criminal act punishable by fine and/or imprisonment for up to one year.

COMMON SIGNS OF IMPAIRMENT

Caveat: While these behaviors and signs may suggest chemical abuse or dependency, they can also be consistent with other problems, for example, depression.

Physical signs:

- Deteriorating appearance
- Weight loss
- Decline in personal hygiene
- Frequent use of mints/mouthwash
- Slurred speech
- Unsteady gait
- Odor of alcohol

Psychological signs:

- Mood swings
- Lying/deception
- Isolation from coworkers
- Forgetfulness or poor concentration
- Behavior inappropriate to the setting

Job Performance issues:

- High rate of absenteeism for implausible reasons
- Deteriorating performance
- Inability to meet deadlines/goals that others manage easily
- Narcotic supply discrepancies
- Patient complaints of not receiving pain medications
- Reports of excessive amounts of wasted narcotics
- Reports of excessive numbers of broken vials
- Noncompliance with policies/procedures

Revision History: 04/07, 10/08, 10/12, 5/20

LAGUNA HONDA HOSPITAL
DEPARTMENT OF PHARMACEUTICAL SERVICES

01.02.00

POLICY AND PROCEDURE FOR MEDICATION ORDER RECORDS

Policy:

The pharmacy will keep medication requisition and prescription records.

Purpose:

To comply with federal and state regulations for auditing purposes.

Procedures:

- A. All ~~Floor stock medication requisitions~~ restock reports will be kept for three years.
- B. ~~For Individual Resident Prescriptions: All physician orders will be considered prescriptions after they are filled and will be kept for three years.~~
- C. All prescriptions that are filled by the pharmacy will be kept for ten years.
- D. All ~~narcotic and hypnotic controlled substance records sheets when completed~~ will be kept for three years ~~as required by State law.~~
- E. The approved ward stock for Laguna Honda Hospital floor stock accessible via open bins in the automated dispensing cabinet is limited to over the counter items. is as follows (See attachment 1):

| | | |
|-------------------------------|-------------------------------|----------------------------------|
| A&D Ointment lb. or 2 oz tube | Docusate 100mg caps | Mineral Oil |
| Acetaminophen Supp. 650mg | Docusate 250mg caps | Multiple Vitamins, capsules/tab |
| Acetaminophen tab 325mg | Docusate liquid | Multiple Vitamins, liquid |
| Acetic Acid 0.25% | Disinfectant Alcohol | Multiple Vitamins (Therapeutic) |
| Analgesic Balm | Bisacodyl Supp. 10mg | Nivea Oil, or Ointment |
| Aquaphor | Bisacodyl tablets 5mg | Oral Syringes 5cc |
| Aspirin, Buffered 325mg | Enema, aqueous, phosphate | Oral Syringes 10cc |
| Aspirin Enteric, Coated 325mg | Enema, Oil retention | Phisoderm (skin cleaner) |
| Aspirin Supp. 300mg & 600mg | Eucerin | Rubbing Alcohol |
| Aspirin tablets 325mg | Glycerine Supp. | Senokot tablets |
| Baby Powder | Hydrogen Peroxide | Sorbitol |
| Barbicide Disinfectant | I0 Prep 1/100 | Throat Lozenges |
| Dakin's 1/2% (Full Strength) | Kaopectate (diarrhea mixture) | Vitamin B 1 (Thiamine) 100mg tab |
| Dakin's 1/4% (Half Strength) | Liquid Soap | Vitamin C 500mg tab. |
| Desitin Ointment | Metamucil | White Vaseline lb. or 1oz tube |
| Milk of Magnesia | | Zinc Oxide |

- F. Other items may be requested for stock use when the volume or frequency of use suggests stock administration would be advantageous.

Revision History: 8/3/99, 04/06, 04/07, 12/08, 4/11, 35/20

Attachment 1: List of floor stock medications

LAGUNA HONDA HOSPITAL
DEPARTMENT OF PHARMACEUTICAL SERVICES

01.02.01

POLICY AND PROCEDURE FOR ORDERS FOR MEDICATIONS AND STANDING ORDERS

Policy:

Only medications prescribed by a physician, affiliated healthcare practitioners credentialed by the medical staff, dentist, or podiatrist will be administered to a resident and no standing orders will be used. Standing orders are defined Per California Code of Regulations Title 22 §72109 Standing Orders are orders written which are used or intended to be used in the absence of a prescriber's specific order for a specific patient.

Purpose:

To ensure proper administration of medications to residents.

Procedure:

- I. All prescription orders must be in writing or electronically prescribed and should contain the following:
 - A. Date and time order is written
 - B. Patient name and medical record number
 - C. Medication name (generic preferred)
 - D. Strength or concentration
 - E. Dose
 - F. Frequency or time of administration of the medication
 - G. Route, e.g. PO, IM, SC, IV or rectal
 - H. Rate of administration for continuous IV medications
 - I. All orders (PRN and scheduled) must include the indication for use of the medication. PRN orders must also include how often the medication may be given.
 - J. Duration of therapy or quantity if applicable (e.g. antibiotics, outpatient prescriptions, pass medications)
 - K. Prescribing practitioner signature (written or electronic)
- II. All verbal or telephone orders to the nurse or pharmacist should be immediately recorded in the resident's chart and signed by the prescriber within 48 hours for the acute unit and within five days for SNF units.
- III. There will be no standing orders for medications or treatments.
- IV. The provider will complete a medication reconciliation each month. This will serve as the monthly medication renewal for SNF medications.

- V. Residents have a right to elect the dispensing pharmacy. When using an outside pharmacy, the family assumes the responsibility for supplying correct, properly labeled medications on a timely basis. Such medications will be delivered directly from the resident's pharmacy to Laguna Honda Pharmacy during our normal pharmacy hours. Such medications will be checked by Laguna Honda Pharmacy before delivery to the resident's unit. Only those medications which have been ordered by the resident's physician will be allowed.
- A. Controlled Substances may not be obtained from another pharmacy unless approved by the Pharmacy Director.

~~VI. All signed physician's orders will be sent to the pharmacy within 48 hours.~~

~~VII. Residents have a right to elect the dispensing pharmacy. When using an outside pharmacy, the family assumes the responsibility for supplying correct, properly labeled medications on a timely basis. Such medications will be delivered directly from the resident's pharmacy to Laguna Honda Pharmacy during our normal pharmacy hours. Such medications will be checked by Laguna Honda Pharmacy before delivery to the resident's unit. Only those medications which have been ordered by the resident's physician will be allowed.~~

Revision History: 6/99, 9/00, 9/04, 4/11, 5/14, 2/15, 2/19, 5/20

LAGUNA HONDA HOSPITAL
DEPARTMENT OF PHARMACEUTICAL SERVICES

01.04.00

POLICY AND PROCEDURE ON MEDICATION ERRORS

Policy:

Medication errors shall be reported through the hospital's Unusual Occurrence Report system, and reviewed by the Medication ~~Incident Review~~Error Reduction Subcommittee of the Pharmacy and Therapeutics Committee.

Purpose:

1. Medication errors and incompatibilities are identified and reported to maintain resident/patient safety.
- 1.2. Medication errors are investigated to identify and change systems issues that contribute to errors.

~~To monitor medication use and assure that resident's drug therapy is free of significant medication errors, as defined below in section 4.~~

Definitions:

~~I. MEDICATION ERROR CLASSIFICATION~~

~~MEDICATION ERROR:~~

~~Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer. Such events may be related to professional practice, or health care products, procedures, and systems, including prescribing, order communication, product labeling, packaging and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use.¹~~

~~ACTUAL MEDICATION ERROR: A mistake in prescribing, dispensing or administering of drugs that is not detected before the drug reaches the resident. All actual medication errors should be reported on an Unusual Occurrence Report form and immediately forwarded to the Quality Improvement Coordinator.~~

~~POTENTIAL MEDICATION ERROR: A mistake in prescribing, dispensing or planned administration of drugs that is detected and corrected through intervention before actual medication administration. Examples of potential errors that should be reported on the Unusual Occurrence Report form include transcription errors, pharmacy dispensing errors, and physician order writing errors.~~

~~II. TYPES OF MEDICATION ERRORS²~~

~~PRESCRIBING ERROR: Incorrect drug selection, dose, dosage form, quantity, route, concentration, rate of administration, or instructions for use of a drug product ordered or authorized by the physician; illegible prescriptions or medication orders that lead to errors that reach the resident.~~

~~OMISSION ERROR: Failure to administer an ordered dose to a resident before the next scheduled dose, if any.~~

~~TIME ERROR: Administration of medication outside a predefined time interval from its scheduled administration time.~~

~~UNAUTHORIZED DRUG ERROR: Administration to the resident of medication not authorized by a legitimate prescriber, or not authorized pursuant to Pharmacy and Therapeutics Committee approved protocols for therapeutic or generic substitution of drugs.~~

~~DOSE ERROR: Administration of a dose that is greater than or less than the amount ordered by the prescriber or administration of duplicate doses.~~

~~DOSAGE FORM ERROR: Administration of a drug product in a different dosage form than ordered by the prescriber.~~

~~DRUG PREPARATION ERROR: Drug product incorrectly formulated or manipulated before administration.~~

~~ADMINISTRATION TECHNIQUE ERROR: Inappropriate procedure or improper technique in the administration of a drug.~~

~~DETERIORATED DRUG ERROR: Administration of a drug that has expired or for which the physical or chemical dosage form integrity has been compromised.~~

~~MONITORING ERROR: Failure to review a prescribed regimen for appropriateness and detection of problems, or failure to use appropriate clinical or laboratory data for adequate assessment of patient response to prescribed therapy.~~

~~OTHER MEDICATION ERROR: Any medication error that does not fall into one of the above medication error types.~~

III. ~~MEDICATION ERROR SEVERITY INDEX³~~

~~CATEGORY A: No error occurred, but circumstances or events that have the capacity to cause error are identified.~~

~~CATEGORY B: An error occurred but the medication did not reach the resident.~~

~~CATEGORY C: An error occurred that reached the resident but did not cause the resident harm.~~

~~CATEGORY D: An error occurred that resulted in the need for increased resident monitoring but no resident harm.~~

~~CATEGORY E: An error occurred that resulted in the need for treatment or intervention and caused temporary resident harm.~~

~~CATEGORY F: An error occurred that resulted in initial or prolonged acute hospitalization and caused temporary resident harm.~~

~~CATEGORY G: An error occurred that resulted in permanent resident harm.~~

~~CATEGORY H: An error occurred that resulted in a near-death event (e.g., anaphylaxis, cardiac arrest.)~~

~~CATEGORY I: An error occurred that resulted in resident death.~~

~~IV. SIGNIFICANT MEDICATION ERROR AND SENTINEL EVENTS~~

~~SIGNIFICANT MEDICATION ERROR: An error that causes the resident discomfort or jeopardizes his/her health and safety⁴. Errors classified as severity categories D through I, are significant medication errors.~~

~~SENTINEL EVENTS: Medication errors classified as severity categories F through I, may be sentinel events and should be investigated as outlined by the Hospital-Wide Policy and Procedure on Sentinel Events.~~

~~Procedures: See Hospitalwide Policy for Medication Errors and Incompatibilities 25-11~~

- ~~1. The individual who makes or discovers the actual or potential medication error shall complete the online Unusual Occurrence Report (UO) and forward supporting documents to the confidential mail box of the Quality Improvement Coordinator (QIC.)~~
- ~~2. Errors that result in an adverse effect to the resident shall be immediately reported by the individual who makes or discovers the medication error to the appropriate physician and supervisor.~~
- ~~3. Errors that result in no harm to the resident shall be reported by the individual who makes or discovers the medication error to the appropriate physician and supervisor as soon as they are available.~~
- ~~4. The Quality Management (QM) staff will assign a unique log number to each UO. QM staff then will triage the UOs within 24 hours or the next business day and request for follow up information as follows:
 - ~~i. Follow up and Investigation Report:
 - ~~-The original UO, UO follow up and an investigation report are assigned to managers as appropriate for additional information.~~~~~~
- ~~4. The QIC will forward another copy of the UO form and/or a log or record of all reported medication errors for each month to the Medication Error Reduction Subcommittee.~~
- ~~5. The Medication Error Reduction Subcommittee will:
 - ~~a. note the type and severity of the medication error on the UOR form or log, and forward this information to the QIC. If not already initiated, medication errors that may be sentinel events will be immediately referred to the QIC for further investigation and action as outlined in the Hospital-Wide Policy and Procedure on Sentinel Events.~~
 - ~~b. review the manager's investigation and follow up actions for completeness.~~
 - ~~c. identify trends and/or systems issues that may have contributed to the medication error, and recommend a plan of correction to the appropriate department managers, committees, or Executive Staff.~~
 - ~~d. provide at least annually to the Pharmacy and Therapeutics Committee, the estimated medication error rate at the hospital, as calculated by the following formula:~~~~

Medication Error Rate⁴ =

~~$$\frac{\text{Number of errors reported on UOR form}}{\text{Estimated opportunities for errors}} \times 100$$~~
[Approximate # doses administered]

~~6. The Pharmacy Director shall be responsible for assuring the development of and adherence to procedures intended to prevent significant medication errors.~~

Citations and Adaptations from:

~~¹ National Coordinating Council for Medication Error Reporting and Prevention. What is a Medication Error?. May 2008. www.nccmerp.org~~

~~² ASHP guidelines on preventing medication errors in hospitals. *Am J Hosp Pharm.* 1993; 50:305-14~~

~~³ Dunn ED, Wolfe JJ. Medication error classification and avoidance. *Hospital Pharmacy.* 1997; 32:860-865.~~

~~⁴ Guidance to surveyors—Long Term Care Facilities; State Operations Manual.~~

Revision History: 11/97, 05/08, 4/12, 3/5/20

Laguna Honda Hospital
Department of Pharmaceutical Services

01.04.01

Policy and Procedure for Medication Error Quality Assurance Program (SB1339)

Policy:

To establish a guideline for tracking and trending of medication errors made by the Pharmacy staff in accordance with SB 1339.

Purpose:

To establish quality assurance programs for reducing medication errors and minimizing their recurrence. The primary goal is to advance error prevention by identifying and analyzing the cause and any contributing factors that allowed for an error to occur [see also [LHH Pharmacy P&P 01.04.00 Hospitalwide Policy 25-11](#) for definition of an *actual* medication error].

Definition:

California Code of Regulations Title 16, Section 1711 defines medication error as any variation from a prescription or drug order not authorized by the prescriber and ***not corrected prior to furnishing the drug to the patient.***

Procedure:

An investigation of each actual [pharmacy](#) medication error shall commence as soon as is reasonably possible, but no later than 2 business days from the date the medication error is discovered.

1. Upon identification of a medication error, the pharmacist shall assess the significance of the error (assess the clinical situation and the resident), notify the prescriber, and take the necessary steps to mitigate the error or avoid injury.
2. The pharmacist who initially evaluates the medication error will document it in the pharmacy medication error database
3. If not already done, an Unusual Occurrence Report shall be completed and submitted to Quality Management.
4. A quality assurance review will be conducted for all discovered actual medication errors. The review shall be documented in the pharmacy medication error database and it shall include the following:
 - a. Date, location and participants in the review
 - b. Pertinent data and detailed information relating to the medication error reviewed
 - c. Documentation of appropriate notification
 - d. Findings and determinations generated by the quality assurance review
 - e. Recommended changes to pharmacy policy, procedure, systems, or processes, if any.
5. The findings shall be reported quarterly to the Medication Error Reduction Committee (MERC, a subcommittee of the Pharmacy and Therapeutics Committee) for tracking and trending [and evaluation for system or process improvements to reduce future risk for errors and systems assessment for possible correction.](#)
6. Records of the quality assurance review shall be retained in the pharmacy for at least 1 year from the date the record was created.

Revision History: 05/03, 2/19

LAGUNA HONDA HOSPITAL
DEPARTMENT OF PHARMACEUTICAL SERVICES

02.01.02

POLICY AND PROCEDURE FOR DISPOSITION OF MEDICATIONS

Policy:

All discontinued medications will be returned to the pharmacy for disposal, return to stock, or hold. Medications will be returned to the pharmacy when resident is deceased, discharged, or the medication is discontinued.

Purpose:

To ensure residents' medications are appropriately disposed or destroyed.

Procedures:

- I. Returned medications from Automated Dispensing Cabinets (ADCs). *See Automated Dispensing Cabinet Dispensing Procedures (PHAR 09.0~~1.000~~)*
- II. Returned medications from units
 - A. Controlled Substances: Schedule II, III, IV, and V not in ADC
 1. Sign-out sheets with unused medications are returned to pharmacy.
 2. Sheet must be properly signed.
 3. Amount of medication returned must correspond with sign-out sheet inventory.
 4. Returned medications, if in unit dosages, properly labeled and identified, will be reissued to other units.
 - B. Nonscheduled Medications
 1. Pharmacy staff will check all medications returned to the pharmacy.
 2. Unopened, properly labeled medications may be returned to stock and credit applied when appropriate.
 3. Contaminated medications will be disposed.
 4. Unidentifiable medications will be disposed.
 5. Outdated medications will be returned to manufacturer for credit.

III. Medications on Hold

A. Medications may be temporarily held (e.g. resident discharged to acute hospital outside LHH but is expected to return, or medication temporarily stopped) in the Pharmacy until resident returns to LHH ~~or until a temporarily discontinued medication order is renewed and medication is reordered. The Nurse will bag the medications and label them with resident's name, date, and write the word "HOLD", and forward to Pharmacy.~~

IV. Pharmaceutical Waste Disposal

A. Pharmaceutical Waste Containers (Blue & White) shall be used to dispose of any medications that are opened but not administered, including partially used medications (e.g. pills, capsules, ointments, paste, and patches) and any remaining crushed, dissolved or disguised medications that are not hazardous. Environmental Services will dispose through a certified medical waste disposal vendor. (cross reference NPP J 1.0 Medication Management)

B. Controlled substances returned from units that are not suitable for use ~~due to damaged packaging~~ or part of patient personal medications ~~upon admission stored that have been stored~~ in the pharmacy for greater than 30 days will be disposed via the Cactus Sink which makes them irretrievable. The waste will be documented by two staff who witness the destruction. [See Pharmacy Policy 02.02.01 Outdated, Deteriorated, and Unusable Controlled Substances.](#)

C. DISPOSAL of Hazardous Drug Waste: See Hospital wide policy on Hazardous Drugs Management 25-05 and Pharmacy Policy 07.02.00

Reference:

[Pharm 09.01.00 Automated Dispensing Cabinets](#)

[Pharm 02.02.01 Outdated, Deteriorated, and Unusable Controlled Substances](#)

[Nursing J1.0 Medication Administration](#)

[HWP 25-05 Hazardous Drugs Management](#)

[Pharm 07.02.00 Preparation, Handling and Disposal of Hazardous Drugs](#)

Revision History: 06/08, 10/09, 4/10, 2/15, 2/19, 10/19, 4/5/20

LAGUNA HONDA HOSPITAL
DEPARTMENT OF PHARMACEUTICAL SERVICES

02.01.05

POLICY AND PROCEDURE FOR PHARMACY COMPUTER DOWN-TIME

Policy:

In the event of computer downtime, the pharmacist shall implement a manual system of pharmacy operation.

Purpose:

To assure that prescription orders are properly and uniformly processed during computer downtime periods.

Procedure:

I. ~~Verify that all computer servers are down by phoning IS. Inquire as to the estimated downtime. Pharmacy staff will sSubmit a helpdesk ticket in the event of suspected downtime. Request estimated length of downtime when submitting ticket.~~

The downtime procedures should be implemented if the system will be down ~~longer than two hours for greater than 30 minutes during pharmacy operations or as advised by the Hospital Incident Command System (HICS).~~

A. ~~The downtime computer will be used to print patient medication profile for any patient with new orders to facilitate checking for drug interactions, appropriate dosing and allergies.~~

B. ~~The downtime computer will be used to print batch fill lists~~

C. ~~If the downtime is extended, the packaging machines may need to utilize the previous days file for filling the packager fill list. Decision to use the previous day's file will be made by the PIC in conjunction with additional hospital leadership and HICS.~~

A. ~~In the event that only one pharmacy server is down, the workflow may be directed through the other server.~~

- ~~B. If both pharmacy servers will be down for a long period of time, it may be possible to access a functional terminal on nursing wards or in IS.~~
- ~~C. When no alternate servers are available, the following procedures for manual processing and filling will be implemented.~~

II. ALL NEW ORDERS: Prescriptions will be filled directly from the written order. The labels will be typed manually using pharmacy typewriters or handwritten. The label (if greater than 48 hour supply of medication provided) and the pharmacy copy of the order will note the following:

1. Resident's name and unit
2. Medication and strength
3. Quantity dispensed
4. Administration instructions
5. Manufacturer
6. Physician's name
7. Date of expiration
8. Date of fill
9. Filling pharmacist's initials and pharmacy technician initials (as applicable)
10. Drug description (discharge and pass medications only)III.

III. ALL REFILL ORDERS: Fill lists will be printed from the downtime computer for scheduled batches. Prescriptions that are not part of the cart fill may be refilled from one of the following sources: the printed medication profile.

- ~~A. Original written order from the chart~~
- ~~B. Rx hard copy retrieved from pharmacy files~~
- ~~C. Pharmacy monthly pick list~~

D.A. Prescription labels and pharmacy copy of the order must contain all of the information noted in #2 above, in addition to marking the order as a "Refill".

IV. After dispensing, copies of all manually filled new and refill orders will be placed in a specially designated area for later inputting into the computer electronic system.

V. When the computer system is again functional downtime is clear, all orders dispensed by the above procedures must be entered into the computer system by pharmacy. The correct written fill date must be used when entering the orders.

VI. For prolonged downtime, pharmacy may need to assist with bulk charging. See downtime binder for step by step instructions on the bulk charging process.

Reference:

HWP 21-21 Electronic Health Record (EHR) Downtime

DPH Wide Epic Admin 9.03 Electronic Health Record (Epic EHR) Downtime

Revision History: 3/97, 10/09, 4/20

LAGUNA HONDA HOSPITAL
DEPARTMENT OF PHARMACEUTICAL SERVICES

07.01.00

POLICY AND PROCEDURE FOR STERILE PRODUCT PREPARATION, HANDLING, AND DISPOSAL

Policy: The pharmacy shall ensure the sterility and integrity of sterile products prepared and used at Laguna Honda.

Purpose: To ensure the appropriate surveillance, prevention, and infection control procedures for sterile products.

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Definitions and Abbreviations

Beyond use date (BUD) - the date or date and time, after which administration of a compounded drug product shall not begin, the preparation shall not be dispensed, and the preparation shall not be stored (other than for quarantine purposes).

Primary engineering control (PEC) – a device that provides an ISO Class 5 or better environment through the use of unidirectional HEPA-filtered first air for the exposure of critical sites when compounding sterile preparations. Examples of PEC devices include, but are not limited to, laminar airflow workbenches, biological safety cabinets, sterile compounding automated robots, compounding aseptic isolators, and compounding aseptic containment isolators.

Compounding aseptic isolator (CAI) – a form of isolator specifically designed for **non-hazardous compounding** pharmaceutical ingredients or preparations while bathed with unidirectional air. It is designed to maintain an aseptic compounding environment within the isolator throughout the compounding and material transfer processes

~~**Compounding aseptic containment isolator (CACI)** – a unidirectional compounding aseptic isolator designed to provide worker protection from exposure **hazardous drugs** airborne drug throughout the compounding and material transfer processes and to provide an aseptic environment for compounding sterile preparations. The exhaust air from the isolator is removed by external building ventilation~~

~~**Containment primary engineering control (C-PEC):** A ventilated device designed and operated to minimize worker and environmental exposures to HDs by controlling emissions of airborne contaminants through the following:~~

- ~~1. The full or partial enclosure of a potential contaminant source~~
- ~~2. The use of airflow capture velocities to trap and remove airborne contaminants near their point of generation~~
- ~~3. The use of air pressure relationships that define the direction of airflow into the cabinet~~
- ~~4. The use of HEPA filtration on all potentially contaminated exhaust streams~~

Hazardous Drug (HD): Any drug which poses significant risk to a healthcare worker by virtue of its teratogenic, mutagenic, carcinogenic, reproductive toxicity potential, or which can cause serious organ or other toxic manifestation at low doses. Drug classes listed as HD include: cytotoxic/chemotherapy agents, hormonal agents, immunosuppressants, some antiviral agents, some antibiotics and some biological response modifiers.

ISO- International Organization of Standardization (ISO) classification of particulate matter in room air. The number following ISO refers to air quality determined by the number of particles in a cubic meter of air. An ISO-5 environment level of quality must be maintained in the direct compounding area.

Direct Compounding Area (DCA) - Critical area within a primary engineering control exposed to unidirectional filtered air.

Isolator Gauntlet – A glove that is attached to the isolator sleeve intended for repeated use and changed at least monthly. Sterile gloves are donned over isolator gauntlets whenever engaged in compounding activities.

IV room – The designated area of positive pressure separate from routine work traffic that contains the primary engineering control (CAI) to compound non-hazardous sterile products. Refers specifically to room P2334 “IV PREP”

Hazardous drug room – The designated area of negative pressure separate from routine work traffic ~~that contains the compounding aseptic containment isolator (CACI)~~ used for compounding sterile and non-sterile hazardous drugs. Refers specifically to room P2332 “CHEMO PHARMACY”

Line of demarcation – A line on the floor marked with tape in both the IV and hazardous drug rooms that designates an ante-area for garbing towards the door separated from the clean working areas around the primary engineering control where personnel must be full gowned and garbed.

Qualified personnel – Pharmacists and pharmacy technicians that have completed required training and successfully passed all of the required competency assessments for sterile compounding

USP – United States Pharmacopoeia

RCRA – Resource Conservation and Recovery Act enacted in 1972 that governs the disposal of certain hazardous waste in the pharmacy.

CSP – Compounded sterile preparation

Pharmacy Areas for Preparing Sterile Products

1. Access to the IV room is limited to necessary/trained personnel.
2. Solutions, drugs, supplies and equipment used to prepare and administer sterile products shall be stored in accordance with manufacturer or USP requirements. Sterile products that require special storage conditions, for example, refrigeration and protection from light, shall be so stored. Refrigerator temperatures shall be wirelessly monitored and documented per hospital wide policy 31-01 wireless refrigerator and freezer temperature monitoring system.
3. Outdated products should be removed from active storage areas.
4. Before each use, each drug, ingredient, and container should be visually inspected for damage, defects and expiration date.
5. Particle generating activities, such as removal of items from or manipulation of cardboard boxes, should be performed outside of the IV room.
6. Disposal of packing materials, used syringes, containers, and needles should be performed as needed.

7. Waste shall be disposed of in the appropriate container of pharmaceutical (blue), trace hazardous waste (yellow), of bulk hazardous/RCRA designated waste (black). Eating, drinking, and smoking are prohibited in the IV room.
8. Non-sterile to sterile "high risk" compounding shall not be performed by Laguna Honda Hospital Pharmacy

Hand Hygiene and Garbing procedure for IV room

1. See policy and procedure 07.02.00 for hand hygiene and garbing procedure for hazardous drug room
2. Prior to entering IV room inform a pharmacist of any change in eligibility to compound sterile preparations:
 - a. Personnel with signs or symptoms of respiratory infection, exposed rashes, sunburn, conjunctivitis, fever, open wounds, or weeping sores shall be excluded from sterile compounding until condition is resolved.
 - b. Any person wearing cosmetics, nail polish, or artificial nails shall not participate in sterile compounding. Fingernails should be kept clean and trimmed.
3. Remove any hand, wrist, finger, or other visible jewelry
4. Remove any neck lanyards, ties, or necklace jewelry
5. Don hair cover and face mask to cover bridge of nose down to the chin. Don additional facial hair cover if necessary.
6. Don shoe covers placing the first covered shoe over the line of demarcation to the clean side prior to donning the second shoe cover.
7. Wash hands with soap and warm water up to the elbow scrubbing for at least 30 seconds and clean under nail bed with a clean nail pick whenever entering or re-entering the controlled area.
8. Dry hands with a non-shedding disposable paper towel and don a non-shedding gown.
9. Disinfect hands again using waterless surgical scrub and allows hands to dry before placing hands in isolator gauntlets.
10. If working in the IV room outside of the CAI then don gloves and disinfect with sterile 70% isopropyl alcohol making sure the elastic wrists of the gown covers the glove cuff. These gloves can be removed when hands are placed inside the isolator gauntlets to compound.
11. When preparing sterile products in the CAI sterile gloves must be donned over the isolator gauntlets prior to any compounding activities.
12. At the end of non-hazardous sterile compounding:
 - a. Remove and discard gloves, facial hair cover, mask, and hair cover in the regular trash.
 - b. Remove and discard gown in the regular trash or hang on a hook on the clean side of the line of demarcation to be re-used by the same personnel during the same shift only. Re-used gowns must be discarded by the end of shift.
 - c. Perform hand hygiene with soap and water for at least 30 seconds
 - d. Remove shoe covers one at a time ensuring that the uncovered foot is placed over the line of demarcation.
 - e. Discard shoe covers in the regular trash and disinfect hands prior to leaving the IV room.
 - f. Ensure all garb is removed and discarded appropriately before leaving the IV room.
 - g. Wash hands with soap and warm water up to the elbow scrubbing for at least 30 seconds and clean under nail bed with a clean nail pick whenever entering or re-entering the controlled area.

Environmental Controls in the IV room

1. Engineering controls reduce the potential for airborne contamination in workspaces by limiting the amount and size of contaminants in the CSP processing environment
2. The primary engineering control (PEC) at Laguna Honda Hospital Pharmacy is the compounding aseptic isolator (CAI)
 - a. Isolator gauntlets shall be changed at least every month or whenever there is damage or a tear according to the manufacturer's directions and specifications.
 - b. Isolator sleeves shall be changed every 6 months or whenever there is damage or a tear according to the manufacturer's directions and specifications
 - c. Pre-filter shall be changed at least every 3 months according to the manufacturer's directions and specifications
3. Secondary engineering controls are used reduce airborne particles in the areas surrounding the primary engineering control and include:
 - a. Separating the sterile compounding areas in rooms with a pressure differential relative to adjacent spaces (See next section for monitoring)
 - i. IV room will be maintained at positive pressure relative to adjacent areas
 - ii. Hazardous drug room will be maintained at a negative pressure between -0.01 and -0.03 inches water column relative to adjacent areas
 - b. Rigorous cleaning program (described in cleaning and sanitizing of the workspace)
 - c. Standardized gowning, garbing, and hand hygiene procedure
 - d. A line of demarcation to designate areas surrounding the primary engineering control that require qualified personnel to be fully gowned and garbed.
 - e. Only the furniture, equipment, supplies, and other goods required for the tasks to be performed may be brought into this room, and they should be non-permeable, non-shedding, and resistant to disinfectants.
 - i. Carts should be of stainless steel wire or sheet metal construction with good quality, cleanable casters to promote mobility.
 - ii. Storage shelving counters, and cabinets should be smooth, impervious, free from cracks or crevices, non-shedding, cleanable, and sanitary. Their number, design, and manner of installation should promote effective cleaning and sanitizing.
 - f. Maintaining an organized and uncluttered environment with minimal horizontal workspaces
 - g. The surface of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in the IV room are to be smooth, impervious, free from cracks and crevices, and non-shedding, thereby promoting clean ability and minimizing spaces in which microorganisms and other contaminants may accumulate. The surfaces should be resistant to damage by sanitizing agents.
 - h. Items brought into the CAI disinfected with sterile 70% isopropyl alcohol prior to transporting.

4. Sterile product preparation will be performed in a CAI that provides at least ISO 5 air quality.
 - a. International Organization of Standardization (ISO) Classification of Particulate Matter in Room Air (Limits are in particles 0.5µm and larger per cubic meter (current ISO)

| Class Name | | Particle Count | |
|------------|---------------|-----------------------|----------------------------|
| ISO Class | US FS 209E | (ISO,m ³) | (FS 209E ft ³) |
| 3 | Class 1 | 35.2 | 1 |
| 4 | Class 10 | 352 | 10 |
| 5 | Class 100 | 3,520 | 100 |
| 6 | Class 1000 | 35,200 | 1000 |
| 7 | Class 10,000 | 352,000 | 10,000 |
| 8 | Class 100,000 | 3,520,000 | 100,000 |

Testing and Monitoring of Environmental Controls in the IV room

1. Pressure Differential Monitoring
 - a. IV room relative to adjacent areas
 - i. Measured wirelessly and continuously by engineering via the TEMPTRAK system.
 - ii. If differential pressure becomes negative in the IV room engineering will be consulted to evaluate the potential causes and the supervising pharmacist will determine if any changes in workflow or beyond use dating are necessary until the desired pressure differential is restored.
 - iii. Pressure differential will be manually documented on a daily basis when the pharmacy is open on the "air pressure differential log"
 - b. CAI
 - i. Pressure differential of the antechamber and main workspace within the CAI will be checked daily when the pharmacy is open by qualified personnel and recorded on the "air pressure differential log"
 - ii. The CAI will sound an audible alarm in the event that pressure differentials fall out of the manufacturer specified operation ranges. When the alarm is sounded the supervising pharmacist will be informed to evaluate and troubleshoot before any sterile compounding activities are continued and will determine if any compounded preparations made at the time of the alarm were compromised.
2. Temperature monitoring
 - a. Refrigerator temperature in the IV room is wirelessly monitored and documented per hospital wide policy 31-01 wireless refrigerator and freezer temperature monitoring system.
 - b. The temperature of the IV room and hazardous drug room are continuously monitored wirelessly with limits set for operator comfort and manufacturer recommended storage conditions for IV drugs.
 - c. Humidity gauges are present in the IV room to detect significant changes that would affect operator comfort.
3. Certification and testing of primary and secondary engineering controls shall be performed every six months and whenever a primary engineering control or area designated for compounding is relocated, altered or a service to the facility is performed that would impact the device or area.

- a. Certification will be performed by a qualified operator to meet test standards of CETA Certification Guide for Sterile Compounding Facilities under dynamic conditions to include viable particle counts, non-viable particle counts, and smoke pattern testing.
- b. Viable particle counts
 - i. Viable surface sampling is performed every six months in the primary engineering controls and the surrounding areas by an outside qualified operator as part of routine certification testing
 - ii. Viable particles in the air are tested by volumetric air sampling procedures by an outside qualified operator every six months as part of routine certification testing. Volumetric air sampling will test a sufficient volume of air (400 to 1,000 liters) at locations inside the PEC and surrounding area.

Cleaning and Sanitizing of the Workspaces

1. Procedure for cleaning of primary engineering controls (CAI in IV room)
 - a. The cleaning, sanitizing and organizing of the direct compounding areas (DCA) is the responsibility of qualified pharmacists and pharmacy technicians and is performed prior to any compounding activities and at least daily when the pharmacy is open.
 - b. Sanitize the gauntlets of the CAI with a germicidal detergent followed by sterile water and allow to dry.
 - c. Disinfect the gauntlets of the CAI with sterile 70% isopropyl alcohol
 - d. Replace the non-shedding pad on the isolator cleaning tool and utilize it during the following cleaning procedures to clean surfaces that would normally be out of reach.
 - e. Sanitize all surfaces in the primary engineering control (including the gauntlets again) with a germicidal detergent followed by sterile water to remove gross filth. A pre-saturated non-shedding wipe or spray may be used with the isolator cleaning tool.
 - f. Do not directly spray the ceiling towards the HEPA filter because it can cause damage and compromise its integrity. When cleaning surfaces use an overlapping horizontal motion in one direction starting at the top of the isolator working down. Clean the ceiling first, then the back, then the sides, and finally the bottom surface inside the primary engineering control. Be sure to clean the antechamber in addition to the direct compounding areas.
 - g. After sanitizing with a germicidal detergent and sterile water then disinfect the surfaces of the primary engineering control (including the gauntlets again) with sterile 70% isopropyl alcohol following the previous procedures.
 - h. Once a week replace the germicidal detergent with a sporicidal detergent for sanitizing all surfaces including the gauntlets in the primary engineering control.
 - i. After completing the cleaning process, document the activity in the "cleaning record for sterile compounding room"
 - j. Prior to donning sterile gloves and after the initial cleaning procedures for the surfaces of the CAI disinfect the gauntlets with sterile 70% isopropyl alcohol
 - k. If the primary engineering control has been turned off between aseptic procedures, it should be operated for at least 30 minutes to allow complete purging of room air from the direct compounding area, then cleaned with the above procedures before performing any compounding activities

- I. Once a month the CAI will undergo a deep cleaning in which the front panel is opened and the bottom work tray is lifted out to clean area underneath working in a horizontal unidirectional motion from right to left starting from the back and working forward with overlapping strokes. The deep clean will consist of sanitizing with a sporicidal detergent and sterile water followed by disinfecting with sterile 70% isopropyl alcohol
2. All ISO class 5 surfaces, work table surfaces, carts, counters, and floor shall be cleaned at least daily when the pharmacy is open using a germicidal detergent and sterile water followed by disinfecting with sterile 70% isopropyl alcohol. Once a week the germicidal detergent shall be replaced with a sporicidal detergent.
3. Floors in the compounding areas are sanitized and cleaned by mopping once daily when the pharmacy is open and when no aseptic operations are in progress. Mopping may be performed by trained and supervised custodial personnel using approved agents described in section 2 above. Only approved cleaning and sanitizing agents are used with careful consideration of compatibilities, effectiveness, and inappropriate or toxic residues. All cleaning tools, such as wipers, sponges, and mops, are non-shedding and dedicated a specific compounding area.
4. Walls and ceilings are sanitized with a sporicidal detergent and sterile water followed by disinfection with sterile 70% isopropyl alcohol at least weekly and documented on the appropriate cleaning log
5. Storage shelving is emptied of all supplies and sanitized with a sporicidal detergent and sterile water followed by disinfection with sterile 70% isopropyl alcohol at least weekly and documented on the appropriate cleaning log
6. Trash is collected in suitable plastic bags and removed with minimal agitation. Pharmaceutical waste is collected when approximately two thirds full.
7. Cardboard, shipping cartons, or high particle generating containers shall NOT be brought into the IV room or hazardous drug room. All supplies required for compounding and cleaning activities will be disinfected with 70% sterile alcohol prior to being introduced to the IV room.
8. Supplies required for compounding are disinfected with sterile 70% isopropyl alcohol before being placed in the antechamber of a primary engineering control.

Master Compounding Formula

1. Prior to any compounding activities a master formula approved by a pharmacist must be created or obtained from the library of master formulas stored on the pharmacy intranet.
2. A master formula must include the following:
 - a. Active and inactive ingredients to be used
 - b. Equipment to be used including the appropriate primary engineering control
 - c. The maximum allowable beyond use date for the preparation, and the rationale or reference source justifying its determination
 - d. Specific and essential compounding steps used to prepare the drug
 - e. Quality reviews required at each step in the preparation of the drug including:
 - i. Review calculations on master formula to confirm that the measurement of each additives and diluent will result in the final labeled concentration

- ii. Visual inspection of all ingredients to be used for manufacturer expiration dating and integrity of manufacturer packaging such as broken seals on vials or punctures in a stopper or injection port.
 - iii. Visual inspection of any reconstituted products for complete dissolution
 - iv. Visual inspection of any vial stopper or injection port punctured for evidence of leaking or coring.
 - v. Pharmacist to verify volume or measurement of any additive prior to final dilution and confirm it matches the master formula.
 - vi. Visual inspection after final dilution against a well-lit contrasting background to detect the presence of impurities such as particulate matter, unexpected change in color, precipitation, or coring.
- f. Instructions for storage or special handling requirements
- g. An "update log" section shall be included on every master formula to include the date of creation with pharmacist initials. Any modifications to an existing master formula shall be documented in the "update log" sections with the description of changes as well as the date and pharmacist initials.

Aseptic Technique and Pharmacy Sterile Product Preparation

1. Sterile preparations shall be compounded in a primary engineering control that maintains an ISO class 5 environment under dynamic conditions using aseptic technique.
2. Aseptic technique refers to standardized compounding procedures intended to decrease the risk of contamination of a compounded sterile product. Talking should be minimized during aseptic preparation.
3. Ingredients used to compound sterile products should be determined to be stable, compatible, and appropriate for the product to be prepared, according to manufacturer or USP guidelines or appropriate scientific references. Ingredients and compounding process for each preparation is determined in writing and reviewed by a pharmacist on a master formula before compounding begins.
4. All ingredients should be inspected for defects, expiration date, and product integrity before use. Expired or defective products should not be used for compounding. Defective products should be reported to the FDA Med Watch Program, <https://www.accessdata.fda.gov/scripts/medwatch/>, or 1- 800-FDA-1088.
5. Prior to performing any activities in the primary engineering control inspect the isolator gauntlets and sleeves for any defects or tears.
6. Any ingredient, equipment, or item required for sterile compounding shall be disinfected with sterile 70% isopropyl alcohol on all surfaces before placing inside the antechamber
7. Wait at least 10 seconds after placing items into the antechamber before opening the divider and bringing items into the work area inside the primary engineering control.
8. During any sterile compounding in the CAI ~~or CACI~~ all of the surfaces and isolator gauntlets are disinfected frequently with sterile 70% isopropyl alcohol including:

- a. The beginning of each shift and before each lot
 - b. At least every 30 minutes when continuously compounding
 - c. After each spill or when surface contamination is suspected
9. All rubber stoppers of vials and bottles, the necks of ampoules, and injection ports into an IV bag are disinfected by wiping with sterile 70% isopropyl alcohol and waiting at least 10 seconds before they are used to prepare sterile products.
 10. Only materials essential for preparing the sterile product should be placed in the primary engineering control. Products must be adequately separated so as not to disrupt the unidirectional airflow leaving the high efficiency particulate air (HEPA) filter. Overcrowding of materials should be avoided also to minimize disruption of clean airflow.
 11. Extreme care must be taken to prevent obstruction of clean air across the critical area or site, defined as the area immediate to the point of entry area in to a container, including the needle or device used to enter the container. The pharmacist or technician must be aware about the relation of other objects within the cabinet so that these objects never become an obstacle between the HEPA filter and critical area, as this can cause contamination of the critical area. Avoid reaching directly over the critical area because contaminants from the person or clothing may fall on the critical area. Only the cleanest air should be allowed to flow over the critical area of all the materials within the hood.
 12. Avoid touch contamination of sterile needles, syringe parts, and other critical sites.
 13. Solutions from ampoules must be properly filtered to remove particles.
 14. Solutions from reconstituted powders should be mixed carefully, ensuring complete dissolution of the drug with the appropriate diluents.
 15. Needle entry into vials should be performed at a 45-60° angle with the beveled side facing upwards to avoid coring of the vial closure.
 16. After completion of the product, an additive cap or seal should be placed over the stopper or additive portal, to signify completion of the product as well as protect the portal from contamination.
 17. Before, during and after the preparation of sterile products, the pharmacist or technician should carefully check the identity and verify the amounts and sequence of the additives in the sterile preparations detailed in the master drug formula against the original prescription, medication order, or other appropriate documentation before the product is released or dispensed.
 18. After the preparation of every compounded sterile product, the contents of the container are thoroughly mixed and then inspected for the presence of particulate matter, evidence of incompatibility, or other defects.
 19. After procedures are completed, used syringes, bottles, vials, and other supplies are removed, but with a minimum of exit and re-entry into the direct compounding area so as to minimize the risk of introducing contamination into the aseptic workspace.

Beyond Use Dating

1. Shall be defined the date or date and time, after which administration of a compounded drug product shall not begin, the preparation shall not be dispensed, and the preparation shall not be stored (other than for quarantine purposes).
2. Single dose vials or containers shall not be stored for re-use unless approved by the pharmacist in charge at the time of opening in which case it may be stored for not more than 1 hour in an ISO class 5 environment. Single dose vials or containers shall not be re-used under any circumstance if exposed to a non-ISO class 5 environment after opening.
3. Multiple-dose vials containing antimicrobial preservative may be used for up to 28 days after initial puncture or opening unless otherwise specified by the manufacturer.
4. The rationale or reference source justifying the beyond use date of any compounded product shall be included on the master drug formula
5. The beyond use date of any compounded product shall not exceed those identified by California board of pharmacy regulation
6. The beyond use date of any compounded sterile product shall not exceed those identified in chapter 797 of the United States Pharmacopoeia.
7. The beyond use date of any compounded non-sterile products shall not exceed those identified in chapter 795 of the United States Pharmacopoeia.

Qualifications of Personnel Who Prepare Sterile Products

1. Qualified personnel that compound sterile products for patient use shall pass the following competency assessments at least annually. (See [Appendix Attachment 1†](#))
 - a. Hand hygiene
 - b. Gowning and garbing
 - c. Sterile compounding calculations and terminology exam
 - d. Cleaning and disinfection of controlled compounding areas and equipment
 - e. Accurate documentation of compounding activities, cleaning, and monitoring of environmental controls
 - f. Pharmacy calculations and terminology exam
 - g. Sterile compounding knowledge assessment
 - i. Shall include review of most current policy and procedure
 - ii. Contents to be determined and re-evaluated annually or more frequently at the discretion of the pharmacist in charge
 - h. Gloved fingertip testing (see [attachment 1e†](#) assessment for results recording and incubation process)
 - i. Defined as a process whereby compounding personnel lightly press each fingertip and thumb onto appropriate growth media, which are then incubated at a

- temperature and period of time conducive to multiplication of microorganisms as determined by the manufacturer.
- ii. Presence of any microbial growth is considered a failed gloved fingertip test and shall require remediation and reassessment before personnel can continue to compound sterile products
 - iii. Gloved fingertip testing shall be performed with sterile gloves donned over the gauntlets of the compounding aseptic isolator prior to a media fill challenge and after a media fill challenge for both the right and left hands.
 - iv. Incubation temperature and growth media evaluation will be recorded daily when the pharmacy is open on the associated competency assessment form.
- i. Media fill challenge (see attachment 1ed assessment for results recording and incubation process)
 - i. Shall consist of compounding procedures using a growth based media to mimic the most complex procedures performed by the pharmacy.
 - ii. The design of the media fill challenge shall be recorded in the IV competency binder located in the clinical pharmacist office and available on the pharmacy intranet.
 - iii. The design of the media fill challenge shall be re-assessed at least annually and any modifications recorded along with rationale.
 - iv. Incubation temperature and growth media evaluation will be recorded daily when the pharmacy is open on the associated competency assessment form.
 - v. Presence of any microbial growth in any of the growth media used in the media fill challenge is considered a failed media fill challenge and shall require remediation and reassessment before personnel can continue to compound sterile products
 - j. Hazardous drug compounding assessments including decontamination as defined in hazardous drug policy 07.02.00
2. New personnel shall be oriented with the policy and procedure of compounding sterile products and receive adequate training consisting of audio/visual materials, shadowing a qualified compounder, and hands on practice under the supervision of a qualified compounder prior to initial competency assessment. The pharmacist in charge shall determine when new personnel have completed adequate training to begin competency assessment.
 3. New personnel shall complete gloved fingertip assessments on 3 separate occasions prior to compounding sterile products for patient use.
 4. Records of competency assessment shall be available for each individual qualified personnel and retained for three years.

Quality Assurance

1. To ensure continued standardization of procedures any changes made to the pharmacy policy and procedure on compounding of sterile or hazardous preparations will be communicated to all

- qualified personnel in a pharmacy staff meeting or via a learning module assignment which will require an acknowledgement signature which may or may not be electronic.
2. Qualified personnel shall not participate in sterile compounding activities until reviewing all changes to policy and procedure via a learning module assignment or attendance at a designated pharmacy staff meeting which will require an acknowledgement signature which may or may not be electronic.
 3. Environmental service personnel that clean the floors, ceilings, and windows inside the IV room and Hazardous drug room shall be trained on cleaning, garbing, and accurate documentation. Evidence of competency to perform these activities shall assessed at least annually and documented. (See Appendix II Attachment 2)
 4. Any facility workers, environmental sampling personnel, quality assurance personnel, or maintenance personnel shall only be allowed entry in controlled compounding areas under pharmacist supervision and only after being trained on appropriate garbing technique as well as policy and procedure relevant to their duties. This training shall be documented on the "Support Personnel training and entry log"
 5. End product testing for sterility and potency for a single compounded sterile product shall be conducted at least annually and repeated upon receipt of any unacceptable results.
 - a. If end product sterility testing results in microbial growth the supervising pharmacist will recall all sterile preparations from the same lot number according to pharmacy policy and procedure 02.04.00 (drug recall).
 - b. If end product potency testing results in greater than 10% variability of actual concentration vs. labeled concentration the supervising pharmacist will recall all compounded products from the same lot number according to pharmacy policy and procedure 02.04.00 (drug recall).
 - c. In addition to recall a clinical pharmacist and supervising pharmacist will evaluate and document any possible causes for unacceptable results and discuss the evaluation any interventions at a pharmacy staff meeting
 6. Quality of aseptic technique for each personnel will be assessed by directly observed media fill challenge at least annually, whenever unacceptable technique is observed, or when end product sterility testing yields microbial growth.
 7. Standard aseptic technique are described in the above policy and procedure
 8. Action levels for colony-forming units (CFUs) detected during quality assurance activities:

| Classification | Volumetric air sample | Fingertip sample | Surface sample |
|----------------|-----------------------|------------------|----------------|
| ISO Class 5 | >1 | Zero | >3 |
| ISO Class 8 | >100 | N/A | >100 |

- a. When action levels are exceeded during fingertip sampling the employee shall not compound sterile products until remediation and successful resampling
- b. When action levels are exceeded during environmental sampling the pharmacy shall investigate the possible sources of contamination and document interventions along with results of resampling. The beyond use dating of sterile products compounded prior to successful resampling shall be evaluated and potentially adjusted as determined by the pharmacist-in-charge.

- c. When action levels are exceeded during surface sampling or volumetric air sampling the colony-forming units will be sent for identification to at least the genus level.

9. Quality reviews are required before, during, and after compounding sterile products and are described on the compounding master formula

Labeling

1. Finished products should be labeled with at least the following information:
 - Resident's name
 - Prescription number
 - Patient or medical record number
 - Directions including rate of administration for IV medications
 - Name & concentration of all ingredients (including primary solution)
 - Prescribing physician's name
 - Date filled
 - Expiration date
 - Pharmacist's, technician's initials
 - Pharmacy telephone number
 - Instructions for storage & handling
 - All hazardous or cytotoxic preparations shall bear a special label stating: "Chemotherapy – Dispose of Properly" or "Hazardous – Dispose of properly"
2. The label should be legible and affixed to the final container in a manner enabling it to be read while the sterile product is being administered.

End Product Evaluation

- ~~1. The final product should be inspected when preparation is completed and again when the product is dispensed. This inspection includes an evaluation for container leaks, container integrity, solution cloudiness or phase separation, particulates in the solution, appropriate solution color, and solution volume.~~
- ~~2. The pharmacist shall verify that the product was compounded accurately with the correct ingredients, quantities of each ingredient, containers, and reservoirs.~~

Handling of Sterile Products Outside the Pharmacy

1. Sterile products should be transported in a manner to protect the medication from extremes of temperature outside their range of stability and from light if they are photosensitive.
2. Delivery personnel should be instructed on special handling procedures.
3. Once delivered to the end user, sterile products should be appropriately stored before use.
4. Special instructions for storage shall be a part of the label or separate information sheet.
5. Sterile products that display evidence of contamination or instability, or are improperly labeled shall be returned to the pharmacy for disposition,

6. Pharmacists shall participate in training end users on the proper care and storage of sterile products, either directly or through written instructions.

Administration of Sterile Products

1. Medications will be competently and safely administered. The Nursing Service is responsible for the safe administration of sterile products. See LH Nursing Policies & Procedures: J 1.0-10.0 on Medication Administration.

Documentation and Recordkeeping

1. The following should be documented and maintained on file for an adequate period of time, according to organizational policies and state regulatory requirements:
 - a. Records of training and demonstrated competence shall be available for each individual and retained for three years beyond the period of employment.
 - b. Refrigerator and freezer temperatures,
 - c. Certification of CAI ~~and CACI~~.
 - d. Master formula compounding sheets
 - e. Lot number assignment log for compounded products ~~for sterile and non-sterile compounds~~
 - f. Results of annual end product testing for sterile and non-sterile products
2. ~~A record of medications dispensed shall be made in the resident's medication file. (See LH Pharmaceutical Services Policy 02.01.00: P & P for Distribution of Medications and Medication Order Processing.) In addition, the following information relevant to parenteral therapy shall be maintained:~~
 - ~~a. Resident's name, age, and sex,~~
 - ~~b. Diagnosis related to prescribed therapy,~~
 - ~~c. Relevant medication history, and~~
 - ~~d. Relevant laboratory data.~~

Revision History: 8/03, 06/07, 01/08, 04/09, 2/10, 10/10, 08/11, 5/14, 10/15, 08/17, 7/19, 3/20

Attachment 1: Pharmacy Staff IV competency

Attachment 2: Assessment of hand hygiene, garbing, and cleaning of EVS personnel