PIONEERS MEMORIAL HEALTHCARE DISTRICT
207 West Legion Road, Brawley, CA 92227
REGULAR MEETING OF THE BOARD OF DIRECTORS

Thursday, December 14, 2023
PMH Auditorium
5:00 pm

AGENDA

PMHD MISSION: Quality healthcare and compassionate service for families of the Imperial Valley

In compliance with the Americans with Disabilities Act, if you require special accommodations to participate in a board meeting, please contact the District at (760) 351-3250 at least 47 hours prior to the meeting.

I. CALL TO ORDER (*time: 5:00 pm – 5:15 pm)*

A. Roll Call

B. Election of Officers for the Board of Directors
1. President
2. Vice President
3. Secretary
4. Treasurer
5. Assistant Secretary/Treasurer

C. Designation of Members to Committees
1. Women's Auxiliary
2. Medical Executive Committee
3. LAFCo Representative
4. Agenda Review Committee
5. Ad Hoc Heffernan Committee
6. Ad Hoc Funding Requests Committee
7. Ad Hoc CEO Evaluation Committee
8. Ad Hoc General Counsel Evaluation Committee
9. Ad Hoc CPO Evaluation Committee.

D. Approval of Agenda

II. BOARD MEMBER COMMENTS

III. PUBLIC COMMENTS – At this time, the Board will hear comments on any agenda item and on any item not on this agenda. If any person wishes to be heard, he or she shall stand; address the chairperson and state the subject, or subjects, upon which he or she desires to comment. Time limit for each speaker is 5 minutes. A total of 15 minutes shall be allocated for each item. *(time: 5:15 pm – 5:30 pm)*

SECTION

IV. POLICIES/PROCEDURES/REVIEW OF OTHER ITEMS – The Board will consider and may take action on the following: (*time: 6:00 pm – 6:45 pm)*

A. Hospital Policies
   1. Bloodborne Pathogen Exposure Control Plan
   2. California Sick Leave
   3. Care of an Emergency Patient Contaminated with Hazardous Materials – CODE ORANGE
   4. Code Stroke – Emergency Department
   5. Communication with the Patient/Family After a Harm Event
   6. COVID 19 Vaccination Program
   7. Guidelines for Influx of Patients with Highly Communicable Diseases
   8. Hazardous Drugs Communication Program
   9. Influenza Vaccination Program
   10. ISO Preventive Action
   11. Medication Error Reduction and Prevention Performance Improvement Plan
   12. Pain Assessment in Children
   13. Risk Management Plan

B. Approval of Minutes
   1. 11/28/23 Regular Meeting

C. Update Reports
   1. Women's Auxiliary
   2. LAFCO

D. November 2023 Finance Report

E. Human Resources Report

F. Authorize Renewal of Membership Dues to the District Hospital Leadership Forum
Contract Value: $60,026.[29]; Contract Term: One (1) year; Budgeted: Yes; Budget Classification: Dues and Subscriptions

G. Authorize Donation of STORZ Laparoscopic Tower
Contract Value: $16,556; Contract Term: One-time donation; Budgeted: N/A; Budget Classification: Capital

H. Authorize Proposal for Seismic Plan with Material Design Architects
Contract Value: $299,900; Contract Term: Project completion; Budgeted: Yes; Budget Classification: Purchased Services

V. MANAGEMENT REPORTS – The Board will receive the following information reports and may take action. *(time: 6:45 pm – 7:30 pm)*

A. Operations Reports – Damon Sorensen, Interim CEO

   1. CEO Report (Interim Chief Executive Officer)

   2. Hospital operations (Chief Nursing Officer)

3. Clinics operations (Chief of Clinic Operations)
4. Medical staff (Chief Nursing Officer)
5. Finance (Chief Financial Officer)
6. Information technology (Chief Nursing Officer)
7. Marketing (Director of Marketing)
8. Facilities, logistics, construction, support
9. Quality resources (Director of Quality Resources)
10. Board matters

B. Legal Counsel Report – Sally Nguyen

1. All matters to be discussed in Closed Session

VI. CLOSED SESSION – The following matters will be considered by the Board in closed session; the Board will reconvene in open session to announce any action taken on matters considered in closed session. *(time: 7:30 pm – 7:50 pm)*

A. QUALITY ASSURANCE – Safe Harbor: Health & Safety Code 32155 the Board will hear reports of a hospital medical audit committee relating to:

1. Quality Report/Scorecard

B. CONSIDERATION OF MATTERS INVOLVING TRADE SECRETS – Safe Harbor: Health and Safety Code §32106, subparagraph (b)

1. Based on the Board's prior findings regarding Trade Secret classification, as contained in Resolution 2023-01, consideration and discussion of possible initiation of the following:
    a. Updating Certain District Strategic Planning Initiatives

C. PENDING OR THREATENED LITIGATION – Safe Harbor: Subdivision (b) of Government Code Section 54956.9

1. Potential Cases: 2

D. PENDING OR THREATENED LITIGATION – Safe Harbor: Subdivision (b) of Government Code §54956.9

1. Conference with Legal Counsel regarding threatened litigation involving possible facts or circumstances not yet known to potential party or parties, disclosure of which could adversely affect the District's position.
    a. Compliance Issues

VII. RECONVENE TO OPEN SESSION (*time: 7:50 – 8:00 pm)*

A. Take Actions as Required on Closed Session Matters

VIII. ADJOURNMENT *(time: 8:00 pm)*

Pioneers Memorial Healthcare District

Title: **Bloodborne Pathogen Exposure Control Plan**	Policy No. CLN-02303
	Page 1 of 5
Current Author: Lizbette Cordova, RN	Effective: 04/21/2010
Latest Review/Revision Date:09/2023	Manual: Clinical – Infection Control

Collaborating Departments: Infection Control; Human Resource Department		Keywords: Infectious Disease, Blood Exposure	
Approval Route: List all required approval			
MARCC 9/19/2023	PSQC	Other: Safety Committee 10/2023	
Clinical Service _____		MSQC 11/2023	MEC 11/2023	BOD 11/2023

Note: *If any of the sections of your final layout are not needed do not delete them, write "not applicable".*

1.0 Purpose:

1.1 The purpose of the Bloodborne Pathogen Exposure Control Plan is to comply with Standard (Title 8, Chapter 4, Section 5193, http://www.dir.ca.gov/title8/5193html) and protect healthcare workers and employees from bloodborne infectious diseases by eliminating or reducing the risk of this type of exposure.

2.0 Scope: District wide

3.0 Policy: PMHD is committed to providing a safe work environment for our entire staff. The following exposure control plan (ECP) is provided to eliminate or minimize occupational exposure to bloodborne pathogens in accordance with OSHA standard 29 CFR 1910.1030, "Occupational Exposure to Bloodborne Pathogens."

4.0 Definitions:

4.1 Blood – Human blood, human blood components, and products made from human blood.

4.2 Bloodborne Pathogens – Pathogenic microorganisms that are present in human blood and can cause disease in humans. These pathogens include, but are not limited to, hepatitis B virus (HBV), hepatitis C virus (HCV) and human immunodeficiency virus (HIV).

4.3 Contaminated – The presence or the reasonably anticipated presence of blood or other potentially infectious materials on a surface in or on an item.

4.4 Clinical Laboratory – A workplace where diagnostic or other screening procedures are performed on blood and other potentially infectious materials

4.5 Decontamination – The use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use or disposal.

4.6 Exposure Incident – A specific eye, mouth, or other mucous membrane, non-intact skin, or parenteral contact with blood or other potentially infectious materials (OPIM) that result from the performance of an employee's duties.

4.7 EVS – Environmental Services

4.8 Hand Washing Facilities – Facilities providing adequate supplies of running potable water, soap, and single use towels or hot air dying machines and/or hand anti-microbial gel dispensers throughout the hospital.

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4.9 HBV – Hepatitis B virus
4.10 HCV – Hepatitis C virus
4.11 HCW – Health Care Worker – Any employee, medical staff or other healthcares professional that has the potential for bloodborne or other exposures and works in our facility.
4.12 HIV – Human Immunodeficiency
4.13 Occupational Exposure – Reasonably anticipated skin, eye mucous membrane, or parenteral contact with blood or potentially infectious materials that may result from the performance of an employee's duties.
4.14 OPIM – Other Potentially Infectious Materials are as follows:
- 4.14.1 Human Body Fluids – semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, amniotic fluid, saliva in dental settings, any other body fluid that is visibly contaminated with blood such as saliva or vomitus, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids such as emergency response.
- 4.14.2 Any unfixed tissue or organ (other than intact skin) from human (living or dead)
- 4.14.3 Any of the following, if known or reasonably likely to contain or be infected with HIV, HBV, or HCV
  - 4.14.3.1 Cell, tissue, or organ cultures from humans or experimental animals
  - 4.14.3.2 Blood, organs, or other tissues from experimental animals
  - 4.14.3.3 Culture medium or other solutions

4.15 Parental Contact – piercing mucous membranes or the skin barrier through such events as needle sticks, human bites, cuts, and abrasions.
4.16 PPE – Personal Protective Equipment – Specialized clothing or equipment worn or used by HCW for protection against a hazard. General work clothes (e.g. uniforms, pants, shirts or blouses) not intended to function as protection against a hazard is not considered to be personal protective equipment. Personal protective equipment will be considered "appropriate only if it does not permit blood or OPIM to pass through to or reach the HCW's work clothes, street clothes, undergarments, skin, eye, mouth, or other mucous membranes under normal conditions of use and for the duration of time which the PPE will be used.
4.17 Regulated Waste
- 4.17.1 Liquid or semi-liquid blood or OPIM
- 4.17.2 Contaminated items that:
  - 4.17.2.1 Contain liquid or semi-liquid blood, or are caked with dried blood or OPIM.
  - 4.17.2.2 Are capable of releasing these materials when handled or compressed
- 4.17.3 Contaminated sharps
- 4.17.4 Pathological and microbiological wastes containing blood or OPIM
- 4.17.5 Regulated waste includes "medical waste" regulated by Health and Safety Codes

4.18 Sharp – Any object used or encountered in the industries covered by subsection (a) that can be reasonably anticipated to penetrate the skin or/and other part of the body, and to

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result in an exposure incident, including, but not limited to, needle devices, scalpels, lancets, broken glass, and broken capillary tubes.

4.19 Standard Precautions – An approach to infection prevention. According to the concept of Standard Precautions, all human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV, and other bloodborne pathogens.

5.0 Procedure:

5.1 Employee Exposure Risk Determination

5.1.1 Category Risk I: Is a job classifications in which **all** employees have occupational exposure.

5.1.2 Category Risk II: Is a job classifications in which **some** employees have exposure.

5.2 Responsibilities:

5.2.1 Employee Health Services is responsible for coordinating the annual review and update of the Bloodborne Pathogen Exposure Control Plan. Employee Health provides the initial employee training of the Exposure Control Plan during general orientation and works with Infection Control Department to identify and select safety devices. They also serve as a resource for infection prevention and control information.

5.2.1.1 Employee Health Services is responsible for evaluating the circumstances surrounding exposure incidents, providing the hepatitis B vaccination for all employees who are at risk of occupational exposure to bloodborne pathogens, and for reporting safety-related incidents to the Safety Committee. Employee records for vaccinations, exposures and exposure follow-up, and confidential Sharp Injury Log are maintained by Employee Health Services.

5.2.2 The Safety Officer will assist Infection Control in overseeing the use of standard precautions by all HCW/personnel for Pioneers Memorial Healthcare District. The Safety Officer also provides input for review and update of the Exposure Control Plan as appropriate and reports safety-related incidents to the Safety Committee.

5.2.3 Human Resources is responsible for maintaining documentation of annual training.

5.2.4 Department Directors are responsible for:

5.2.4.1 Determining which employees have potential occupational exposure to bloodborne disease.

5.2.4.2 Ensuring that employees receive all required training and education

5.2.4.3 Ensuring that personal protective equipment is available for employee use

5.2.4.4 Ensuring that employees use safe practices and PPE when there is a potential of exposure to bloodborne pathogens

5.2.4.4.1 Monitoring employees for compliance with Standard Precautions and work practice controls

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5.2.4.4.2 Maintaining current department-specific policies and procedures addressing engineering and work practice controls and PPE

5.2.4.4.3 Training and counseling employees who are not using safe practice while handling sharps and/or bloodborne pathogens

5.2.5 Employees are responsible for:

5.2.5.1 Knowing what tasks they perform that have potential for bloodborne exposure and using safe practices, PPE, and devices as appropriate.

5.2.5.2 Reviewing the Bloodborne Pathogens and associated policies as part of their annual review

5.2.5.3 Maintaining a clean and safe environment

5.3 Work Practice Controls and Procedures have been implemented to minimize exposure to bloodborne pathogens. Each Department Manager is responsible for implementing, evaluating, and monitoring compliance with work practices on an ongoing basis..

5.3.1 Engineering and work practice controls include: Needleless systems where applicable, use of needles with engineered safety devices, and disposal of sharps in sharp containers,

5.4 Standard precautions are used to prevent contact with blood or other potentially infectious materials and are to be applied to all patients. When necessary, transmission-based precautions are used in addition to standard precautions. (See policy CLN-02308; Isolation Guidelines)

5.5 Specimen Handling and Contact with Blood or Body Fluids:

5.5.1 Eating, drinking, applying cosmetics, or lip balm, and handling contact lenses are prohibited in work areas where there is a reasonable likelihood of Occupational exposure to blood or body fluids.

5.5.1.1 Clinical departments may clearly identify areas of the department where bloodborne pathogens may be present, such as areas where clinical specimens' or blood glucose monitoring devices may be placed. Direct patient care areas are included in these designated areas.

5.5.1.2 Clinical departments may clearly identify areas of the department where items which may carry bloodborne pathogens may not be present, such as clean work areas or staff rest areas. Gloves should not be worn in these areas. Items which may carry bloodborne pathogens shall not be placed in theses identified areas.

5.5.1.3 Staff may drink liquids, while working as allowed by their director in designated clean department areas where bloodborne pathogens are not kept. Care should be taken to minimize the risk of spilling by covering liquid.

5.5.1.4 Staff food and drink are not allowed in patient refrigerators.

5.5.2 Food, drink, and oral medications will not be kept in refrigerators, freezers, shelves, cabinets, on countertops where blood or body fluids may be present.

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5.5.3 Specimens' of blood or body fluids will be placed in containers that prevent leakage during collection, handling, processing, storage, transportation or shipping.

5.5.4 If an exposure occurs, mucous membranes and eyes will be immediately flushed copiously with water following exposure to blood or body fluids (See policy HRD-00127; Postexposure prophylaxis after occupational exposure to blood & body fluids).

5.6 Housekeeping:

5.6.1 Environmental Services (EVS) is responsible for maintaining the facility in a clean and sanitary manner. Policies and procedures have been developed and implemented to ensure that cleaning methods and schedules are appropriate. The Infection Control and Medical Staff Quality committee (MSQC) will review and approve all policies and procedures that address cleaning, disinfection, and/or sterilization of equipment or environmental surfaces that become contaminated.

6.0 References:

6.1 CAL/OSHA and NIOSH, Calif. Code of Regulations: Title 8, Division 1, Chpt. 4, Subchapter 7, Group 16, Art. 109, 5193, http://www.dir.ca.gov/title8/5193.html

7.0 Attachment List: None

8.0 Summary of Revisions:

8.1 5.1 added to include exposure risk categories per Title 8, 5193

Pioneers Memorial Healthcare District

Title: **California Sick Leave**	Policy No. HRD-01398
	Page 1 of 2
Current Author: Charity Dale	Effective: 1/1/2024
Latest Review/Revision Date: 12/6/2023	Manual: Human Resources/Benefits

Collaborating Departments: Administration		Keywords: Sick Leave, Benefits	
Approval Route: List all required approval			
MARCC 5/18/2023 virtual approval	PSQC	Other:	
Clinical Service _____		MSQC	MEC	BOD 52023

Note: *If any of the sections of your final layout are not needed do not delete them, write "not applicable".*

1.0 Purpose:

1.1 Pioneers Memorial Healthcare District provides paid California Sick leave to employees who have worked 30 or more days in California within a year of their employment with the company.

2.0 Scope: Full-Time, Part-Time, Per Diem employees.

3.0 Policy:

3.1 Eligibility:

3.1.1 An employee becomes eligible for paid sick leave by working in California for at least 30 days within a year. Before an employee can take any sick leave, he or she must satisfy a 90-day employment period at PMHD.

3.1.2 CA sick leave hours may be used at the employee's discretion.

3.1.3 Current employees and newly hired employees will receive a lump-sum grant of 40 hours or 5 days on 1/1/2024. This CA Sick bank will then be repopulated into the employees' CA sick bank on January 1st of each subsequent year if the employee remains eligible.

3.1.4 Paid sick leave may be used after an employee has worked for the district for at least 90 days. Unused sick leave granted under this policy does not carry over from one year to the following year and will not be paid upon status change or termination.

3.1.5 As of 12/31 of each year or upon hire, whatever work schedule is assigned whether classified as an 8-, 10- or 12-hour employee will determine their CA sick leave allocation for the next year.

3.1.6 Leave under this policy may run concurrently with leave taken under other applicable policies as well as under local, state or federal law, including leave taken pursuant to the California Family Rights Act (CFRA) or the Family and Medical Leave Act (FMLA).

4.0 Definitions:

4.1 An immediate family member includes:

4.1.1 Spouses registered domestic partners, children (regardless of age), parents (including step-parents and parents-in-law), grandparents, grandchildren, siblings or a designated person.

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Title: **California Sick Leave**	Policy No. HRD-01398
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Current Author: Charity Dale	Effective: 1/1/2024
Latest Review/Revision Date: 12/6/2023	Manual: Human Resources/Benefits

5.0 Procedure:

5.1 After successfully completing 90 days of employment at PMHD, eligible employees may begin to request time off under CA sick leave in increments of no less than two hours, up to a maximum of 40 hours or 5 days per calendar year.
5.2 If the need for paid sick leave is foreseeable, the employee shall provide reasonable advance notification to their supervisor. If the need for paid sick leave is unforeseeable, the employee shall provide notice of the need for the leave as soon as practicable.
5.3 Employees will not be requested to provide a physician's note in support of the leave taken.
5.4 Unused time under this policy is not paid out at the time of separation from employment.
5.5 Sick leave balances are available for viewing on the employee's pay stub and in the human resources self-service information systems.

6.0 References:

6.1 Healthy Workplace Healthy Family Act (AB 1522)

7.0 Attachment List: Not applicable

8.0 Summary of Revisions:

8.1 New Policy

Pioneers Memorial Healthcare District

Title: **Care of an Emergency Patient Contaminated with Hazardous Materials – CODE ORANGE**	Policy No. EOC-00095
	Page 1 of 9
Current Author: Jorge Mendoza	Effective: 8/1/1995
Latest Review/Revision Date: 8/19/2023	Manual: EOC / Hazardous & Waste Mgmt

Collaborating Departments: ED, Facilities, EVS		Keywords: Hazmat, Hazardous Materials, Decontamination, Contaminated		
Approval Route: List all required approval				
MARCC 9/9/2023	PSQC	Other: Safety Committee 10/2023		
Clinical Service _____		MSQC 11/2023	MEC 11/2023	BOD 12/2023

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1.0 Purpose:

1.1 PMHD may be confronted with patients that have been contaminated by residual biological spores, chemical and/or radioactive effects from natural or man-made incidents. This policy will establish guidelines for facilitating safe and efficient decontamination of patients.

1.2 The primary concern for a hazardous materials response is for the safety and security of patients, staff and the facility.

2.0 Scope: Hospital wide

3.0 Policy:

3.1 The PMHD Emergency Operations Plan (EOC-00213) will be activated for all hazmat/decontamination events.

3.2 At a minimum, an Incident Commander and Safety Officer will be assigned for all hazmat/decontamination events.

3.3 The PMHD decontamination team will consist of trained personnel, may be clinical or non-clinical, from various departments at PMHD.

3.4 All PMHD Employees who will serve as part of the PMHD decontamination team will receive training that meets the requirements set forth in 29 CFR 1910.120(q)(6)(ii) "Hazardous Materials First Responder Operations (FRO)" requirements.

3.5 Employees will receive annual refresher training that meets the requirements set forth in the above regulation.

3.6 The PMHD EMS/Emergency Preparedness Manager will be responsible for procuring and maintaining decontamination equipment and personal protective equipment.

3.7 Upon notification of a hazmat incident, the assigned Incident Commander will complete the hazardous materials incident checklist.

4.0 Definitions:

4.1 Decontamination – Procedures taken to rid of contamination

4.2 Decontamination Team – A team of individuals properly trained to decontaminate victims of hazardous materials incidents.

4.3 Hospital Incident Command System (HICS) – A system designed to establish command and control for hospitals in response to an emergency/disaster situation.

4.4 FEMA – Federal Emergency Management Agency

Pioneers Memorial Healthcare District

Title: **Care of an Emergency Patient Contaminated with Hazardous Materials – CODE ORANGE**	Policy No. EOC-00095
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Latest Review/Revision Date: 8/19/2023	Manual: EOC / Hazardous & Waste Mgmt

4.5 Hazardous Material (HazMat) – A material considered to be a danger to life or the environment if released without precautions (i.e., chemical agent, biological agent, radioactive material, etc.)

5.0 Procedure:

5.1 Initial notification of possible patients from a hazmat incident in the community can come from various sources including, but not limited to:
- 5.1.1 Fire Department/EMS
- 5.1.2 Law Enforcement
- 5.1.3 Media Sources
- 5.1.4 Patients

5.2 Upon receiving initial notification of an incident potentially requiring patient decontamination, the following information should be obtained as rapidly as possible:
- 5.2.1 Type and nature of the incident (motor vehicle accident, explosion, etc.)
- 5.2.2 Contact information of the notifying agency (name, phone number, etc.)
- 5.2.3 Approximate number and ages of victims
- 5.2.4 Victim signs and symptoms
- 5.2.5 Nature/degree of victim injuries
- 5.2.6 Type of chemical or other agent involved
- 5.2.7 Extent of victim decontamination occurring in the field
- 5.2.8 Approximate time of EMS arrival
- 5.2.9 Expected number of self-presenting patients
- 5.2.10 PPE should be immediately gathered from the Hazmat Trailer and brought to the Emergency Department break room or other empty ED room to establish a PPE donning area.

5.3 In order to effectively protect PMHD in response to a hazmat event, the following internal notifications must be made immediately:
- 5.3.1 Emergency Department Charge Nurse
- 5.3.2 House Supervisor
- 5.3.3 Security
- 5.3.4 Safety Officer
- 5.3.5 Administration
- 5.3.6 EMS/Emergency Preparedness Manager
- 5.3.7 Brawley Police/Fire Dispatch Center via 9-1-1 or the 800MHz radio system
  - 5.3.7.1 Coordinate with Brawley Fire Department if decontamination assistance is necessary. Brawley Fire Department may be available to assist or may contact the Imperial County Hazardous Emergency Assistance Team (HEAT Team) for a larger operation.

5.4 The Hospital Operator will be contacted to page a “Code Orange” overhead.

5.5 The PMHD Emergency Operations Plan will be activated for all incidents that require patient decontamination.
- 5.5.1 A full complement of HICS staff is not necessary; however an Incident Commander and Safety Officer must be assigned.

Pioneers Memorial Healthcare District

Title: **Care of an Emergency Patient Contaminated with Hazardous Materials – CODE ORANGE**	Policy No. EOC-00095
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Latest Review/Revision Date: 8/19/2023	Manual: EOC / Hazardous & Waste Mgmt

5.6 In the event an unannounced patient(s) presents to PMHD from a suspected hazmat incident, the employee who first encounters the patient shall immediately direct the patient(s) to the decontamination showers outside the Emergency Department and notify the Emergency Department Charge Nurse, who will ensure the notifications listed in 5.3 are made.

5.6.1 The first member of the PMHD Decontamination team to arrive, will don the highest level of PPE available (Level C), described in this policy, unlock the decontamination showers and begin to interview the patient.

5.6.2 Attempt to identify and characterize the product with which the patient was contaminated:

5.6.2.1 What is the name or chemical ID number for the product?

5.6.2.2 What is the chemical used for?

5.6.2.3 What is the chemical's classification (oxidized, flammable, corrosive, etc.)?

5.6.2.4 Is the chemical water soluble?

5.6.2.5 Number of possible patients who may present from the incident

5.6.2.6 If the chemical is unknown or cannot be identified, what were the circumstances surrounding the use of the agent (i.e. spraying plants, cleaning, machinery, etc.)?

5.7 The following resources may be used to determine the contaminant; level of PPE required and suggested treatment plans:

5.7.1 Current Emergency Response Guidebook (must know name or chemical ID number) – located in ED reference book section as well as triage desks

5.7.2 MSDS sheets (must know name of chemical)

5.7.3 WISER app/WebWiser (wiser.nlm.nih.gov)

5.7.4 Regional Poison Control Center (800) 222-1222

5.8 Immediately upon notification of a hazmat incident, PMHD will initiate a controlled access plan and all foot traffic into the facility will be directed through the Emergency Department. Decontamination team members in appropriate PPE will prevent contaminated individuals from entering the facility until they have been properly decontaminated.

5.9 PPE selection for decontamination team members is critical at the onset of a hazmat event. The guidelines below describe the PPE available, process for selection of PPE, donning and doffing procedures:

5.9.1 Level C PPE is available for decontamination team members and includes:

5.9.1.1 Powered-Air Purifying Respirator (PAPR) with organic vapor cartridge and Butyl Rubber Hood

5.9.1.1.1 PAPRs and butyl rubber hoods are located in the PAPR/Backboard closet in the ED, near the ambulance entrance

5.9.1.2 Chemically protective suit

5.9.1.3 Two layers of gloves including (from inner layer to outer layer):

5.9.1.3.1 Nitrile Gloves

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5.9.1.3.2 Chemically Protective Gloves
5.9.1.4 Chemically protective rubber boots or shoe covers
5.9.1.5 Suit openings sealed with chemically protective tape.
5.9.1.6 Level C PPE is stored in the PMHD Hazmat Trailer, located outside the Emergency Department Ambulance Entrance
5.9.1.6.1 The key to the Hazmat Trailer should be obtained from one of the following:
5.9.1.6.1.1 House Supervisor
5.9.1.6.1.2 Emergency Department Manager
5.9.1.6.1.3 Emergency Preparedness Manager
5.9.1.6.1.4 Emergency Department Key Locker

5.10 Upon notification of a possible decontamination event, PPE should be obtained from the Hazmat Trailer and brought to the Emergency Department break room or other empty ED room to establish a PPE donning area
5.10.1 An assistant is required to don PPE, the donning sequence is as follows:
5.10.1.1 Assemble and test the PAPR using the manufacturer's recommendations
5.10.1.2 Remove watches, jewelry, name badges and personal clothing and put on scrubs
5.10.1.3 Inspect all PPE for damage prior to donning, if any damage is present discard and obtain a replacement
5.10.1.4 Put on the inner nitrile gloves
5.10.1.5 Put on the chemical protective suit to waist.
5.10.1.6 Put on boots/shoe covers
5.10.1.7 Put on the chemically protective outer gloves
5.10.1.8 Put on PAPR hood and position the inner shroud
5.10.1.9 Pull chemical protective suit up and over the inner shroud
5.10.1.10 Pull suit sleeves over gloves, zip-up and ensure the Velcro closure covers the zipper
5.10.1.11 Pull outer PAPR hood shroud over the suit
5.10.1.12 Secure PAPR belt to waist
5.10.1.13 Pull suit cuff over top of boot/shoe cover
5.10.1.14 Use chemically protective tape to seal all openings; sleeve cuffs and zipper
5.10.1.15 Place a piece of tape on the front and back of the hood exterior and label with the employee's name with a permanent marker

5.11 Employee safety is crucial to ensure safe decontamination operations. The assigned Safety Officer will closely monitor and document the length of time each employee is in Level C PPE.
5.11.1 The Incident Commander and Safety Officer will coordinate to ensure employees are rotated efficiently to ensure their safety.
5.11.2 The Incident Commander or Safety Officer will need to designate a location to be used as a rehabilitation area for staff during decontamination operations.

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5.11.3 The Incident Commander will coordinate with the dietary department to provide hydration and nutritional items for staff in the rehabilitation area.

5.11.4 While in the rehabilitation area, employees should be monitored for signs of heat stress.

- 5.11.4.1 Hot, unusually dry, red or spotted skin
- 5.11.4.2 Elevated body temperature
- 5.11.4.3 Altered level of consciousness, confusion or delirium
- 5.11.4.4 Weakness or fatigue
- 5.11.4.5 Vomiting
- 5.11.4.6 Body cramps

5.11.5 Any employee who shows signs and symptoms of a heat related illness should be immediately removed and will no longer participate in the operations. They will be taken immediately to the Emergency Department for appropriate treatment.

5.11.6 Prior to leaving the rehabilitation area and returning to operations in PPE the following conditions must be met:

- 5.11.6.1 Diastolic Blood Pressure ≤ 95
- 5.11.6.2 Heart Rate ≤ 110
- 5.11.6.3 Respirations ≤ 20
- 5.11.6.4 Oral Temperature ≤ 99.5

5.11.7 If an employee's vital signs persistently remain above these limits, they should be taken to the Emergency Department for evaluation.

5.12 Prior to leaving the Hospital Decontamination Zone to enter the Rehabilitation Area the following procedure must be followed, while still in PPE, using soap and running water:

5.12.1 An assistant in PPE should decontaminate employees, in a separate area from victims (Technical Decontamination Area), using a soft bristled brush with gentle scrubbing in a unilateral direction from top down.

5.12.2 Remove tape from exterior of suit.

5.12.3 Thoroughly wash exterior gloves

5.12.4 Thoroughly wash PAPR Hood

5.12.5 Thoroughly wash torso front and back

5.12.6 Thoroughly wash PAPR Hose and PAPR unit including belt

5.12.7 The employee should reach down and remove PAPR from waist, while leaving the hood on, and hold it away from body. The PAPR unit may be placed on a chair, gurney or hung from an IV pole if available.

5.12.8 Thoroughly wash each leg and boots.

5.12.9 Thoroughly wash the bottom of each boot

5.12.10 Step out of the technical decontamination area into the PPE doffing area.

5.12.11 Remove PAPR Hood – place in waste

5.12.12 Remove chemical boots – place in waste

5.12.13 Unzip chemical suit

5.12.14 Remove exterior gloves – place in waste

5.12.15 Remove the chemical suit from the torso – roll the suit away from you inside out touching the inside of the suit.

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5.12.16 Remove each leg from the chemical suit – place in waste
5.12.17 Step over clean line and remove nitrile gloves – place in waste

5.13 In the event a decontamination team member has an emergency during decontamination operations, they should immediately follow the above procedure and be moved to the post decontamination zone for treatment or new PPE.

5.14 Patient Decontamination:

5.14.1 Ambulatory Patient Decontamination:

5.14.1.1 Ambulatory patients should be directed by a decontamination team member to self-decontamination in the decontamination showers.

5.14.1.2 Children should be kept with their parents, if possible; if no parent or older sibling is available then a decontamination team member should provide needed assistance to a child

5.14.1.3 Separate decontamination showers should be designated for male and female victims to maintain privacy if necessary.

5.14.1.4 Victims should be given a personal decontamination kit prior to entering decontamination showers.

5.14.2 The following decontamination instructions should be provided:

5.14.2.1 Remove all valuables and seal in the small plastic bag.
5.14.2.2 Remove all clothing and seal in the larger plastic bag.
5.14.2.3 Seal both the valuables bag and clothing bag in a third plastic bag that has been labeled with unique patient identifiers.
5.14.2.4 Place the final sealed bag in the barrel at the exit of the decontamination showers for future disposition.
5.14.2.5 Gently brush off dry contaminants being careful to avoid contact with eyes, nose and mouth.
5.14.2.6 Using the soap provided wash from head-to-toe paying special attention to the hair and all body crevices.
5.14.2.7 Wash time cycle should be five (5) minutes per person.
5.14.2.8 Use a gentle, unilateral scrubbing motion from top down.
5.14.2.9 Upon completion of decontamination, the patient should step out of the wash area towel dry and put on supplied gown or given a sheet/blanket to cover.
5.14.2.10 Place wash cloths and towels in the designated barrel

5.14.3 The patient should then be directed to the Emergency Treatment Area, if established, and re-triaged for treatment in the Emergency Department.

5.14.4 Non-Ambulatory Patient Decontamination:

5.14.4.1 Patients who are unable to perform self-decontamination should be taken to the non-ambulatory decontamination area; this includes but is not limited to patients who are non-ambulatory due to:

5.14.4.1.1 Injury/illness caused by the incident
5.14.4.1.2 Patients who have an underlying medical condition that prevents them from performing self-decontamination (i.e. paralysis, dementia, bed/wheelchair bound, etc.)

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5.14.4.1.3 Age-affected; consider elderly and infant patients who cannot perform decontamination.

5.14.4.2 Non-ambulatory patient decontamination should be performed simultaneously with patient stabilization. Basic Life Support (ABC's) will be maintained until the patient is decontaminated, to a degree that ensures staff safety and that invasive procedures will not increase the patient's risk of systemic absorption.

5.14.4.3 The two black cots located in the hazmat trailer should be used for non-ambulatory decontamination and the patient placed on a plastic/fiberglass backboard. **Infants should be decontaminated in infant baths or similar baskets*.

5.14.4.3.1 Emergency Department gurneys, with the mattresses removed, should be used to transport patients after the decontamination process.

5.14.4.4 The following procedures should be used for non-ambulatory decontamination:

5.14.4.4.1 Follow the procedures for removal and bagging of personal valuables.

5.14.4.4.2 Patient clothing should be removed using blunt tipped trauma shears and bagged using the above procedures.

5.14.4.4.3 Wash the patient from head-to-toe using a gentle, unilateral scrubbing motion from top down paying special attention to the patient's hair and body crevices.

5.14.4.4.4 Remove any dressings applied prior to decontamination and use copious amounts of water to irrigate wounds.

5.14.4.4.5 A clean dressing should be applied if necessary to control bleeding.

5.14.4.4.6 The patient should then be transferred to a clean Emergency Department gurney, without the mattress, and moved to the designated area to be transferred to the post-decontamination zone.

5.14.5 Special Considerations:

5.14.5.1 Glasses and contact lenses:

5.14.5.1.1 Patients with glasses should keep them if they cannot see without them. They must be washed and rinsed thoroughly during the decontamination process before being worn. Otherwise, the glasses should be placed in the valuables bag.

5.14.5.1.2 Contact lenses should be removed, after thoroughly washing hands, and discarded or placed in the valuables bag.

5.14.5.2 Patients who use walking assist devices may retain them, but the device must be washed and rinsed thoroughly during the decontamination process.

5.14.5.3 Intravenous lines and Saline locks should be removed prior to

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decontamination. After the area is cleaned, a dressing should be applied until the patient reaches the treatment area.

5.14.5.4 Hearing aids should be removed and placed in the valuables bag.

5.14.5.5 Dentures:

5.14.5.5.1 Unless the oral cavity is contaminated dentures should remain in place and no special decontamination is necessary.

5.14.5.5.2 If the oral cavity is contaminated, then the dentures should be removed, placed in a clear plastic bag for later decontamination based on poison control or dentist recommendations.

5.14.5.6 Law Enforcement Officers with Weapons:

5.14.5.6.1 In most cases law enforcement personnel who have been injured on the scene will have had their gun(s) removed before arrival and given to a fellow officer.

5.14.5.6.2 If an officer arrives and still has a weapon, it should be left in the holster and the gun belt removed by a decontamination team member and sealed in two clear plastic bags labeled with the officer's name. It should be transferred to the treatment area and given to a fellow officer for safe keeping.

5.14.5.6.3 Decontamination team members should be aware that oftentimes an officer may have a second weapon that can usually be found in a holster near the ankle, their pocket, in a ballistic vest or near an armpit. If found the weapon should be handled following the above guidelines.

5.14.5.6.4 An officer's duty-belt may also contain items that can be dangerous if allowed in the wrong hands. Thus, the duty-belt should be collected and sealed as described above and handed to a fellow officer or hospital security for safekeeping.

5.14.5.6.5 Decontamination of an officer's weapon or duty belt will be the responsibility of their respective agency.

5.14.6 Personnel Decontamination:

5.14.6.1 Prior to leaving the decontamination area, decontamination team members must undergo decontamination using the guidelines outlined in this policy (5.12.1 – 5.12.17)

5.14.6.2 Once the above steps have been completed, each decontamination team member must remove all clothing, shower and dress in replacement scrubs or personal clothes.

5.14.6.3 After redressing, each decontamination team member must present to the Emergency Department for appropriate medical screening and monitoring for chemical exposure as determined by the Emergency Department Physician.

5.15 Decontamination Water Containment and Run-Off:

5.15.1 During an emergency, PMHD will take all necessary steps to protect staff, the public and save lives. Once imminent threats to human health and life are

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addressed PMHD will take all reasonable steps to contain contamination and avoid or mitigate environmental consequences.

5.15.2 For all incidents, PMHD decontamination team members will use the fixed decontamination showers as the primary means for patient, staff and equipment decontamination

5.15.3 In the event the number of victims that present to PMHD exceeds the capacity of the fixed decontamination shower facilities the following steps will be taken after imminent life threats have been mitigated:

5.15.3.1 The storm drain adjacent to the decontamination showers will be sealed with two layers of plastic sheeting and secured.

5.15.3.2 Reasonable efforts to collect water run-off from mass decontamination efforts should be taken (i.e., diking, waste-water bladders, etc.)

5.15.3.3 In the event that waste-water run-off cannot be collected prior to entering the storm drain, the Imperial County Office of Environmental Health will be notified immediately.

5.15.4 After decontamination operations have been completed, the PMHD hazardous waste contractor will be contacted to assist in cleaning, testing and disposal of waste-water and equipment.

5.16 After Action Reporting/Improvement Plan:

5.16.1 Immediately following the event, the PMHD EMS/Emergency Preparedness Manager or designee will conduct Hot-washes with all staff and coordinating agencies involved to identify the effectiveness and deficiencies of the response.

5.16.2 Within forty-five (45) days after the termination of operations, the Emergency Preparedness Coordinator will submit a Draft After Action Report and Improvement Plan to the PMHD Safety Committee for approval.

5.16.3 The After Action Report/Improvement Plan will be submitted to the Imperial County Medical Health Operational Area Coordinator and other appropriate agencies upon request.

6.0 References:

6.1 CFR 1910.120 HAZWOPER

6.2 OSHA, Best Practices for Hospital-Based First Receivers of Victims from Mass Casualty Incidents Involving the Release of Hazardous Substances, 2004

6.3 FEMA Center for Domestic Preparedness, Hospital Emergency Response Training for Mass Casualty Incidents, 2008

7.0 Attachment List

7.1 Attachment A – Hazardous Materials Incident Checklist

8.0 Summary of Revisions:

8.1 Author changed.

Hazardous Material Incident Checklist

Name of Person Receiving Call:_____

Title:_____

Date:_____Time:_____Phone:_____

*Reporting Agency:_____*Unit #/Name:_____

*Contact Information (phone/radio):_____

Location of Incident:_____

Threat to Hospital (Circle): Yes No Comment:_____

_____

Nature of Incident (i.e. traffic accident, explosion, leak, etc.):_____

_____

Name of Chemical:_____

Approximate # of Patients:_____Children (Circle): Yes No Elderly: Yes No

Victim Signs/Symptoms:_____

_____

On Scene Decontamination: Yes No Description:_____

_____

EMS Transport: Yes No ETA of First Arriving Unit:_____

Estimated # of Patients Who May Self Present:_____

This form is to be completed, with as much information as possible, by the employee who receives initial notification from field personnel. The ED Charge Nurse will immediately notify the on-duty House Supervisor and proceed as directed by PMHD Policy EOC-00095. Additional information regarding the incident and pre-hospital treatment provided may be recorded on the back of this form.

Attachment A – EOC-00095

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Collaborating Departments: Pharmacy, Radiology, Nursing Administration, Registration, Emergency Department, Dr. Nelson	Keywords:

Approval Route: List all required approval				
MARCC 11/9/2023	PSQC	Other:		
Clinical Service Medicine 1/2024		MSQC 2/2024	MEC 2/2024	BOD 2/2024

Note: *If any of the sections of your final layout are not needed do not delete them, write "not applicable".*

1.0 Purpose:

1.1 Describe PMHD's clinical response process to facilitate urgent assessment, evaluation and treatment of patients experiencing stroke symptoms, presenting to the Emergency Department.

2.0 Scope: Emergency Department (ED)

3.0 Policy:

3.1 When a patient is exhibiting stroke symptoms, a Code Stroke is activated, and the Stroke Team will respond to support the care of the patient as needed.

- 3.1.1 Any patient, who presents to the ED with neurological signs and symptoms, will be treated as a STAT triage and given an Acuity level 1.
- 3.1.2 EMS Patients:
  - 3.1.2.1 EMS will pre-notify the Licensed Independent Practitioner (LIP) of any patients who are experiencing symptoms of a possible stroke.
  - 3.1.2.2 The ER LIP will be notified of EMS report and a Code Stroke will be activated based on the EMS report and/or LIP discretion.
- 3.1.3 Private Transport/Walk-In patients:
  - 3.1.3.1 Registration will call out on the overhead "Triage FAST" for patients experiencing neurological signs and symptoms or severe headache to alert triage nurse.
  - 3.1.3.2 Patients who arrive by private transport/walk-in with symptoms of possible stroke will be triaged immediately and taken to treatment area. The ER LIP will be notified and a Code Stroke will be initiated per ER LIPs order.

3.2 Benchmark Goals:

- 3.2.1 ED LIP evaluation: 10 minutes from ED arrival
- 3.2.2 Door to CT scan of head <20 minutes
- 3.2.3 Door to CT scan of head with results <45
- 3.2.4 DOOR TO NEEDLE <60 minutes

4.0 Definitions:

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4.1 Code Stroke – The single call activation mechanism for stroke. It ensures that appropriate staff and departments are alerted to assess, diagnose, and treat stroke patients in the ED.
4.2 Stroke Team – Team that responds to Code Stroke.

5.0 Procedure:

5.1 Anyone who notices acute neurological changes consistent with signs/symptoms of an acute stroke may activate Code Stroke by dialing extension 4-4-4-4 stat.
- 5.1.1 Guidelines for Initiating Code Stroke –
  - 5.1.1.1 Any neurological changes with a time of onset (last time "known to be well") less than 24 hours.
    - 5.1.1.1.1 Unilateral weakness- hemiplegia or facial droop
    - 5.1.1.1.2 Changes in speech pattern – aphasia/dysarthria
    - 5.1.1.1.3 When patient presents with symptoms of a posterior stroke: Dizziness, Diplopia, Dysarthria, Dysphagia, Dystaxia

5.2 When a Stroke Code is activated:
- 5.2.1 The Health Unit Clerk or designee will:
  - 5.2.1.1 Notify the Hospital Operator, who will place an overhead page announcement.
    - 5.2.1.1.1 The operator will state, "Code Stroke, Emergency Department, room # ___"
  - 5.2.1.2 Call neurologist on-call to notify of Code Stroke Activation.
- 5.2.2 The Primary Nurse will obtain a verbal order for Code Stroke Activation and enter order into electronic medical record

5.3 The Stroke Team will arrive to assess patient with 5 minutes of activation.
5.4 The Stroke Team will consist of:
- 5.4.1 Primary Nurse – will assess patient, obtain blood glucose level via point of care testing and measure vital signs
- 5.4.2 Charge Nurse – will serve as a resource to the team and/or assist with care of the patient as needed
- 5.4.3 ER LIP – will evaluate and treat patient as medically needed.
  - 5.4.3.1 May deactivate Code Stroke if outside treatment parameters or upon his/her discretion
- 5.4.4 Laboratory – A laboratory phlebotomist's will obtain blood for diagnostic testing. Lab draw will not delay CT scan.
  - 5.4.4.1 Code Stroke specimens will be processed STAT.
- 5.4.5 Radiology– Radiology will prioritize access to the CT scanner. Scanner will be kept vacant for 30 minutes. Studies already in progress (i.e. liver biopsy) and other studies being performed on clinically unstable patients will not be interrupted.

5.5 Refer to Emergency Department Code Stroke Protocol (attachment A) for nursing orders.
5.6 Refer to the following pre-printed order sets, guidelines and forms as needed:

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5.6.1 NIH Stroke Scale Form – See attachment B
5.6.2 Inclusion and Exclusion Criteria Check-Off List, Fibrinolytic Therapy for Ischemic Stroke – See Attachment C
5.6.3 Consent for treatment of Ischemic Stroke with Tenecteplase – English Version – See attachment D
5.6.4 Consent for treatment of Ischemic Stroke with Tenecteplase – Spanish Version – See attachment E
5.6.5 Ischemic Stroke Tenecteplase Pre-Printed Order Set – (360˚ Compliance Pre-Printed Order Manual PPO# ERM)
5.6.6 Post Tenecteplase Administration Pre-Printed Order Set – (360˚ Compliance Pre-Printed Order Manual PPO# ERM-00334)
5.6.7 Admission order set **NON** Tenecteplase Patient – (360˚ Compliance Pre-Printed Order Manual PPO# ERM-00330)

5.7 Code Stroke will be de-activated upon LIPs request based on his/her discretion.

6.0 References:

6.1 (2023) Guidelines for the Early Management of Patients with Acute Ischemic Stroke: A guideline for healthcare professionals from the American Heart Association/American Stroke Association.

7.0 Attachment List:

7.1 Attachment A – Emergency Department Code Stroke Protocol
7.2 Attachment B – NIH Stroke Scale Form
7.3 Attachment C – Inclusion and Exclusion Criteria Check-Off list, Fibrinolytic Therapy for Ischemic Stroke
7.4 Attachment D – Consent for treatment of Ischemic Stroke with Tenecteplase – English Version
7.5 Attachment E – Consent for treatment of Ischemic Stroke with Tenecteplase – Spanish Version

8.0 Summary of Revisions:

8.1 Deleted 5.1.1.1.3 Extended-window Code Stroke debilitating stroke symptoms with onset between 8 and 24hours, including wake-up stroke known to be normal within previous 24 hours.
8.2 Deleted 3.2.4 Laboratory tests resulted <45 minutes
8.3 Modified policy to reflect TNKase – Tenecteplase instead of tPA
8.4 6.1 updated reference.
8.5 Created Ischemic Stroke Tenecteplase Pre-Printed Order Set this and above made 9/2023
8.6 Modified policy 5.1.1.1 to extend time to 24 hours this and below, 11/2023
8.7 Addition: CT scan head/neck with angiography to 7.1 Attachment A.

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8.8 Modified Attachement A Emergency Department Code Stroke Protocol extended -Order CTA head and neck from 18 to 24 hours

8.9 Modified Attachement A- Code Stroke Protocol from “NURSING WILL COMPLETE THE FOLLOWING ORDERS:” to “NURSING WILL COMPLETE AND ENTER THE FOLLOWING ORDERS:”

EMERGENCY DEPARTMENT **Code Stroke Protocol**

Any Patient, who presents to the Emergency Department as a walk-in, by Private Own Vehicle or EMS, with neurological signs and symptoms, will be treated as a STAT triage and be given an Acuity level – 1.

EMS Patients:

- EMS will Pre-notify the ED of any patients who are experiencing symptoms of a possible stroke.
- The ER physician will be notified of EMS report and a Code Stroke will be activated based on the EMS report and physician discretion.

Private Transport/Walk in Patients:

- Patients, who arrive by private transport/walk-in with symptoms of possible stroke will be triaged immediately and taken to treatment area. The ER physician will be notified and a Code Stroke will be initiated per ER physician's order.

GOALS OF CODE STROKE:

Note: The only diagnostic test that may delay CT scan of the brain is a fingerstick blood glucose test.

ED Physician evaluation	10 minutes from ED arrival
Door to CT scan of head	<20 minutes
Door to CT scan of head with results	<45 minutes
DOOR TO NEEDLE	**<60 MINUTES**

CODE STROKE ACTIVATION:

- Code stroke will be activated overhead – "Code Stroke, Emergency Department, Room # _____" when a patient is experiencing signs and symptoms of a stroke with an onset of less than 8 hours.
  - Neurologist on call will be contacted and notified of Code Stroke activation
- When a code Stroke is activated the primary nurse, charge nurse, ER Physician, and Laboratory technician will present to the bedside for treatment. Radiology will clear CT scan and present to ED to assist with transport of patient to CT scan.
- All diagnostic tests will be completed on a STAT basis (unless outside the time parameters to receive time sensitive treatment).
- Order CTA head and neck if onset of symptoms within 24 hours without waiting for lab results regardless of previous creatine.

ONSET TIME:

Record time of Stroke signs and symptoms. (Last time patient witnessed without signs & symptoms): _____

NURSING WILL COMPLETE and ENTER THE FOLLOWING ORDERS:

□ Complete an fingerstick blood glucose test to r/o hypoglycemia
□ CT SCAN of the head without Contrast
□ CT SCAN of the head/Neck with angiography only after verbal confirmation from the doctor.
□ Attach cardiac monitor, complete vital signs once, including B/P in both arms. Then q15 minutes
□ If the patient is a potential TNK-ase – Tenecteplase candidate and systolic BP is systolic > 185 mm Hg or diastolic >110mm Hg, may repeat labetalol dose one time (maximum dose is 300mg in a 24 hour period)
  □ If BP is not maintained at or below 185/110 mmHg, do not administer Tenecteplase.
□ Place on oxygen therapy if O2 sat <92% on room air
□ Establish IV access. 2 large bore IVs preferred. Keep one line TKO rate.
□ Emergency Department RN: Complete the National Institutes Stroke Scale (NIHSS); complete after CT if time does not allow. Record Score _____.
□ Complete Fibrinolytic Stroke Checklist at once and report results to ER MD
□ Keep patient NPO
□ Draw Stroke Code Lab Panel: CBC, CHEM12, PT, INR, PTT, Cardiac Enzymes **(Lab Draw should not delay CT Scan)**
□ Complete 12 Lead EGK and report findings to ER MD. **(EKG should not delay CT scan)**
□ Chest X-Ray **(Chest X-Ray should not delay CT scan)**
□ Radiology will notify ED staff when CT is ready and a STAT Head CT will be completed.
□ CT results – The Radiologist will contact the ED MD with CT results. The Radiologist will document the time results were called to the ED MD in the CT report.
□ ER MD may call Neurologist/Neurosurgeon on call, or Tele Medicine answering service for consultation.
□ Is the Patient a candidate for thrombectomy? □ YES □ NO If yes start transfer to accepting facility with neuro-interventional capabilities.
□ Is the Patient a thrombolytic candidate? □ YES □ NO
  - If YES initiate the STROKE Tissue Plasminogen Activator (t-PA) Protocol
  - If NO continue to treat the BP, and consider other alternative treatment for excluded patients.
  - If the patient's therapeutic window is >3 hours and less then than 6 hours and CT is negative, the ERMD will discuss with family and neurologist.

Physicians Signature _____ Date _____ Time _____

Nurse Signature _____ Date _____ Time _____

NIH STROKE SCALE

Administer stroke scale items in the order listed. Record performance in each category after each subscale exam. Do not go back and change scores. Follow directions provided for each exam technique. Scores should reflect what the patient does, not what the clinician thinks the patient can do. The clinician should record answers while administering the exam and work quickly. Except where indicated, the patient should not be coached (i.e., repeated requests to patient to make a special effort).

INTERVAL: [ ] BASELINE [ ] 2 HOUR POST TREATMENT [ ] 24 HOURS POST ONSET OF SYMPTOMS ± 20 MIN

INSTRUCTIONS	SCALE DEFINITION	SCORE
1a. Level of Consciousness: The investigator must choose a response, even if a full evaluation is prevented by such obstacles as an endotracheal tube, language barrier, orotracheal trauma/bandages. A 3 is scored only if the patient makes no movement (other than reflexive posturing) in response to noxious stimulation.	0 = **Alert;** keenly responsive. 1 = **No alert;** but arousable by minor stimulation to obey, answer, or respond. 2 = **Not alert;** requires repeated stimulation to attend, or is obtunded and requires strong or painful stimulation to make movements (not stereotyped). 3 = Responds only with reflex motor or autonomic effects or totally unresponsive, flaccid, areflexic.	_____
1b. LOC Questions: The patient is asked the month and his/her age. The answer must be correct – there is no partial credit for being close. Aphasic and stuporous patients who do not comprehend the questions will score 2. Patients unable to speak because of endotracheal intubation, orotracheal trauma, severe dysarthria from any cause, language barrier or any other problem not secondary to aphasia are given a 1. It is important that only the initial answer be graded and that the examiner not "help" the patient with verbal or non-verbal cues.	0 = **Answers both** questions correctly 1 = **Answers one** question correctly. 2 = **Answers neither** questions correctly.	_____
1c. LOC Commands: The patients is asked to open and close the eyes and then to grip and release the non-paretic hand. Substitute another one step command if the hands cannot be used. Credit is given if an unequivocal attempt is made but not completed due to weakness. If the patient does not respond to command, the task should be demonstrated to them (pantomime) and score the result (i.e., follows none, one or two commands). Patients with trauma, amputation, or other physical impediments should be given suitable one-step commands. Only the first attempt is scored.	0 = **Performs both** tasks correctly 1 = **Performs one** task correctly 2 = **Performs neither** task correctly	_____
2. Best Gaze: Only horizontal eye movement will be tested. Voluntary or reflexive (oculocephalic) eye movements will be scored but caloric testing is not done. If the patient has a conjugate deviation of the eyes that can be overcome by voluntary or reflexive activity, the score will be 1. If a patient has an isolated peripheral nerve paresis (CN III, IV or VI) score a 1. Gaze is testable in all aphasic patients. Patients with ocular trauma, bandages, pre-existing blindness or other disorder of visual acuity or fields should be tested with reflexive movements and a choice made by the investigator. Establishing eye contact and then moving about the patient from side to side will occasionally clarify the presence of partial gaze palsy.	0 = **Normal** 1 = **Partial gaze palsy**; gaze is abnormal in one or both eyes, but forced deviation or total gaze paresis is not present. 2 = **Forced deviation**, or total gaze paresis not overcome by the oculocephalic maneuver.	_____

INSTRUCTIONS	SCALE DEFINITION	SCORE
3. Visual: Visual fields (upper and lower quadrants) are tested by confrontation, using finger counting or visual threat as appropriate. Patient must be encouraged but if they look at the side of the moving fingers appropriate, this can be scored as normal. If there is unilateral blindness or enucleation, visual fields in the remaining eye are scored. Score 1 only if a clear-cut asymmetry, including quadrantanopia is found. If patient is blind from any cause score 3. Double simultaneous stimulation is performed at this point. If there is extinction patient receives a 1 and the results are used to answer question 11.	0 = **No visual loss** 1 = **Partial herniaponia** 2 = **Complete herniaponia** 3 = **Bilateral hernianopia** (blind including Cortical blindness)	_____
4. Facial Palsy: Ask, or use pantomime to encourage the patient to show teeth or raise eyebrows and close eyes. Score symmetry of grimace in response to noxious stimuli in the poorly responsive or non-comprehending patient. If facial trauma/bandages, orotracheal tube, tape or other physical barrier obscures the face, these should be removed to the extent possible.	0 = Normal symmetrical movement. 1 = Minor paralysis (flattened nasolabial fold, asymmetry on smiling) 2 = Partial paralysis (total or near total paralysis of lower face) 3 = Complete paralysis of one or both sides (absence of facial movement in the upper and lower face)	_____
5 Motor Arm: The limb is placed in the appropriate position: extend the arms (palms down) 90 degrees (if sitting) or 45 degrees (if supine). Drift is scored if the arm falls before 10 seconds. The aphasic patient is encouraged using urgency in the voice and pantomime, but not noxious stimulation. Each limb is tested in turn beginning with the non-paretic arm. Only in the case of amputation or joint fusion at the shoulder, the examiner should record the score as untestable (UN), and clearly write the explanation for this choice.	0 = **No drift**; limb holds 90 (or 45) degrees for full 10 seconds. 1 = **Drift**; Limb holds 90 (or 45) degrees, but drifts down before full 10 second; does not hit bed or other support. 2 = **Some effort against gravity**; limb cannot get to or maintain (if cued) 90 (or 45) degrees, drifts down to bed, but has some effort against gravity. 3 = **No effort against gravity**; limb falls. 4 = **No movement**. UN = Amputation, joint fusion explain: _____ 5a. Left Arm 5b. Right Arm	_____ _____
6. Motor Leg: The limb is placed in the appropriate position: hold the leg at 30 degrees (always tested supine). Drift is scored if the leg falls before 5 seconds. The aphasic patient is encouraged using urgency in the voice and pantomime, but not noxious stimulation. Each limb is tested in turn, beginning with the non-paretic leg. Only in the case of amputation or joint fusion at the hip, the examiner should record the score as untestable (UN), and clearly write the explanation for this choice.	0 = **No drifts**; leg holds 30 degrees position for full 5 seconds. 1 = **Drift**; leg falls by the end of the 5 seconds period but does not hit bed. 2 = **Some effort against gravity**; leg falls to bed by 5 seconds, but has some effort against gravity. 3 = **No effort against gravity;** leg falls to bed immediately. 4 = No movement. UN = **Amputation**, joint fusion explain: _____ 6a. Left Leg 6b. Right Leg	_____ _____

INSTRUCTIONS	SCALE DEFINITION	SCORE
7. Limb Ataxia: This item is aimed at finding evidence of a unilateral cerebella lesion. Test with eyes open. In case of visual defect, insure testing is done in intact visual field. The finger-nose-finger and heel-shin tests are performed on both sides, and ataxia is scored only if present out of proportion to weakness. Ataxia is absent in the patient who cannot understand or is paralyzed. Only in the case of amputation or joint fusion, the examiner should record the score untestable (UN), and clearly write the explanation for this choice. In the case of blindness, test by having the patient touch nose from extended arm position.	0 = **Absent** 1 = **Present in one limb** 2 = **Present in two limbs** UN = amputation or joint fusion, explain: _____	
8. Sensory: sensation or grimace to pin prick when tested, or withdrawal from noxious stimulus in the obtunded or aphasic patient, Only sensory loss attributed to stroke is scored as abnormal and the examiner should test as many body areas {arms (not hands), legs, trunk, face} as needed to accurately check for hernisensory loss. A score or 2, "severe or total" should only be given when a severe or total loss of sensation can be clearly demonstrated. Stuporous and aphasic patients will therefore probably score 1 or 0. The patient with brain stem stroke who has bilateral loss of sensation is scored 2. If the patient does not respond and is quadriplegic score 2. Patients in coma (item 1a=3) are arbitrarily given a 2 on this item.	0 = **Normal**; no sensory loss. 1 = **Mild to moderate sensory loss**; patient feels pin prick is less sharp or is dull on the affected side; or there is a loss of superficial pain with pinprick but patient is aware of being touched. 2 = **Severe to total sensory loss;** patient is not aware of being touched in the face, arm, and leg.	
9. Best Language: A great deal of information about comprehension will be obtained during the preceding sections of the examination. The patient is asked to describe what is happening in the attached picture, to name the items in the attached naming sheet, and to read from the attached list of sentences. Comprehension is judged from responses here as well as to all of the commands in the preceding general neurological exam. If visual loss interferes with the tests ask the patient to identify objects placed in the hand, repeat, and produce speech. The intubated patient should be asked to write. The patient in coma (question 1a=3) will arbitrarily score 3 on this item. The examiner must choose a score in the patient with stupor or limited cooperation but a score of 3 should be used only if the patient is mute and follows no one step commands.	0 = **No aphasia;** normal 1 = **Mild to moderate aphasia;** some obvious loss of fluency or facility of comprehension, without significant limitation on ideas expressed or form of expression. Reduction of speech and/or comprehension, however, makes conversation about provided material difficult or impossible. For example conversation about provided materials examiner can identify picture or naming card from patient's response. 2 = **Severe aphasia;** all communication is through fragmentary expression; great need for inference, questioning, and guessing by the listener. Range of information that can be exchanged is limited; listener carries burden of communication. Examiner cannot identify materials provided from patient response. 3 = **Mute, global aphasia;** no usable speech or auditory comprehension.	
10. Dysarthria: If patient is thought to be normal, an adequate sample of speech must be obtained by asking patient to read or repeat words from the attached list. If the patient has severe aphasia, the clarity of articulation of spontaneous speech can be rated. Only if the patient is intubated or has other physical barriers to producing speech, the examiner should record the score as untestable (UN) and clearly write an explanation for this choice. Do not tell the patient why he/she is being tested.	0 = **Normal** 1 = **Mild to moderate;** patient slurs at least some words and, at worst, can be understood with some difficulty. 2 = **Severe;** patient's speech is so slurred as to be unintelligible in the absence of or out of proportion to any dysphasia, or is mute/ anarthric. UN= Intubated or other physical barrier, explain: _____	

***DO NOT ADD 9'S INTO TOTAL SCORE**

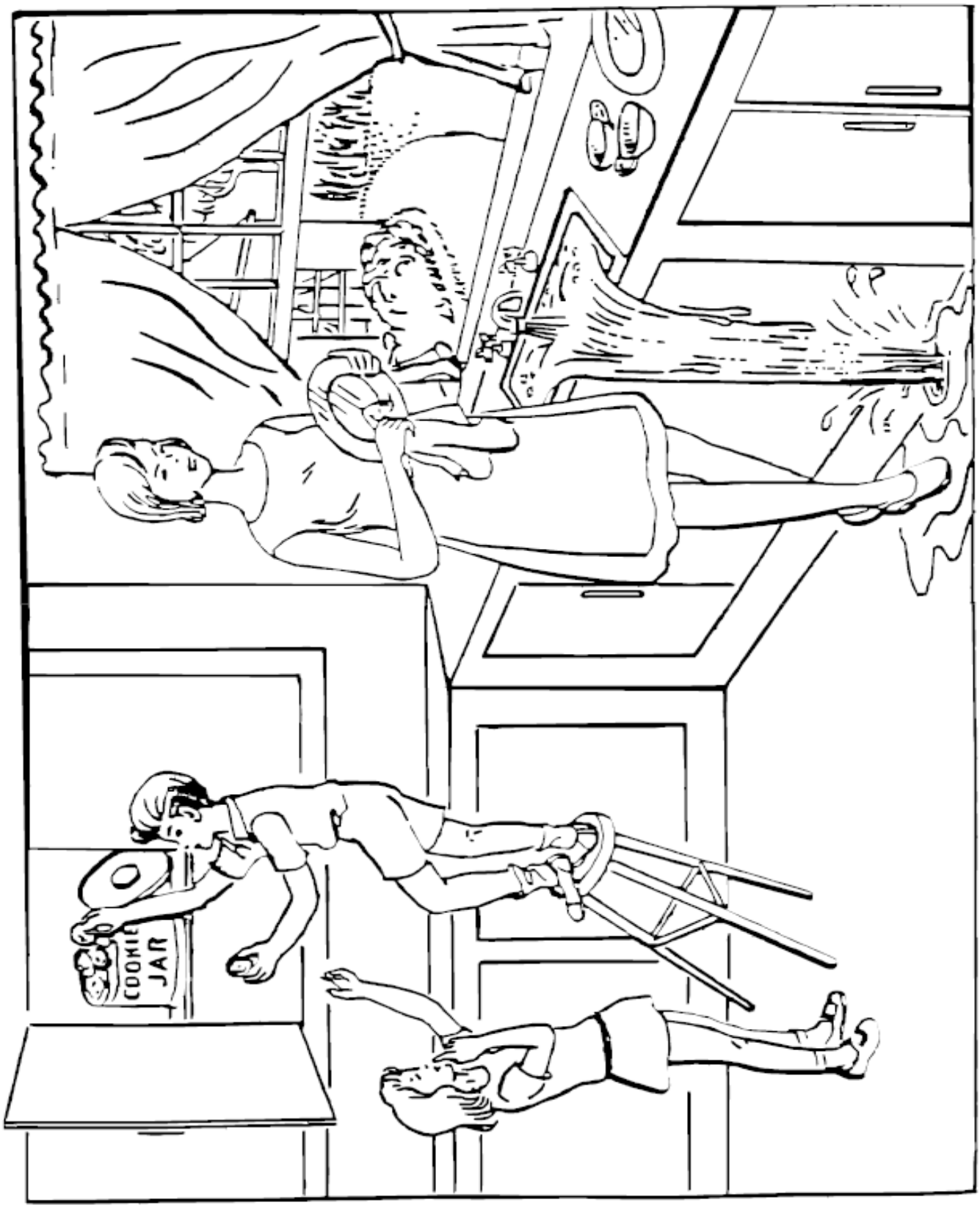
INSTRUCTIONS	SCALE DEFINITION	SCORE
11. Extinction and Inattention (formerly Neglect); Sufficient information to identify neglect may be obtained during the prior testing. If the patient has a severe visual loss preventing visual double simultaneous stimulation, and the cutaneous stimuli are normal, the score is normal. If the patient has aphasia but does appear to attend to both sides, the score is normal. The presence of visual spatial neglect or anosagnosia may also be taken as evidence of abnormality, Since the abnormality is scored only if present, the item is never untestable.	0 = **No abnormality**. 1 = **Visual, tactile, auditory, spatial, or personal inattention or extinction** to bilateral simultaneous stimulation in one of the sensory modalities. 2 = **Profound hemi-inattention or extinction to more than one modality;** does not recognize own hand or orients to only one side of space.	

TOTAL NIH STROKE SCALE SCORE_____

Registered Nurse Date Time

Physician Signature Date Time

PIONEERS MEMORIAL HealthcareDistrict


COOKIE
JAR

You know how.

Down to earth.

I got home from work.

Near the table in the dining room.

They heard him speak on the radio last night.

MAMA

TIP – TOP

FIFTY – FIFTY

THANKS

HUCKLEBERRY

BASEBALL PLAYER

INCLUSION/EXCLUSION CRITERIA CHECK-OFF LIST
FibrinolyticTherapy for Ischemic Stroke (tPA)

IMPORTANT: *All of the (YES) boxes in inclusion criteria section and all the (NO) boxes in exclusion criteria(absolute) section must be checked off before fibrinolytic therapy may be given.*

INCLUSION CRITERIA:

YES	NO	
□	□	Diagnosis of ischemic stroke causing measurable neurological deficit
□	□	Onset of symptoms < 3 hours before beginning treatment (Patient is excluded if awakened from sleep with signs and symptoms)
□	□	Age ≥18 years

EXCLUSION CRITERIA (ABSOLUTE):

YES	NO	
□	□	CT diagnostic for hemorrhage
□	□	Significant head trauma or prior stroke within prior 3 months
□	□	History or symptoms suggestive of intracranial or subarachnoid hemorrhage.
□	□	Intracranial neoplasm
□	□	Intracranial or intraspinal surgery within the last 3 months
□	□	Uncontrolled elevated blood pressure (systolic > 185 mm Hg or diastolic > 110 mm Hg) on repeated measurements or requiring aggressive treatment.
□	□	Active Internal bleeding
□	□	Acute bleeding Diathesis including but not limited to:
□	□	Platelet count < 100,000/mm3
□	□	Heparin received within 48 hours, resulting in abnormally elevated aPTT greater than the upper limit of normal Low molecular weight heparin (LMWH) treatment dose within 24 hours
□	□	Current use of anticoagulant with INR > 1.7 or PT > 15 seconds
□	□	Current use of direct thrombin inhibitors or direct factor Xa inhibitors with elevated sensitive laboratory tests (such as aPTT, INR, platelet count and ECT;TT; or appropriate factor Xa activity assays)
□	□	CT demonstrates multilobar infarction (hypodensity > 1.3 cerebral hemisphere)

EXCLUSION CRITERIA (RELATIVE):

Recent experience suggests that under some circumstances with careful consideration and weighting of risk to benefit – patients may receive fibrinolytic therapy despite 1 or more relative contraindications. Consider risk to benefit of IV t-PA administration carefully if any of these relative contraindications are present:

□	□	Minor or rapidly improving stroke symptoms (clearing spontaneously)
□	□	Pregnancy
□	□	Seizure at onset with postictal residual neurological impairments
□	□	Major surgery or serious trauma within previous 14 days
□	□	Recent gastrointestinal or urinary tract hemorrhage (within 21 days)
□	□	Giant unruptured and unsecured intracranial aneurysm
□	□	Untreated Intracranial vascular malformation

ADDITIONAL INCLUSION AND EXCLUSION CHARACTERISTICS OF PATIENTS WHO COULD BE TREATED WITH IV tPA WITHIN 3 TO 4.5 HOURS FROM SYMPTOM ONSET.

INCLUSION CRITERIA:

□	□	Diagnosis of ischemic stroke causing measurable neurological deficit
□	□	Onset of symptoms within 3 to 4.5 hours before beginning treatment

Physicians Signature _____ Date _____ Time _____

Nurse Signature _____ Date _____ Time _____

PIONEERS MEMORIAL HealthcareDistrict

Consent for treatment of Acute Ischemic Stroke with Tissue *P*lasminogen *A*ctivator

What is a stroke?
A stroke is a problem with the tubes or vessels bringing blood to the brain, such that a part of the brain is injured. There are two main types of stroke, those associated with rupture of the blood vessels (hemorrhagic strokes) and those associated with the blockage of blood vessels (ischemic strokes).

What happens in an acute ischemic stroke?
In an acute ischemic stroke, the blood flow to a part of the brain interrupted because of sudden blockage of a blood vessel. The blockage is usually due to a blood clot and starves the brain of needed oxygen and nutrients. The center of the starved area may die quickly, and the surrounding area may die slowly over hours.

What is tissue Plasminogen activator or tPA?
tPA is a medication that can dissolve blood clots. Because of its strong blood thinning action, bleeding into or around the brain can result as a side effect of its use. Bleeding can also occur in other parts of the body.

How can tPA help someone with an acute ischemic stroke?
tPA can sometimes dissolve the clot that is blocking the blood vessel and causing the ischemic stroke. If it does so, the blocked blood vessel reopens, allowing the previously starved brain to receive blood flow again with oxygen and nutrients. If the clot is dissolved soon enough, some or all of the brain may be rescued from the threatened injury. Rescuing brain that was starved may decrease the amount of disability that results from the ischemic stroke. A research study demonstrated that, overall, patients given tPA within 3 hours of ischemic stroke onset had better outcomes 3 months later than patients not given any treatment.

Do all stroke patients get this treatment?
No. Specific criteria are used to identify those patients most likely to benefit and to avoid serious side effects. If a stroke patient does not fulfill all of these criteria, the risks of therapy are probably higher and the chance of benefiting probably lowers - exactly how much is unknown. (See below)

What are the potential benefits?
The potential benefits are all related to an increased chance of having a good outcome, namely little or no disability remaining after recovery from the stroke. If stroke patients meet all the below criteria, their chances of having a good outcome increase from 29% without tPA to 41% with tPA. Thus, even though the chances for a good outcome are improved, over half of the stroke patients who are given tPA will still have disability from their stroke. A good outcome is not guaranteed.

What are the potential risks?
The major risk of tPA therapy in stroke patients is that they can bleed into the injured area of the brain, causing a worsening of their condition and possibly death. The chance of serious bleeding into a stroke area is less than 0.6% in stroke patients not treated with tPA **versus** 6.4% in those who are treated with tPA. In other words, tPA increases bleeding in the brain by about 10%. Despite the increased risk of hemorrhage caused by tPA, patients who are appropriately selected, are more likely to benefit as a result of using tPA.

What tests will be done?
No testing beyond what would be routine in a patient with stroke will need to be done. These standard tests include blood work and imaging, including a CT scan of the head to make sure no hemorrhage is present before proceeding with the tPA therapy. A repeat CT scan and further blood testing may be performed depending on how the patient responds to treatment.

Consent: Check One Below

_____I give consent for use of tPA:

I have read and understand the above. My physician has offered to answer all inquiries concerning the proposed treatment with tPA. I understand that I am free to withhold or withdraw consent to the proposed treatment with tPA at any time before the drug is given. I understand that the results of tPA treatment for stroke cannot be guaranteed.

Signature of person giving consent | Date signed | Time | Relationship to patient (if applicable)

Witness | Date signed | Time

_____I DO NOT give consent for tPA:

I have read and understand the above. My physician has offered to answer all inquiries concerning the proposed treatment with tPA. I understand that I am free to reconsider and give consent for tPA if I remain in the nationally accepted time frame of 3 hours.

Signature of person NOT giving consent | Date signed | Time | Relationship to patient (if applicable)

Witness | Date signed | Time

Signatures as Pertains:

_____ ***Date:*** _____ ***Time:*** _____

ED Physician/Neurologist

_____ ***Date:*** _____ ***Time:*** _____

Emergency Department RN

Consentimiento para el tratamiento del ataque agudo con Tissue *P*lasminogen *A*ctivator

¿Qué es un ataque cerebral?
Un ataque cerebrovascular ocurre cuando se bloquea el flujo de sangre en las arterias que nutren el cerebro, o cuando ocurre un sangrado en el cerebro mismo o en las membranas que lo rodean. Existen dos tipos de ataque cerebral, hemorrágico (sangrado) o isquémico (falta de oxígeno).

¿Qué sucede en un ataque agudo cerebral isquémico?
En un ataque cerebral isquémico, el flujo cerebral a cierta parte del cerebro es interrumpido debido a un bloqueo de los vasos sanguíneos. El bloqueo normalmente es debido a un coagulo sanguíneo, impidiendo que la sangre llegue a esa parte del cerebro. Esa parte del cerebro que le falta sangre puede morir rápidamente, y las áreas que lo rodean pueden morir lentamente.
¿Qué es Activador Tisular del Plasminógeno (tPA)?
tPA es un medicamento que disuelve coágulos. Debido a que adelgaza fuertemente la sangre, sangrado dentro o alrededor del cerebro puede resultar como un efecto secundario. El sangrado puede también ocurrir en otras partes del cuerpo.

¿Cómo puede el tPA ayudar a alguien con ataque cerebral isquémico?
tPA puede en ocasiones disolver los coágulos que están bloqueando el vaso sanguíneo causando la isquemia en el cerebro, si esto sucede, los vasos sanguíneos ocluidos son abiertos, permitiendo al cerebro recibir flujo sanguínea al área que estaba sufriendo. Si el coagulo es disuelto en un tiempo apropiado, parte o todo el cerebro puede ser rescatado. Al rescatar el cerebro de este problema puede disminuir el grado de incapacidad que resulta de la isquemia cerebral. Un estudio de investigación demostró que, en su mayoría, pacientes que recibieron tPA en las primeras 3 horas del ataque cerebral tuvieron mejores resultados 3 meses después que personas que no recibieron el tratamiento.

¿Reciben este tratamiento todos los pacientes con ataque cerebral isquémico?
No. Un criterio específico es usado para identificar a pacientes a los cuales dará el mayor beneficio y así poder evitar efectos secundarios serios. Si un paciente con ataque cerebral no reúne todos los criterios, el riesgo para terapia son probablemente altos y la oportunidad de beneficio son probablemente bajos, exactamente cuánto, no se sabe.

¿Cuáles son los probables beneficios?
Los beneficios potenciales están todos relacionados en tener la oportunidad de un mejor pronóstico, poder tener mínimo o nada de discapacidad después de un ataque cerebral. Si el paciente reúne todos los criterios, la oportunidad de un mejor resultado incrementan de 29% sin tPA a 41% con tPA. A pesar que la oportunidad incrementa, la mitad de los pacientes que reciben tPA aun tendrán discapacidad del ataque cerebral. Un buen resultado no es garantizado.

¿Cuáles son los riesgos potenciales?
El mayor riesgo de administrar tPA en pacientes con ataque cerebral es que pueden sangrar en el área dañada del cerebro, causando un deterioro de la persona y posiblemente la muerte. La probabilidad de un sangrado serio es menos del 0.6% en pacientes que no fueron tratados con tPA, en comparación con pacientes que fueron tratados con tPA la probabilidad aumento al 6.4%. En otras palabras, tPA incrementa el riesgo de sangrado hasta el 10%. A pesar del incremento de riesgo, pacientes que son seleccionados apropiadamente, son más probablemente beneficiados por el uso de Tpa.
¿Qué estudios se llevaran a cabo?
Ningún examen aparte de los de rutina en un paciente de con ataque cerebral se llevaran a cabo. Estos exámenes incluyen muestras sanguíneas y de radiología, incluyendo una tomografía del cerebro para asegurar que no hay un sangrado antes de la administración de la terapia con tPA. Puede que sea necesario repetir la tomografía y algún otro examen sanguíneo, dependiendo como reaccione el paciente al tratamiento.

Consentimiento: Marque una de las dos opciones.

_____Yo doy consentimiento para usar tPA:

Yo he leído y entendido la hoja anterior. Mi doctor ha ofrecido responder cualquier duda relacionada con el tratamiento de tPA. Entiendo que tengo la libertad de cambiar de opinión acerca de mi consentimiento al propuesto tratamiento con tPA en cualquier momento antes que el medicamento sea administrado. Entendiendo que los resultados al tratamiento con tPA no pueden ser garantizados.

Firma de la persona dando consentimiento	Fecha	Hora	Relación con el paciente (si es aplicable)

Testigo	Fecha	Hora

_____Yo no doy consentimiento para usar tPA:

Yo he leído y entendido la hoja anterior. Mi doctor ha ofrecido responder cualquier duda relacionada con el tratamiento de tPA. Entiendo que tengo la libertad de reconsiderar y dar consentimiento para el tratamiento con tPA si permanezco dentro del marco nacional aceptable de 3 horas.

Firma de la persona dando consentimiento	Fecha	Hora	Relación con el paciente (si es aplicable)

Testigo	Fecha	Hora

Firmas:

_____ ***Date:*** _____ ***Time:*** _____
ED Physician/Neurologist

_____ ***Date:*** _____ ***Time:*** _____
Emergency Department RN

Pioneers Memorial Healthcare District

Title: **Communication with the Patient/Family After a Harm Event**	Policy No. ADM-00134
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Current Author: Merlina Esparza / Carol Bojorquez	Effective: 1/25/2005
Latest Review/Revision Date: 5/2023	Manual: Administration / Risk

Collaborating Departments: Nursing Admin., CEO, Medical Staff, Chief of Staff, Compliance		Keywords: Sentinel Event, Adverse Event, Adverse Outcome, Medical Error, Disclosure		
Approval Route: List all required approval				
MARCC 5/9/2023	PSQC 6/2023	Other:		
Clinical Service All medical staff service committees 6/2023, 7/2023, 8/2023		MSQC 9/2023	MEC 9/2023	BOD 10/2023

Note: *If any of the sections of your final layout are not needed do not delete them, write "not applicable".*

1.0 Purpose:

1.1 The purpose of this policy is to provide structure and guidelines for communication with patient and families after harm, unanticipated or adverse medical outcomes. The goal is to provide a coordinated process for prompting timely, transparent, empathetic communication with patients and their families. It is recognized that communicating with patients and families is a process rather than one conversation in time, with additional information being shared as it is learned and understood.

2.0 Scope: District wide

3.0 Policy:

3.1 It is the policy of Pioneers Memorial Healthcare District to ensure all patients and /or their family members receive timely, empathic communication from the patients' healthcare team or other designated organizational representatives about all relevant aspects of their care including information about patient related harm events and /or unanticipated or adverse medical outcomes of their diagnostic test, medical treatment and surgical intervention.

3.2 When harm is related to care or treatment, the hospital personnel and medical staff will strive to follow the procedure below in communicating to patients and families. Patient and families should be fully informed about unanticipated or adverse medical outcomes, which include events related to medical errors, as well as other complications of care or patient care issues which resulted in a negative and/or adverse patient and family outcome or experience.

3.3 Adverse events, medical errors and complications can cause emotional stress and fear among providers, patients and families. This fear may prohibit communication and transparency which may cause mistrust; all of which may interfere with communications. Therefore, it is essential that the patient/family receive consistent, coherent and accurate information about the event, complication or issues with patient care process in a timely fashion.

3.4 It is the responsibility of the care providers to assure communication of the harm event with the patient/family occurs timely, coordinated, consistent and accurate manner. Every effort will be made to begin the communication process with the patient/family within **sixty minutes** of the harm event.

3.5 At the time of the initial communication about a harm event, the patient/family should be

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informed about when they can expect follow-up communication about the event. This is not a disclosure communication but acknowledging the harm event and offering an apology.

4.0 Definitions:

4.1 Harm Event – Any measurable amount of physical, psychological, or financial injury.

4.2 Condition H – A service within an organization that can be summoned 24/7 to provide advice, coaching, or direct communication for a patient or family who is upset or dissatisfied that may not be related to inappropriate care. (See Condition H/ Condition Help policy CLN-00017)

4.3 Communication – The process of conveying information verbally or in writing to a patient/family member or other designee after a healthcare related event.

4.3.1 Empathetic – one that expresses a concern and curiosity about the impact of a harm event on a patient and their loved ones.

4.3.2 Apology – an empathic communication that includes the expression of sorrow to the patient or family for inappropriate care that caused harm.

4.3.3 Disclosure of Medical Error – Telling the patient or family the facts of what happened and the way in which mistakes or errors caused the healthcare related harm. (Disclosure is not an isolated conversation; rather it is a series of conversations).

4.4 Empathy – the ability to share in another's emotions, thoughts or feelings

4.5 Leadership – members of the Board of Directors, Hospital Administration and Medical Staff, and Clinical Directors.

4.6 Timely – Initial communication to the patient/family is to occur within sixty minutes of actual knowledge of the harm event.

5.0 Procedure:

5.1 Communication of patient harm events to patients/ families

5.1.1 Communication huddle prior to speaking with the patient/family. The initial communication huddle should include the following:

5.1.1.1 Identification of who shall participate in the pre-communication discussion and when and where the communication discussion should occur

5.1.1.1.1 Who should participate in the discussion with the family; who has the most trusted relationship with the family and can they be present for the conversation?

5.1.2 Review the message which shall take place during the planned communication and, if possible, rehearse with participants at least once prior to patient/family meeting.

5.1.2.1 What emotion should be anticipated and how will you validate and respond to them?

5.1.3 Identify clinical support staff which may be needed, social services, interpreter services, chaplain, nursing or other as needed.

5.1.4 Determine family's concrete needs, e.g. cultural services, food and parking

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assistance, family accommodations, travel, other.

5.1.5 Review the goals of this specific interaction.

5.1.6 When you should reach out further with the patient/family (set a date/time) and who the contact person is for the patient/family.

5.1.7 How you will open the conversation and what you will say.

5.1.8 What information is known and can be shared and discussed.

5.1.9 What questions can you anticipate from the patient/family.

5.1.9.1 What emotions do you expect and how will you identify and validate them.

5.1.9.2 Who takes the lead in responding to the patient/family as more information becomes available?

5.1.10 How do you respond to and support your caregiver.

5.1.11 Notify attending physician of communication plans if he/she is not the individual carrying out the initial communication.

5.1.12 An interpreter shall be used if the preferred language is other than English or the patient and family do not speak or understand English. (Refer to ADM-00001)

5.1.13 The cultural aspects of the patient/family are to be considered as well

5.2 The initial communication shall occur in accordance with the following guidelines:

5.2.1 All efforts will be taken to initiate communication with the patient and family within **sixty minutes** of actual knowledge of the harm event. The initial patient/family communication contact around harm events checklist will be utilized to guide to ensure all aspects of the communication process are considered. (See Attachment A)

5.2.2 The harm event will be acknowledged to the patient/family. This is not admission of guilt; rather it acknowledges that a harm event occurred while the patient was under the organizations care.

5.2.3 First priority is to take care of the patient and meet their healthcare, social and emotional needs.

5.2.4 Patients and families should be reassured that the harm event will be investigated with the goal of learning what contributed to the event so that the organization can take steps to prevent recurrence. Patient and family should also be reassured that they will be given more information as it becomes available.

5.2.5 The initial communication should include the nature of the harm event, what is known about the potential impact of the event on the patients' health and what is being done to mitigate any effects on the patients' health.

5.2.6 Avoid speculation and conjecture. Communicate facts known at the time. If the facts are not known then state that at this time we do not know but will look into and get back to them within a specific and agreed upon timeframe of the next communication.

5.2.7 Avoid expressions of blame or fault.

5.2.8 The communication should not include information on errors or so called "near-misses" which at the time of the event did not appear to have affected the patients' medical condition or outcome.

5.2.9 Ask the patient and family if there are any immediate needs that have not been

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addressed. Offer support services such as social worker, chaplain, patient advocate, interpreter etc. as needed.

5.2.10 Patients' families should be reassured the hospital clinical staff and physicians will continue to provide ongoing care including the management of the harm event.

5.2.11 It is always appropriate to express empathic regret for an event or a medical error and apologize to the patient and or family affected by the event.

5.3 How to communicate and empathize:

5.3.1 Be honest and truthful while acknowledging the event.

5.3.2 Explain what happened slowly and show empathy such as "this must be very difficult." "I can't even imagine how difficult this must be right now for your family." "Is there anything you need right now?"

5.3.3 Apologize to express empathy.

5.3.4 Avoid use of technical language.

5.3.5 Pause and allow ample time for questions to ensure the patient/family understand the communication.

5.3.6 Inform the patient/family that an investigation and analysis will be completed to understand what occurred and that results will be shared.

5.3.7 Designate an organizational contact person the patient/family who will reach out to the patient/family within an agreed upon time period and that the patient/family can contact with questions.

5.3.8 Ensure the patient/family has written contact information of the organizational contact person such as a business card.

5.4 Activation of the communication team once a harm event is identified;

5.4.1 Activation of the communication team, at a minimum, should be considered for:

5.4.1.1 Events that full under California Health and Safety Code Section 1279.1 (Reportable Adverse Events to the California Department of Public Health)

5.4.1.2 Any instance of serious bodily harm or death, or

5.4.1.3 Any instance where a patient or family is extremely upset or angry regarding the care received or an adverse event.

5.4.2 Once a harm event is identified the employee will notify the House Supervisor at ext. 5500 for activation of the communication team.

5.4.3 The communication team member on call will guide the clinician in the initial **sixty-minute** communication with the patient/family.

5.4.4 If a communication team member is present on campus they will come to the area of the organization where the clinicians are present and guide the clinicians in the conversation.

5.4.5 If communication team members are not physically on campus, the on-call communication team member will guide the clinicians on the phone in the communication process.

5.5 Who shall communicate the harm event to the patients/families:

5.5.1 It is the responsibility of the attending physician or designee and the organizational leaders to assure communication of the harm event with the

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patient/family occurs in a timely, coordinated, consistent and accurate manner.

5.5.2 Upon knowledge of a harm event the communication team shall be notified and the lead on the team or designee will guide the clinician(s) in communication of the harm event. A communication team member will also be present if possible for the actual provider's communication with the patient.

5.6 Documentation of the conversation:

5.6.1 The communication lead shall document the conversation in the medical record. The record note must be factual only and not state conjecture or opinions but rather the facts of the conversation.

5.6.2 The note shall include the date, time and place of the discussion and the names, titles and relationships of those present. The information provided and the plan of care going forward will be noted. Offers of assistance to the patient/family as well as the patient's/families' response shall be documented. The documentation shall also include any referrals/consults initiated as a result of the harm event.

5.7 Follow up communication:

5.7.1 As more facts become known throughout the continual investigation the contact person will inform the patient/family.

5.7.2 The organizational contact person will ensure the patient family has written contact information such as their business card for further communication and any questions the patient or family may have.

5.7.3 The contact person will arrange specific dates and times for follow-up at regular intervals.

5.8 Debriefing the effectiveness of the communication:

5.8.1 There will be a debriefing of the communication team members after the meeting to discuss what went well and to identify any opportunities for improvement. The results of the debriefing will be communicated to the leadership as well. (See Attachment B)

6.0 References:

6.1 Health and Safety Code 1279.1

6.2 Title 22, California Code of Regulations Section 70737

6.3 Communication and Optimal Resolution (CANDOR) Toolkit. Content last reviewed September 2017. Agency for Healthcare Research and Quality, Rockville, MD. http://www.ahrq.gov/professionals/quality-patient-safety/patient-safety-resources/resources/candor/introduction.html

6.4 The Joint Commission Sentinel events and communication; https://www.jointcommision.org/sentinel_event.aspx

6.5 AHRQ TeamsSTEPPS – Pocket guide.

6.6 Interpreter and Translator Service: Communication with Persons with Limited English Proficiency policy ADM-00001

6.7 Condition H/ Condition Help policy CLN-00017

7.0 Attachment List:

7.1 Attachment A – Initial Communication Checklist

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7.2 Attachment B – Post Communication Debrief Form

8.0 Summary of Revisions:

8.1 Submitted with no changes.

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Initial Patient/Family Communication Contact Around Harm Events Checklist

Purpose: To provide guidance to individuals who are conducting initial and/or follow up communication to patient/families around harm event conversations, including key communication skills to be utilized for the communication process.

Who should use this tool? The communication lead and any staff who will be engaged in conversations surrounding harm events.

How to use this tool: Use Part I of the checklist to prepare for the initial conversation, which should occur within 60 minutes after a potential adverse event is identified. Part II can be used to conduct all follow up communication. Remember to review the key communication skills listed below prior to the initial conversation.

MEDICAL RECORD NUMBER:

Key Communication Skills

Show empathy

- **Allow** the patient to express his/her emotions.
- **Acknowledge** the patient's emotions.
- **Validate** the patient's emotions by saying that their response is understandable.

Be honest

- **Explain** the facts about the adverse event without the patient having to do a lot of probing.
- **Give** direct answers to the patient's questions.
  - If you do not know the answer to the patient's questions, state this directly and explain your plan to learn more and keep them updated.

Utilize effective communication strategies

- **Show** sincere interest in the patient's questions and concerns.
- **Use** good non-verbal expression (e.g., eye contact).
- **Avoid** medical jargon.
- **Check** for the patient's understanding of the information throughout the conversation.
- **Be** yourself!

Complete ✓	Part I – Initial Contact Conversation
	■ Within 60 minutes after the potential adverse event is identified, advise the patient and/or family that an adverse event may have occurred.
	■ Affirm that the first priority is to take care of the patient and meet their health care, social, and emotional needs.
	■ Inform the patient/family that the organization will conduct an event investigation and analysis to understand what happened and will share the results.
	■ Ensure that the family is treated compassionately and provided with the necessary resources to help support their needs.
	■ Designate an organizational contact person the patient and family can reach with questions or concerns. ■ Provide the designee's contact information to patient/family.
	■ Activate the Care for the Caregiver support system to provide support for staff who were involved in the event.
Complete ✓	**Part II – Event Communication**
	Prepare
	■ Review the event with team members, as applicable, so that you are familiar with relevant information.
	■ Discuss the goal for the conversation with other team members that might be involved in the communication. ■ Consider: what emotions should you expect and how will you validate and respond to them?
	■ Strongly consider including one or more team members in the conversation with the patient to help debrief, remember, and document the discussion.
	■ Anticipate the patient's emotional response and consider how you will respond empathically.
	■ Consider whether a surrogate/family member should be present.
	■ Anticipate likely questions from the patient/family.
	■ Rehearse (in person or by phone) the discussion with another communication team member.
	■ Recognize that this is likely to be one in a series of discussions with the patient/family about the event.
	■ Consider your own feelings and seek support, as needed.
	Set the Stage
	■ Turn off/sign out beepers and phones, if possible (or silence, if not possible).
	■ Find a quiet, private area for the conversation.
	■ Sit down.
	■ Describe the purpose of the conversation.
	Listen and Empathize Throughout
	■ Assess the patient's/family's understanding of what happened.
	■ Identify the patient's/family's key concerns.
	■ Actively listen to the patient.

	■ Acknowledge and validate the patient's feelings.

	Explain the Facts
	What happened?
	■ Identify the adverse event early in the conversation.
	■ Explain what happened in a way that is easy to understand.
	■ Explain what is known about why the adverse event occurred; do not speculate.
	■ Tell the patient whether the adverse event was preventable, if known.
	■ Explain your role in the event to the patient/family; avoid blaming others or "the system" for the event.
	What are the potential consequences?
	■ Tell the patient/family what will be done now to care for the patient and how the event may impact his/her long-term health care.
	■ Tell the patient/family what the organization is committed to doing to mitigate the impact on the patient's long-term health.
	Apologize
	■ Say you are sorry for the adverse event in a sincere manner early in the conversation.
	If the Event Was Preventable (Due to Error)
	■ Tell the patient/family what was learned and based on what is known, what should have happened.
	■ Tell the patient/family what will be done differently to prevent a similar event from happening to another patient, or that a plan will be developed to this effect.
	Close the Discussion
	■ Discuss next steps and plan for a follow up conversation.
	■ Ask if there are any final questions and provide responses; if unable to answer, promise to follow up with the answers.
	After the Conversation
	■ Debrief the conversation with colleagues who were present. Review key elements of discussion and establish consensus about what was said and next steps. Discuss what went well and what could be done going forward to enhance communication.
	■ Document the conversation in the medical record, including only the facts of the conversation and follow up plans. If you are not certain what to document, contact the risk manager.
	■ Consider ways to involve patients in post-event learning.

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Post Communication Debrief Form

*Each Communication Team Member is to complete a debrief form and submit to the Communication Team Lead for review and follow-up.

PLEASE WRITE IN YOUR RESPONSE TO THE QUESTIONS BELOW

What were the goals of this conversation?

Did the team feel that the goals were met?

Was the communication clear and did the patient/family express an understanding of what was being communicated?

To the extent known, were all patient/family members' questions addressed (or answered – although they may not have all the answers)?

What emotions were identified and named during the conversation?

Was there an expression of sincere empathy?

Were roles and responsibilities of the team members understood by the patient/family?

How were the patient/family emotions identified and managed throughout the conversation?

Were the best/right team members present for the interaction from the perspective of the patient/family? If not, who else would have been a beneficial participant? (What role?) Were there any persons absent whom the family indicated that they would have wanted to be present?

Were resources made available to the patient/family such as social services or spiritual care or financial?

Was the plan for follow-up clearly communicated to the patient/family and did the patient/family understand it?

Does the patient/family have the name/contact information for the person to reach out to with questions? Who is that and what is their role?

What went well during the communication?

What was the most uncomfortable part of the conversation? How was that handled?

What would you suggest be done differently next time?

What do you know now that you wished you had known prior to entering into the conversation?

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Title: **COVID 19 Vaccination Program**	Policy No. HRD-01396
	Page 1 of 2
Current Author: Lizbette Cordova, MSN, RN PHN	Effective: Upon Approval
Latest Review/Revision Date: Created 06/2023	Manual: Human Resources-Employee Health

Collaborating Departments: HR, Infection Control		Keywords: Vaccine, COVID, Testing	
Approval Route: List all required approval			
MARCC 9/19/2023	PSQC	Other: Safety Committee 10/2023	
Clinical Service _____		MSQC 10/2023	MEC 10/2023	BOD 11/2023

Note: *If any of the sections of your final layout are not needed do not delete them, write "not applicable".*

1.0 Purpose:

1.1 To minimize the transmission of COVID-19 between healthcare workers and patients by encouraging COVID-19 vaccination, including booster dose.

2.0 Scope:

2.1 This is a district-wide policy

3.0 Policy:

3.1 Vaccination Recommendations

3.1.1 COVID vaccines are offered at no cost to PMHD employees.

3.1.2 Newly hired individuals will be required to provide proof of vaccination, including booster (if eligible), **or** decline COVID 19 vaccination during new hire process

4.0 Definitions:

4.1 Fully vaccinated means it has been 2 weeks or more since an individual has completed a primary vaccination series for COVID-19

4.2 Primary vaccination series for COVID-19 means the administration of a single-dose vaccine, or the administration of all required doses of a multi-dose vaccine.

4.3 Acceptable vaccine means administration of one of the following:

4.3.1 Pfizer (Comarnity)

4.3.2 Jenssen (Johnson & Johnson)

4.3.3 Moderna

4.3.4 Novavax

4.3.5 A vaccine listed by the World Health Organization (WHO) for emergency use that is not approved or authorized by the FDA, or a vaccine administered in a clinical trial.

4.4 Booster dose recommendation

4.4.1 Moderna & Pfizer: Booster dose at least 2 months after 2nd dose

4.4.2 Johnson & Johnson (Janssen): Booster dose at least 2 months after 1st dose

4.4.3 Novavax: Booster dose at least 2 months after 2nd dose

4.4.4 WHO approved vaccine: Single booster dose of Pfizer vaccine 2 months after getting all recommended doses

5.0 Procedure:

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Current Author: Lizbette Cordova, MSN, RN PHN	Effective: Upon Approval
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5.1 Evidence of Vaccination
- 5.1.1 The following are accepted as proof of COVID Vaccination
  - 5.1.1.1 CDC COVID-19 vaccination record card
  - 5.1.1.2 A photo of COVID-19 vaccination card
  - 5.1.1.3 Documentation of COVID-19 vaccination form from a healthcare provider, or electronic health record
  - 5.1.1.4 Digital vaccine card
  - 5.1.1.5 State immunization information system record
  - 5.1.1.6 If vaccinated outside of the United States or its territories, a reasonable equivalent of any of the previous examples shall suffice

5.2 Tracking of Vaccination Status
- 5.2.1 Documentation, shall be kept confidential and stored by the following:
  - 5.2.1.1 Records of vaccination verification for employees must be submitted to Employee Health/HR;
  - 5.2.1.2 Contracted licensed independent providers (MD's, DO's, PA's, etc.) will submit vaccination verification to the medical staff department
  - 5.2.1.3 Contract security guards will be tracked by their employer and make records available upon request to HR
  - 5.2.1.4 Students will be tracked by their educational institution and make records available upon request to HR
  - 5.2.1.5 Travel & Contract Staff will be tracked by the department liaison responsible for their services
  - 5.2.1.6 Volunteers will submit records of vaccination verification to HR

6.0 References:

6.1 CMS Federal Register 06/05/2023, 42 CFR 416, Final Rule, https://www.federalregister.gov/d/2023-11449

6.2 NHSN Healthcare Personnel, CMS Quality Reporting Program

7.0 Attachment List

7.1 Attachment A: COVID-19 Vaccine Declination Form

8.0 Summary of Revisions:

8.1 Removal of CDPH AFL 21-34.4, COVID-19 Vaccine Requirement for Healthcare Personnel (HCP).

8.2 Removal of line 1.2, CDPH COVID booster vaccine requirement

8.3 Removal of line 1.1, CMS vaccine requirement

8.4 Removal of mitigation plan and masking requirements for unvaccinated

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MEMORIAL HEALTHCARE DISTRICT

COVID-19 Vaccine OR Booster
Medical/Religious Accommodation

Name:	**Date of Birth:**
Department:	**Position/Title:**
☐**Employee** ☐**Traveler** ☐**Student** ☐**Physician/Medical Staff Provider** ☐**Security Guard** ☐ **Dialysis** ☐ **Other Contract** _____	

My employer or affiliated health facility, **Pioneers Memorial Healthcare District**, has recommended that I receive COVID-19 Vaccination. **Despite these facts, I am choosing to decline COVID-19 vaccination at this time.**

I **decline to be vaccinated**: I understand that due to my occupational exposure to aerosol transmissible diseases, I may be at risk of acquiring infection with **Coronavirus- COVID-19 (SARS-COV 2**). I have been given the opportunity to be vaccinated against this disease or pathogen at no charge to me. However, I decline this vaccination at this time. I understand that by declining this vaccine, I continue to be at risk of acquiring **Coronavirus COVID-19 (SARS-COV 2)**, a serious disease. If in the future I continue to have occupational exposure to aerosol transmissible diseases and want to be vaccinated, I can receive the vaccination at no charge to me.

- HCP who are unvaccinated or incompletely vaccinated must always wear, at a minimum, a surgical mask. Respirators as required for exposure tasks and in areas where suspected/confirmed COVID cases may be. I must be provided with a respirator upon my request.

I am seeking reasonable accommodation instead of being vaccinated for COVID-19 on the following basis:

☐ **Medical Accommodation**: I have a medical condition or disability that prevents me from being able to take any COVID-19 vaccine. I understand that I must also provide to my employer a written statement signed by a physician, or other licensed medical professional practicing under the license of a physician, stating that I qualify for the exemption. I may use the next page of this form for that purpose.

☐ **Religious Belief Accommodation Attestation**: I have a sincerely held religious belief, practice, or observance that prevents me from taking any of the FDA authorized or approved COVID-19 vaccines.

Signature: _____

Date: _____

References:

07/20/21 Cal-OSHA ATD Standard
CMS Interim Final Rule Conditions of Participation COVID-19 Vaccination of Hospital Staff 11/05/21
California Department of Public Health (CDPH) All Facilities Letter (AFL21-34.4) of October 5, 2022; Coronavirus Disease 2019 (COVID-19) Vaccine Requirement for Healthcare Personnel (HCP)

PIONEERS MEMORIAL HEALTHCARE DISTRICT

COVID-19 Vaccine Declination
Healthcare Provider Supporting Statement

Per CDPH & CMS Mandatory COVID Vaccination, for a person that provides services at Pioneers Memorial Healthcare District (PMHD) to decline COVID Vaccination and qualify for the Medical/Disability Accommodation, their healthcare provider (only a physician, nurse practitioner, or other licensed medical professional practicing under the license of a physician) must complete the following form to be provided by the person to PMHD.

Completed by individual seeking exemption:		
Name	**Date of Request**	
Department	**Title**	**Director**

I am requesting a medical exception to the requirement for COVID-19 vaccination or a delay becauseof a temporary condition or medical circumstance. I am requesting a medical exemption from administration of the following vaccines (check all that apply):

- □ BioNTech, Pfizer Vaccine
- □ Johnson & Johnson Vaccine
- □ Moderna NIAID Vaccine
- □ Novavax Vaccine
- □ A vaccine listed by the World Health Organization (WHO) for emergency use that is not approved or authorized by the FDA, or a vaccine that is administered in a clinical trial.

Signature	**Date**

Medical Certification for COVID-19 Vaccine Exception: To be Completed by Medical Provider

Dear Medical Provider:

The individual named above is seeking a medical exceptionto the requirement for COVID-19 vaccination or a delay because of a temporary condition or medical circumstance. Please complete this form to assist in a reasonable accommodation process.

Please provide at least the following information, where applicable:

1. The applicable contraindication or precaution for COVID-19 vaccination, and for each contraindication or precaution, indicate: (a) whether it is recognized by the CDC pursuant to itsguidance; and (b) whether it is listed in the package insert or Emergency Use Authorization factsheet for each of the COVID-19 vaccines authorized or approved for use in the United States;
2. A statement that the individual's condition and medical circumstances relating to the individual are such that COVID-19 vaccination is not considered safe, indicating the specificnature of the medical condition or circumstances that contraindicate immunization with a COVID-19 vaccine or might increase the risk for a serious adverse reaction; and
3. Any other medical condition that would limit the employee from receiving any COVID-19vaccine.

Description of the condition for which the employee listed above should be exempted from complying with a COVID-19 vaccination requirement:

The condition described above is:	☐ temporary	☐ long-term

If temporary, date expected to end or expire (allow COVID-19 vaccination to begin after the date you provided):

Medical Provider Name/Title/License Number

Medical Provider Signature	**Date**

If practicing under license of a physician, name & license number of physician:

References:

07/20/21 Cal-OSHA ATD Standard
CMS Interim Final Rule Conditions of Participation COVID-19 Vaccination of Hospital Staff 11/05/21
California Department of Public Health (CDPH) All Facilities Letter (AFL21-34.4) of October 5, 2022; Coronavirus Disease 2019 (COVID-19) Vaccine Requirement for Healthcare Personnel (HCP)

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Title: **Guidelines for Influx of Patients with Highly Communicable Diseases**	Policy No. EOC-00135
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Current Author: Jorge Mendoza	Effective: 10/23/2009
Latest Review/Revision Date: 9/2023	Manual: EOC / Emergency Management

Collaborating Departments: Infection Control; Emergency Room		Keywords:		
Approval Route: List all required approval				
MARCC 9/19/2023	PSQC	Other:		
Clinical Service _____		MSQC 11/2023	MEC 11/2023	BOD 12/2023

Note: *If any of the sections of your final layout are not needed do not delete them, write "not applicable".*

1.0 Purpose:

1.1 To ensure that all hospital departments are prepared, equipped and ready to care for patients in the event of escalating transmission of highly communicable disease.

2.0 Scope: District wide

3.0 Policy:

Recognizing that healthcare facilities must be prepared for the rapid pace and dynamic characteristics of a medical surge related to highly communicable diseases. To the extent appropriate the management of an influx of potentially infectious patients will be conducted in accordance with the organizations emergency operations plan EOC-00213.

4.0 Definitions:

4.1 Pandemic – A pandemic is a sudden outbreak of a disease that becomes very widespread and affects a whole region, a continent, or the world

4.2 Medical Surge Capacity – The ability to evaluate and care for a markedly increased volume of patients, one that challenges or exceeds normal operating capacity. The surge requirements may extend beyond direct patient care to include such tasks as extensive laboratory studies or epidemiological investigations.

5.0 Procedure:

5.1 Health care facilities will be stressed during a medical surge. The Imperial County Public Health Department will assist health care providers and facilities to maximize access of the population with quality health care. PMHD has addressed mitigation, preparedness, and response and recovery activities to effectively prepare for and respond to a highly communicable disease surge.

5.2 During a medical surge of highly communicable diseases, contact will be made with local public health officials. This will provide linkages with community and/or regional task forces that will be responsible for coordinating health care activities. These groups will issue public health advisories, ensure communication with medical care providers and potentially request real-time data to monitor the impact of the medical surge on hospitals in the community. In addition, they will be a source for identifying and allocating critical resources.

5.3 Contact Information

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5.3.1 Local Public Health Department, including after-hours phone number:
5.3.1.1 Main line: (442) 265-1444 and Duty Officer: (760) 455-4083

5.4 Response – Activate HICS / Emergency Operations Plan then continue with the following response activities:
5.4.1 Triage and Patient Management
5.4.1.1 Our facility will use the current case definition provided by local public health to assist clinicians in identifying persons who may have highly infectious diseases, providing appropriate treatment, and separating them from others to reduce the risk of transmitting infection.

5.5 Other key issues include assuring infection control measures are implemented and appropriately managing admissions and follow-up for those not admitted.

5.6 Strategies that can reduce the patient volume at emergency departments and outpatient areas are:
5.6.1 Appropriate use of advice call centers and hotlines
5.6.2 Conduct telephone triage to segregate patients into different treatment sites
5.6.3 Refer patients to other clinics, local physicians' offices or non-traditional care settings when ED care is not required
5.6.4 Limit or cancel elective ambulatory procedures
5.6.5 Review patients to limit unnecessary outpatient visits

5.7 It is important to remember that infection control is the key to disease containment in a medical surge of highly communicable diseases. Strategies for reducing infection transmission through triage include:
5.7.1 Implement plans to enhance infection control, including working with Facility Services to modify air exchange rates, conducting out-venting, or initiating other temporary HVAC procedures to reduce the opportunity of disease transmission.
5.7.2 Establish specific triage and waiting areas for cohorting persons with similar presentation.
5.7.3 Assure that high-risk outpatients presenting for procedures such as dialysis or chemotherapy are separate from those who may have highly communicable diseases.
5.7.4 Expand use of a triage officer to manage patient flow
5.7.5 Convert adjacent urgent care or any available medical office space into segregated patient treatment areas
5.7.6 Provide respiratory etiquette posters and supplies at all treatment sites
5.7.7 To enhance surge capacity contact California Department of Public Health Licensing and Certification Regional Office and request waiver to allow trained nurses to provide a medical screening exam and refer patients directly from triage to home or follow up at physicians' offices.

5.8 Patients admitted with suspected highly communicable diseases should be isolated if possible, in negative pressure rooms with adjoining anterooms until transmission route is confirmed and alternative guidance is provided. Strategies to increase patient isolation areas include:
5.8.1 Place patients with documented or suspected highly communicable diseases in a private room with a HEPA filtration unit if available

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5.8.2 When the number of patients with highly communicable diseases exceeds the available private rooms, try to place patients with similar presentation together in multi-bed rooms or wards

5.8.3 When patients with highly communicable diseases must be placed in a room together, minimize the number of staff having contact with infected patients by assigning all highly communicable diseases patients to a single or small group of healthcare personnel

5.8.4 When numerous cases are identified, consider placing all patients with documents or suspected highly communicable diseases in one designated unit or ward, i.e., an influenza cohort, and assign vaccinated nursing personnel to work in the designated highly communicable diseases cohort unit.

5.9 Strategies for creating additional in-patient bed availability include:

5.9.1 Review and revise criteria for all admissions

5.9.2 Cancel or redirect elective admissions and surgeries

5.9.3 Discharge patients who do not require on going inpatient care or can be moved to a lower level of care

5.9.4 Transport discharged patients home or to other facilities expeditiously. Consider creating a patient discharge holding area or discharge lounge to free up bed space.

5.10 Laboratory Diagnosis

5.10.1 When highly communicable disease in a community is suspected, etiological diagnosis of the disease generally is not needed in persons with compatible clinical disease. Use of diagnostic laboratory testing should be guided by specific surveillance needs outlined by public health officials. Patients can be treated empirically, and infection control measures such as isolation and cohorting should be guided by clinical diagnosis.

5.10.2 Collection and management of specimens from suspected patients will be done in collaboration with the local public health office recommendations.

5.11 Treatment

5.11.1 Treatment guidelines will be provided by public health officials based on the nature of the infectious disease. This may include antiviral medications and antibiotics as indicated for patients with secondary bacterial complications, in addition to supportive care

5.12 Staffing issues – During a medical surge, staffing shortages of up to 30% are predicted and may result from illness, the need to care for ill family members, and possibly from fear of exposure and infection-particularly if the disease is severe and case-fatality rates are high among working-aged adults. Existing high census protocols and emergency preparedness plans may apply. In addition, specific preventive interventions may reduce staff absenteeism during a pandemic.

5.12.1 Determine numbers and qualifications of staff necessary. Determine supply and equipment needs. Contact the Command Center for assistance.

5.12.2 Continue staff call in and provide additional staff to impacted areas

5.12.3 Track and follow up with employee illnesses and absenteeism issues.

5.12.4 Screening of employees and healthcare personnel may be required to determine

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fitness for duty and whether staff can safely provide patient care. Categories of employees may be established to assist with proper work assignment.

5.13 Infection Control – Use of containment measures will be the critical tool to reduce the spread. The following sections describe specific infection control strategies. Guidelines may be amended as more is learned about the highly communicable disease.

5.13.1 Assess the impact of the infectious process on the provision of utility services. Consideration should be given to the following:

5.13.1.1 Impact of airborne agents on air intake systems and circulation

5.13.1.2 Impact of water borne agents on city water supplies and potable water in the facility

5.13.2 If necessary, air handlers and returns may need to be shut down to protect occupants in buildings. Incoming water supply may need to be restricted. Consideration should be made to implement “shelter in place” strategies as warranted.

5.13.3 In addition maintain cleanliness and infection control needs in the care areas. All non-essential cleaning services will be suspended during the emergency. Extra linen, hampers, trash bins, and biohazard waste containers should be brought to the triage and immediate care areas. Ascertain appropriate protective equipment and process needs for staff working in exposed areas.

5.13.4 Should an infectious patient require surgery, the case should – whenever possible – be scheduled at the end of the day. The surgical suite should then be terminally cleaned.

5.13.5 In addition, non-infectious patients should be removed from areas anticipated to house incoming infectious patients. If necessary, a unit should be cleared of non-infectious patients and designated as the admission unit for patients presenting to the organization with an infectious process.

5.13.6 Refer to CLN-02308 for isolation guidelines.

5.13.7 Standard Precautions: Standard precautions should be followed when caring for all patients, regardless of their diagnosis.

5.13.7.1 Wear gloves if hand contact with respiratory secretions or potentially contaminated surfaces is expected.

5.13.7.2 Wear a gown if soiling of clothes with patient’s respiratory secretions is expected.

5.13.7.3 Change gloves and gowns after each patient encounter and before touching any non-contaminated items or touching another patient, and perform hand hygiene.

5.13.7.4 Decontaminate hands before and after touching the patient, after touching the patient’s environment, or after touching the patient’s respiratory secretions, whether or not gloves are worn.

5.13.7.5 When hands are visibly soiled or contaminated with respiratory secretions, mechanically remove visible soil first, and wash hands with either a non-antimicrobial or an antimicrobial soap and water. Hand hygiene with plain soap or detergent for at least 10 to 15 seconds under running water is an effective method of removing soil and

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transient microorganisms.

5.13.7.6 If hands are not visibly soiled and after glove removal, or if sinks are not readily available, use an alcohol-based hand rub for routinely decontaminating hands in clinical situations.

5.13.8 Use of Masks and Respirators – Use of masks and respirators is one component of a system of infection control practices to prevent the spread of infection between infected and non-infected persons where pandemic patients might receive health care services. Based on most current recommendations from the local public health office, the facility will provide masks or respirators for healthcare personnel protection. The type of mask used may vary based on the most current knowledge of the virus causing the pandemic flu; the duration, frequency, proximity and degree of contact with the patient; and availability of masks.

5.13.9 Interim guidance on planning for mask use has recommended:

5.13.9.1 N-95 masks for use during activities that have a high likelihood of generating infectious respiratory aerosols such as:

5.13.9.1.1 Aerosol-generating procedures performed on patients with confirmed or suspected pandemic influenza

5.13.9.1.2 Resuscitation of a patient with confirmed or suspected pandemic influenza

5.13.9.1.3 Providing direct care (e.g. examination, bathing, feeding) for patients with confirmed or suspected pandemic influenza-associated pneumonia, who may produce larger-than-normal amounts of respirable infectious particles when they cough

5.13.9.1.4 For support staff who may have direct contact with pandemic influenza patients.

5.13.9.2 Type of respiratory protection that may be available:

5.13.9.2.1 Surgical or procedure mask – that provide protection from large respiratory droplets that can contaminate the mucous membranes.

5.13.9.2.2 Particulate respirators – filtering face piece respirators made of filter material designated to remove airborne particles.

5.13.9.2.3 Powered air-purifying respirators (PAPRs) – battery-powered blower that provides filtered breathing air

5.13.9.2.4 N-95 respirators – mask that filters out 65% of small inhalable particles; requires fit testing to assure proper fit.

5.13.9.2.5 For patient use when transport from the room is essential, a surgical mask should be placed on the patient.

5.13.9.3 Other Strategies for Preventing Transmission:

5.13.9.3.1 Limit the movement and transport of the patient from the room to essential purposes only. If transport or movement is necessary, minimize patient dispersal of droplets by having the patient wear a surgical mask.

5.13.10 Infection control measures during a influx of a highly communicable

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disease will differ from typical infection control procedures because it can be assumed that risk of transmission is high, immunity within the population is low, an increased number of persons will be seeking medical aid, and resources traditionally used for infection control may be in short supply. Therefore, it is important to review policies such as patient triage, equipment cleaning, and housekeeping services in all clinical areas as well as outpatient departments or clinics. Areas that may require review:

5.13.10.1 Education of staff
5.13.10.2 Bed management
5.13.10.3 Cleaning, disinfection, and sterilization
5.13.10.4 Patient education
5.13.10.5 Visitor policies
5.13.10.6 Personnel/staffing policies
5.13.10.7 Utilization of rooms
5.13.10.8 Discharge management
5.13.10.9 Home health care

5.14 State and local public health departments will work with healthcare organizations and communities:
- 5.14.1 to identify who should be included in defined priority groups,
- 5.14.2 to develop plans for acquiring and distributing antiviral prophylaxis, and
- 5.14.3 to provide education regarding target groups and optimal drug use strategies.

5.15 Equipment and Supplies – Infection control measures and supportive care will be key activities during the first stages of a highly communicable disease outbreak. Maintaining equipment and supplies to support these activities will be essential for containing the disease and ending the medical surge.

5.16 Recovery
- 5.16.1 Deactivation of all units when they are no longer needed
- 5.16.2 Replenish materials and supplies
- 5.16.3 Convene Safety Committee and evaluate the event
- 5.16.4 Develop After Action Report
- 5.16.5 Develop Corrective Action Plan
- 5.16.6 Conduct debriefing
- 5.16.7 Perform additional activities as outlined under applicable sections of the Pandemic Influenza Plan

6.0 References:

6.1 Cal/OSHA Interim Enforcement Policy on H1N1 and Section 5199 (Aerosol Transmissible Diseases)
6.2 PMHD Policy #CLN-02305 and #CLN-02355; Guidelines for Sudden Influx of Patients with a Potentially Communicable Disease
6.3 PMHD Policy #EOC-00213; Emergency Operations Plan
6.4 PMHD Policy #EOC-00192; Emergency Preparedness/Security
6.5 PMHD Policy #EOC-00182; Emergency Preparedness/Communications
6.6 PMHD Policy #EOC-00183; Use of Disaster Shelters

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6.7 PMHD Policy #EOC-00060; Bioterrorism Management Plan
6.8 PMHD Policy #HRD-00100; Influenza Vaccination Program
  6.8.1 Influenza Consent/Declination Form
  6.8.2 H1N1 Consent/Declination Form
6.9 PMHD Policy #EOC-00494; Continuity of Operations Plan
6.10 Imperial County Public Health Department-Pandemic Influenza Preparedness and Response Plan

7.0 Attachment List:

7.1 The following attachments cover disease specific guidelines. Further attachments will be added as necessary upon emerging infectious diseases.
  7.1.1 Attachment A – Influenza Work Instruction
  7.1.2 Attachment B1 – B5 Ebola Work Instruction
  7.1.3 Attachment C – Vector Borne Diseases
  7.1.4 Attachment D – Outbreak Investigation Form

8.0 Summary of Revisions:

8.1 Remove attachment E, 9/2023 CV19
8.2 Author Change.

Influenza Work Instruction

1.1 Notify Infection Control, Administration and the Public Health Department.
- 1.1.1 House Supervisor or Administrator will initiate the Emergency Operations Plan EOC-00213

1.2 *Precautions:* Instruct all patients with respiratory symptoms to wear a mask. Manage these patients with droplet precautions.
- 1.2.1 Actively screen all persons entering the facility for symptoms; all persons shall be required to perform hand hygiene upon entry to the facility.
- 1.2.2 Instruct all patients presenting with febrile illness or respiratory symptoms to wear a mask and place them in isolation. If large numbers, cohort patients with masks.
- 1.2.3 In the case of influx, place signs at all entry points detailing Symptoms of any current epidemiologic risk factors. Signs should Direct any person meeting these criteria to the Emergency Department for evaluation and isolation.
- 1.2.4 Initiate screening of patients on entry to the emergency department For symptoms. Patients with febrile illness and epidemiologic risks Should perform hand hygiene, wear a surgical mask, and be placed In droplet isolation. Co-horting, with all patients wearing surgical Masks, shall be established if droplet isolation is not possible.
- 1.2.5 Triage staff shall practice frequent hand hygiene and wear surgical Masks.

1.3 Personal Protective Equipment (PPE) - Healthcare workers will wear the indicated PPE for the type of precautions indicated for the patient. For respiratory Illness patients should be placed in droplet precautions.
- 1.3.1 Correctly sized gloves (non-sterile examination gloves) when entering the patient care area.
- 1.3.2 A disposable, impermeable gown to cover clothing and exposed skin.
- 1.3.3 A medical mask and eye protection (eye visor, goggles or face shield) to prevent splashes to the nose, mouth and eyes.

1.4 Patient Placement
- 1.4.1 If isolation rooms are unavailable, cohort these patients in specific confined areas.
- 1.4.2 Ensure the items listed for isolation rooms are readily available.

1.5 Staff Allocation
- 1.5.1 Restrict all non-essential staff from isolation patient care areas.

1.6 Visitors
- 1.6.1 Stopping visitor's access to the patient is preferred.
- 1.6.2 If this is not possible, limit their number to include only those necessary for the patient's well-being and care, such as a child's parent.
- 1.6.3 Do not allow other visitors to enter the isolation rooms/areas.

1.7 Hand-Hygiene, PPE, and other Precautions
- 1.7.1 Ensure that all staff, patients and visitors use PPE and perform hand hygiene.
- 1.7.2 Ensure that all HCWs (including aides and housekeeping) wear PPE according to the expected level of risk before entering the isolation

rooms/areas and having contacts with the patients and/or the environment.

1.8 Re-Useable Equipment
- 1.8.1 Carefully clean and decontaminate reusable equipment.
- 1.8.2 Rigorously use dedicated equipment (e.g. stethoscopes) for each patient.
- 1.8.3 If this is not possible, decontaminate the items between each patient contact.
- 1.8.4 For instance, if the stethoscope has to be used on different patients, it is essential that the full stethoscope (i.e. staff hand contact as well as patient contact surfaces) be thoroughly cleaned first with water and soap using appropriate PPE to remove organic matter and then wiped with alcohol.
- 1.8.5 All waste generated during the decontamination process should be treated as infectious waste.
- 1.8.6 Items and equipment should not be moved between isolation rooms/areas and other areas of the facility, unless they are appropriately discarded and disposed.

1.11 Environmental Cleaning
- 1.11.3 Environmental surfaces or objects contaminated with blood, other body fluids, secretions or excretions should be cleaned and disinfected as soon as possible using standard hospital detergents/disinfectants (1:10 Bleach Solution).
- 1.11.4 Cleaning should always be carried out from “clean” areas to “dirty” areas, in order to avoid contaminant transfer.

1.12 Management of Linen
- 1.12.3 Place soiled linen in clearly-labeled, leak-proof bags or buckets at the site of use.
- 1.12.4 Container surfaces should be disinfected before removal from the isolation room/area.
- 1.12.6 If the linen is transported out of the patient room/area, it should be put in a separate container – it should never be carried against the body.

1.13 Waste Management
- 1.13.3 Avoid splashing when disposing of liquid infectious waste.
- 1.13.4 Waste should be segregated at point of generation to enable appropriate and safe handling.
- 1.13.5 Collect all solid, non-sharp, infectious waste using leak-proof waste bags and covered bins. Bins should never be carried against the body (e.g. on the shoulder)

1.14 Post-Mortem Care
- 1.14.1 Any death due to Influenza must be reported to the Health Department per title 17.

EBOLA Work Instruction

1.1 Notify Infection Control, Administration and the Public Health Department. See attachments
  1.1.1 House Supervisor or Administrator will initiate the Emergency Operations Plan EOC-00213
1.2 *Precautions:* Patients shall be placed in standard, contact, and droplet precautions. *Airborne Precautions should be used whenever risk of aerosol generating procedures will be used (i.e. suctioning).*
1.3 Personal Protective Equipment (PPE) - Healthcare workers will wear the indicated PPE for the type of precautions indicated for the patient. In the case of Ebola there are three different types of precaution indicated by the CDC and WHO organizations. It is the recommendation of the Infection Preventionist and the Infection Control Committee for all EBV cases to be place in Droplet Precautions (excepting those patients requiring Airborne Precautions) and Droplet PPE to be worn (gloves, gown, mask, and eyewear). EBV patients receiving aerosol generating procedures will require all the aforementioned PPE with the addition of an N95 OSHA approved respirator mask or facility issued PAPR.
  1.3.1 Correctly sized gloves (non-sterile examination gloves) when entering the patient care area.
  1.3.2 A disposable, impermeable gown to cover clothing and exposed skin.
  1.3.3 A medical mask and eye protection (eye visor, goggles or face shield) to prevent splashes to the nose, mouth and eyes.
  1.3.4 Closed, puncture and fluid resistant shoes (e.g. rubber boots) to avoid contamination with blood or other body fluids or accidents with misplaced, contaminated sharp objects.
1.4 Patient Placement
  1.4.1 If isolation rooms are unavailable, cohort these patients in specific confined areas.
  1.4.2 Rigorously keep suspected and confirmed cases separate.
  1.4.3 Ensure the items listed for isolation rooms are readily available.
  1.4.4 Make sure that there is at least 1 meter (3 feet) distance between patient beds.
  1.4.5 Note: CDC Recommends Airborne Isolation Room if aerosol generating procedures are absolutely necessary (suctioning, etc.).
1.5 Staff Allocation
  1.5.1 Ensure that clinical and non-clinical personnel are assigned exclusively to EVD patient care areas.
  1.5.2 Ensure that members of staff do not move freely between the EVD isolation areas and other clinical areas during the outbreak.
  1.5.3 Restrict all non-essential staff from EVD patient care areas.
1.6 Visitors
  1.6.1 Stopping visitor’s access to the patient is preferred.
  1.6.2 If this is not possible, limit their number to include only those necessary for the patient’s well-being and care, such as a child’s parent.

1.6.3 Do not allow other visitors to enter the isolation rooms/areas and ensure that any visitors wishing to observe the patient do so from an adequate distance (approximately 15 m or 50 feet).
1.6.4 Before allowing visitors to EVD patients to enter the facility screen them for signs and symptoms of EVD.
1.6.5 A non-clinical staff person shall be assigned to each room to monitor visitor traffic flow in and out of the room. A sign in/out sheet will be maintained to document all visitors in and out of the room.

1.7 Hand-Hygiene, PPE, and other Precautions
1.7.1 Ensure that all visitors use PPE and perform hand hygiene and are provided with related instructions prior to entry into the isolation room/area.
1.7.2 Ensure that all HCWs (including aides and cleaners) wear PPE according to the expected level of risk before entering the isolation rooms/areas and having contacts with the patients and/or the environment.
1.7.3 Personal clothing should not be worn for working in the patient areas. Scrub or medical suits should be worn.

1.8 Re-Useable Equipment
1.8.1 Carefully clean and decontaminate reusable equipment.
1.8.2 Rigorously use dedicated equipment (e.g. stethoscopes) for each patient.
1.8.3 If this is not possible, decontaminate the items between each patient contact.
1.8.4 For instance, if the stethoscope has to be used on different patients, it is essential that the full stethoscope (i.e. staff hand contact as well as patient contact surfaces) be thoroughly cleaned first with water and soap using appropriate PPE to remove organic matter and then wiped with alcohol.
1.8.5 All waste generated during the decontamination process should be treated as infectious waste.
1.8.6 Items and equipment should not be moved between isolation rooms/areas and other areas of the HCF, unless they are appropriately discarded and disposed.

1.9 Laboratory specimens
1.9.1 U.S. clinical laboratories can safely handle specimens from these potential Ebola patients by taking all required precautions and practices in the laboratory, specifically designed for pathogens spread in the blood.
1.9.2 Risk assessments should be conducted by each laboratory director, biosafety officer, or other responsible person to determine the potential for sprays, splashes, or aerosol generated during laboratory procedures.
1.9.3 Any person collecting specimens from a patient with suspected Ebola virus disease should wear gloves, water-resistant gowns, full face shield or goggles, and masks to cover all of nose and mouth.
1.9.4 Anyone collecting specimens from a patient should follow the procedures below for transporting them through the healthcare facility, clean-up of spills, storing, packaging and shipping to CDC for testing.

1.9.5 All laboratorians and other healthcare personnel collecting or handling specimens must follow established standards compliant with the OSHA Blood borne pathogens standards

1.9.6 Recommendations for risk assessment to staff: Risk assessments should be conducted by each laboratory director, biosafety officer, or other responsible personnel to determine the potential for sprays, splashes, or aerosols generated from laboratory procedures. They should adjust, as needed, PPE requirements, practices, and safety equipment controls to protect the laboratorian's skin, eyes, and mucous membranes.

1.9.7 Recommendations for specimen collection by staff: Any person collecting specimens from a patient with a case of suspected Ebola virus disease should wear gloves, water-resistant gowns, full face shield or goggles, and masks to cover all of nose and mouth Additional PPE may be required in certain situations.

1.9.8 Recommendations for laboratory testing by staff: Any person testing specimens from a patient with a suspected case of Ebola virus disease should wear gloves, water-resistant gowns, full face shield or goggles, and masks to cover all of nose and mouth, and as an added precaution use a certified class II Biosafety cabinet or Plexiglass splash guard with PPE to protect skin and mucous membranes. All manufacturer-installed safety features for laboratory instruments should be used.

1.10 Use of Injection Equipment

1.10.1 Each patient should have exclusively dedicated injection and parenteral medication equipment which should be disposed of at the point of care.

1.10.2 Syringes, needles or similar equipment should never be reused.

1.10.3 Limit the use of needles and other sharp objects as much as possible.

1.10.4 Limit the use of phlebotomy and laboratory testing to the minimum necessary for essential diagnostic evaluation and patient care.

1.11 Environmental Cleaning

1.11.1 Wear heavy duty/rubber gloves, impermeable gown and closed shoes (e.g. boots) when cleaning the environment and handling infectious waste.

1.11.2 Add facial protection (mask and goggle or face shield) and overshoes if boots are unavailable when undertaking cleaning activities with increased risk of splashes or in which contact with blood and body fluids is anticipated.

1.11.3 Environmental surfaces or objects contaminated with blood, other body fluids, secretions or excretions should be cleaned and disinfected as soon as possible using standard hospital detergents/disinfectants (1:10 Bleach Solution).

1.11.4 Cleaning should always be carried out from "clean" areas to "dirty" areas, in order to avoid contaminant transfer.

1.12 Management of Linen

1.12.1 Linen that has been used on patients can be heavily contaminated with body fluids (e.g. blood, vomit) and splashes may result during handling.

1.12.2 When handling soiled linen from patients, use gloves, impermeable gown, closed shoes (e.g., boots) and facial protection (masks and goggle or face shield).
1.12.3 Place soiled linen in clearly-labeled, leak-proof bags or buckets at the site of use.
1.12.4 Container surfaces should be disinfected before removal from the isolation room/area.
1.12.5 If there is any solid excrement such as feces or vomit, scrape off carefully using a flat firm object and flush it down the toilet or in the sluice before linen is placed in its container.
1.12.6 If the linen is transported out of the patient room/area, it should be put in a separate container – it should never be carried against the body.
1.12.7 Linen should be transported directly to the laundry area and laundered promptly with water and detergent.
1.12.8 For low-temperature laundering, wash curtains with detergent and water, rinse and then soak in 0.05% chlorine for 30 minutes. Curtains should then be dried according to routine standards and procedures.
1.12.9 Washing contaminated linen by hand should be discouraged.
1.12.10 If washing machines are not available or power is not ensured, take the soiled linen out of the container and empty it into a large drum container of hot water and soap. Soak the linen in this drum and make sure it is totally covered with water.
1.12.11 Use a stick to stir; then throw out the water and refill the drum with clean water and add bleach and allow to soak for 10 –15 minutes. Remove the linen and then rinse in clean water. Remove excess water and spread out to dry. Avoid as much splashing as possible.
1.12.12 If safe cleaning and disinfection of heavily soiled linen is not possible or reliable, burn the linen to avoid any unnecessary risks to individuals handling these items.

1.13 Waste Management

1.13.1 Wear heavy duty/rubber gloves, impermeable gown, closed shoes (e.g. boots) and facial protection (mask and goggle or face shield), when handling infectious waste (e.g. solid waste or any secretion or excretion with visible blood even if it originated from a normally sterile body cavity)
1.13.2 Goggles provide greater protection than visors from splashes that may come from below when pouring liquid waste from a bucket
1.13.3 Avoid splashing when disposing of liquid infectious waste.
1.13.4 Waste should be segregated at point of generation to enable appropriate and safe handling.
1.13.5 Collect all solid, non-sharp, infectious waste using leak-proof waste bags and covered bins. Bins should never be carried against the body (e.g. on the shoulder)
1.13.6 Waste will be labeled with EBV written on the Biohazard label to identify EBV for carrier.

1.14 Post-Mortem Care and Transfer of Bodies

1.14.1 Personal protective equipment (PPE): Prior to contact with body, postmortem care personnel must wear PPE consisting of: surgical scrub suit, surgical cap, impervious gown with full sleeve coverage, eye protection (e.g., face shield, goggles), facemask, shoe covers, and double surgical gloves. Additional PPE (leg coverings, apron) might be required in certain situations (e.g., copious amounts of blood, vomit, feces, or other body fluids that can contaminate the environment).

1.14.2 Putting on, wearing, removing, and disposing of protective equipment: PPE should be in place BEFORE contact with the body, worn during the process of collection and placement in body bags, and should be removed immediately after and discarded as regulated medical waste. Use caution when removing PPE as to avoid contaminating the wearer. Hand hygiene (washing your hands thoroughly with soap and water or an alcohol based hand rub) should be performed immediately following the removal of PPE. If hands are visibly soiled, use soap and water.

1.14.3 Preparation of the body: At the site of death, the body should be wrapped in a plastic shroud. Wrapping of the body should be done in a way that prevents contamination of the outside of the shroud. Change your gown or gloves if they become heavily contaminated with blood or body fluids. Leave any intravenous lines or endotracheal tubes that may be present in place. Avoid washing or cleaning the body. After wrapping, the body should be immediately placed in a leak-proof plastic bag not less than 150 µm thick and zippered closed. The bagged body should then be placed in another leak-proof plastic bag not less than 150 µm thick and zippered closed before being transported to the morgue.

1.14.4 Surface decontamination: Prior to transport to the morgue, perform surface decontamination of the corpse-containing body bags by removing visible soil on outer bag surfaces with EPA-registered disinfectants which can kill a wide range of viruses. Follow the product's label instructions. Once the visible soil has been removed, reapply the disinfectant to the entire bag surface and allow to air dry. Following the removal of the body, the patient room should be cleaned and disinfected. Reusable equipment should be cleaned and disinfected according to standard procedures.

1.14.5 Individuals driving or riding in a vehicle carrying human remains: PPE is not required for individuals driving or riding in a vehicle carrying human remains, provided that drivers or riders will not be handling the remains of a suspected or confirmed case of Ebola, and the remains are safely contained and the body bag is disinfected as described above.

1.14.6 Bodies may be temporarily stored in WCH Temporary Morgue until transport to Attamortuary.

Ebola Virus Emergency Room Procedures

If patient answers yes to Ebola Screening Questions:

1. Place mask on patient and visitor(s) with patient.
2. Notify charge nurse by calling Triage Travel
3. Registration will move the patient and visitor(s) to **Triage Treatment Room.**
4. Patient triaged by ER if Ebola is suspected, patient and visitors will be moved to the cardiac suite once the area is prepared.
5. Absolutely minimize number of staff entering room.
6. Charge Nurse will notify infection control, administration and Public Health Officials. Activate Incident Command Center.
7. ER physician will put on appropriate PPE (PAPR if indicated) and perform Medical Screening Exam and provide minimal appropriate treatment.
8. If patient requires lab work (blood or urine), **all specimens are required to remain in the room and lab will collect and perform on STAT only basis while in ER**.
9. Dispose of all patient care items in the room. Do not bring out of room. All items should be placed in biohazard containers.
10. Disinfect any necessary equipment that needs to be removed from the room with 1:10 bleach solution. Do not remove items if not necessary.
11. Patients requiring additional labs - notify lab supervisor before transporting specimens. Always hand-carry specimens to lab. **Do not send in carrier**.
12. After patient disposition, perform terminal clean with CDC recommended Bleach wipes (1:10 dilution).

Hospital Leadership: 760-351-5500 who will call Admin on call or notify during regular hours

Carly Zamora: 760-351-3526 after hour's house supervisor to notify

Public Health Department: Lab: 760-482-4437 General: 760-482-4723

Ebola Virus Disease (EVD) Screening

Emergency Department screening criteria for patient isolation/testing are likely to be:

1. Fever, headache, joint and muscle aches, weakness, fatigue, diarrhea, vomiting, stomach pain and lack of appetite, and in some cases bleeding.

AND

2. Travel to West Africa (Guinea, Liberia, Nigeria, Senegal, Sierra Leone or other countries where EVD transmission has been reported by WHO) within 21 days (3 weeks) of symptom onset.

If both criteria are met, then the patient should be moved to a private room with a bathroom, and STANDARD, CONTACT, and DROPLET precautions followed during further assessment. (Triage room outside ER then Cardiac Stress Suite)

IMMEDIATELY Report Person Under Investigation (PUI) for Ebola to:

1. Hospital Leadership: House Supervisor 760-351-5500
2. Local and State Public Health Authorities: Lab: 760-482-4437 General: 760-482-4723
3. U.S. Centers for Disease Control and Prevention (CDC) by calling the CDC Emergency Operations Center (EOC) at 770-488-7100 or via email at eocreport@cdc.gov .

Sources: http://www.cdc.gov/vhf/ebola/hcp/case-definition.html, http://www.bt.cdc.gov/han/han00364.asp, http://www.cdc.gov/vhf/ebola/hcp/infection-prevention-and-control-recommendations.html

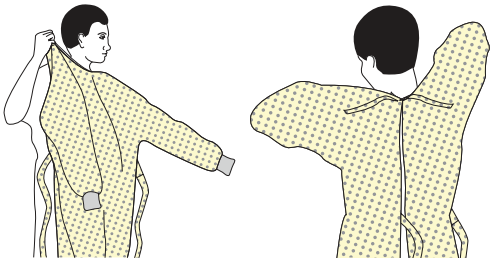
Attachment B-3, EOC-00135,10/16

SEQUENCE FOR PUTTING ON PERSONAL PROTECTIVE EQUIPMENT (PPE)

The type of PPE used will vary based on the level of precautions required, such as standard and contact, droplet or airborne infection isolation precautions. The procedure for putting on and removing PPE should be tailored to the specific type of PPE.

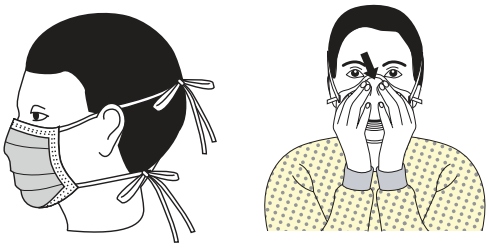
1. GOWN

- Fully cover torso from neck to knees, arms to end of wrists, and wrap around the back
- Fasten in back of neck and waist



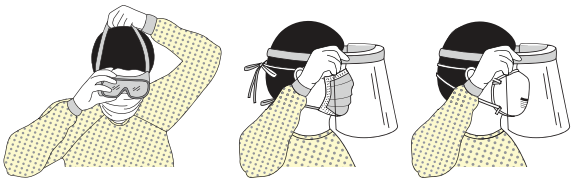
2. MASK OR RESPIRATOR

- Secure ties or elastic bands at middle of head and neck
- Fit flexible band to nose bridge
- Fit snug to face and below chin
- Fit-check respirator



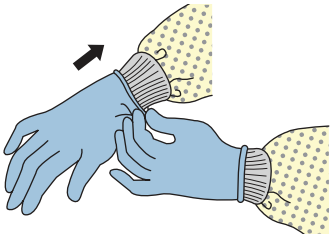
3. GOGGLES OR FACE SHIELD

- Place over face and eyes and adjust to fit



4. GLOVES

- Extend to cover wrist of isolation gown



USE SAFE WORK PRACTICES TO PROTECT YOURSELF AND LIMIT THE SPREAD OF CONTAMINATION

- Keep hands away from face
- Limit surfaces touched
- Change gloves when torn or heavily contaminated
- Perform hand hygiene

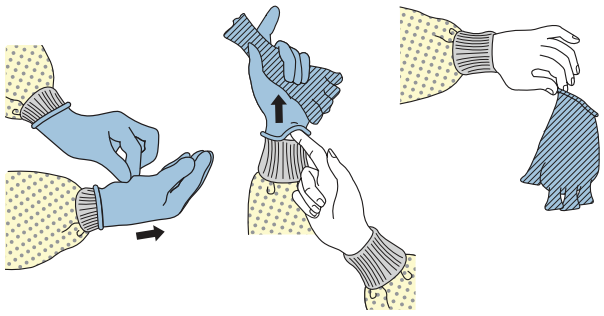
CS250672-D

HOW TO SAFELY REMOVE PERSONAL PROTECTIVE EQUIPMENT (PPE) EXAMPLE 1

There are a variety of ways to safely remove PPE without contaminating your clothing, skin, or mucous membranes with potentially infectious materials. Here is one example. **Remove all PPE before exiting the patient room** except a respirator, if worn. Remove the respirator **after** leaving the patient room and closing the door. Remove PPE in the following sequence:

1. GLOVES

- Outside of gloves are contaminated!
- If your hands get contaminated during glove removal, immediately wash your hands or use an alcohol-based hand sanitizer
- Using a gloved hand, grasp the palm area of the other gloved hand and peel off first glove
- Hold removed glove in gloved hand
- Slide fingers of ungloved hand under remaining glove at wrist and peel off second glove over first glove
- Discard gloves in an infectious* waste container

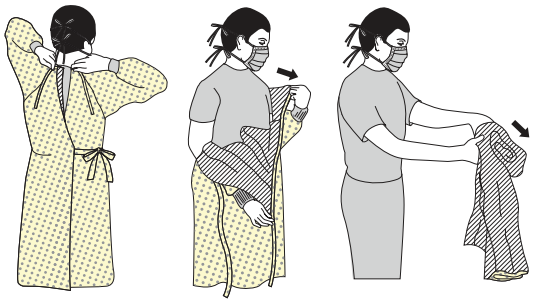


2. GOGGLES OR FACE SHIELD

- Outside of goggles or face shield are contaminated!
- If your hands get contaminated during goggle or face shield removal, immediately wash your hands or use an alcohol-based hand sanitizer
- Remove goggles or face shield from the back by lifting head band or ear pieces
- If the item is reusable, place in designated receptacle for reprocessing. Otherwise, discard in an infectious* waste container

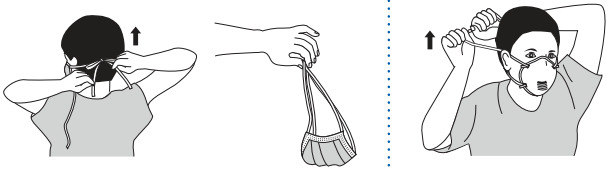
3. GOWN

- Gown front and sleeves are contaminated!
- If your hands get contaminated during gown removal, immediately wash your hands or use an alcohol-based hand sanitizer
- Unfasten gown ties, taking care that sleeves don't contact your body when reaching for ties
- Pull gown away from neck and shoulders, touching inside of gown only
- Turn gown inside out
- Fold or roll into a bundle and discard in an infectious* waste container

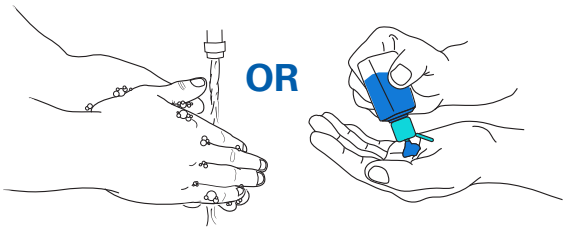


4. MASK OR RESPIRATOR

- Front of mask/respirator is contaminated — DO NOT TOUCH!
- If your hands get contaminated during mask/respirator removal, immediately wash your hands or use an alcohol-based hand sanitizer
- Grasp bottom ties or elastics of the mask/respirator, then the ones at the top, and remove without touching the front
- Discard in an infectious* waste container



5. WASH HANDS OR USE AN ALCOHOL-BASED HAND SANITIZER IMMEDIATELY AFTER REMOVING ALL PPE



* An infectious waste container is used to dispose of PPE that is potentially contaminated with Ebola virus.

PERFORM HAND HYGIENE BETWEEN STEPS IF HANDS BECOME CONTAMINATED AND IMMEDIATELY AFTER REMOVING ALL PPE

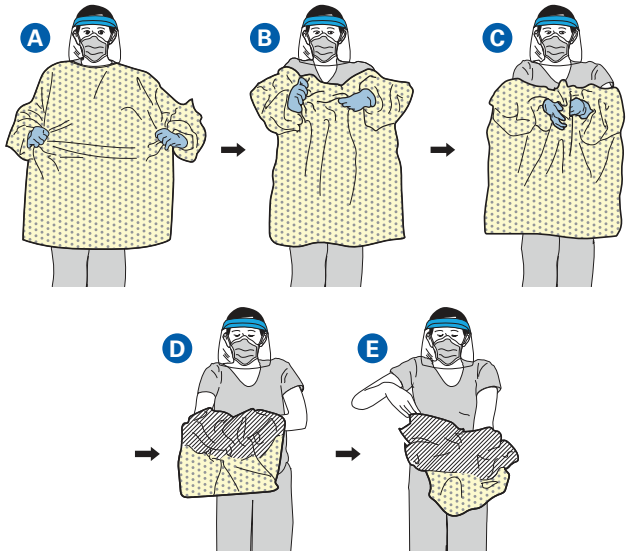
CS250672-D

HOW TO SAFELY REMOVE PERSONAL PROTECTIVE EQUIPMENT (PPE) EXAMPLE 2

Here is another way to safely remove PPE without contaminating your clothing, skin, or mucous membranes with potentially infectious materials. **Remove all PPE before exiting the patient room** except a respirator, if worn. Remove the respirator **after** leaving the patient room and closing the door. Remove PPE in the following sequence:

1. GOWN AND GLOVES

- Gown front and sleeves and the outside of gloves are contaminated!
- If your hands get contaminated during gown or glove removal, immediately wash your hands or use an alcohol-based hand sanitizer
- Grasp the gown in the front and pull away from your body so that the ties break, touching outside of gown only with gloved hands
- While removing the gown, fold or roll the gown inside-out into a bundle
- As you are removing the gown, peel off your gloves at the same time, only touching the inside of the gloves and gown with your bare hands. Place the gown and gloves into an infectious* waste container



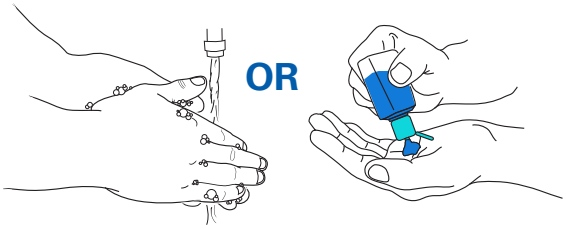
2. GOGGLES OR FACE SHIELD

- Outside of goggles or face shield are contaminated!
- If your hands get contaminated during goggle or face shield removal, immediately wash your hands or use an alcohol-based hand sanitizer
- Remove goggles or face shield from the back by lifting head band and without touching the front of the goggles or face shield
- If the item is reusable, place in designated receptacle for reprocessing. Otherwise, discard in an infectious* waste container

3. MASK OR RESPIRATOR

- Front of mask/respirator is contaminated — DO NOT TOUCH!
- If your hands get contaminated during mask/respirator removal, immediately wash your hands or use an alcohol-based hand sanitizer
- Grasp bottom ties or elastics of the mask/respirator, then the ones at the top, and remove without touching the front
- Discard in an infectious* waste container

4. WASH HANDS OR USE AN ALCOHOL-BASED HAND SANITIZER IMMEDIATELY AFTER REMOVING ALL PPE



* An infectious waste container is used to dispose of PPE that is potentially contaminated with Ebola virus.

PERFORM HAND HYGIENE BETWEEN STEPS IF HANDS BECOME CONTAMINATED AND IMMEDIATELY AFTER REMOVING ALL PPE

CS250672-D

Key Components of Standard, Contact, and Droplet Precautions Recommended for Prevention of EHF Transmission in U.S. Hospitals

Component	Recommendation	Comments
Patient Placement	• Single patient room (containing a private bathroom) with the door closed • Facilities should maintain a log of all persons entering the patient's room	• Consider posting personnel at the patient's door to ensure appropriate and consistent use of PPE by all persons entering the patient room
Personal Protective Equipment (PPE)	• All persons entering the patient room should wear at least: ▫ Gloves ▫ Gown (fluid resistant or impermeable) ▫ Eye protection (goggles or face shield) ▫ Facemask • Additional PPE might be required in certain situations (e.g., copious amounts of blood, other body fluids, vomit, or feces present in the environment), including but not limited to: ▫ Double gloving ▫ Disposable shoe covers ▫ Leg coverings	• Recommended PPE should be worn by HCP upon entry into patient rooms or care areas. Upon exit from the patient room or care area, PPE should be carefully removed without contaminating one's eyes, mucous membranes, or clothing with potentially infectious materials, and either ▫ Discarded, or ▫ For re-useable PPE, cleaned and disinfected according to the manufacturer's reprocessing instructions and hospital policies. • Instructions for donning and removing PPE have been published • Hand hygiene should be performed immediately after removal of PPE

[1]

[1]

Patient Care Equipment	• Dedicated medical equipment (preferably disposable, when possible) should be used for the provision of patient care • All non-dedicated, non-disposable medical equipment used for patient care should be cleaned and disinfected according to manufacturer's instructions and hospital policies	
Patient Care Considerations	• Limit the use of needles and other sharps as much as possible • Phlebotomy, procedures, and laboratory testing should be limited to the minimum necessary for essential diagnostic evaluation and medical care • All needles and sharps should be handled with extreme care and disposed in puncture-proof, sealed containers	

Aerosol Generating Procedures (AGPs)	• Avoid AGPs for Ebola HF patients. • If performing AGPs, use a combination of measures to reduce exposures from aerosol-generating procedures when performed on Ebola HF patients. • Visitors should not be present during aerosol-generating procedures. • Limiting the number of HCP present during the procedure to only those essential for patient-care and support. • Conduct the procedures in a private room and ideally in an Airborne Infection Isolation Room (AIIR) when feasible. Room doors should be kept closed during the procedure except when entering or leaving the room, and entry and exit should be minimized during and shortly after the procedure. • HCP should wear gloves, a gown, disposable shoe covers, and either a face shield that fully covers the front and sides of the face or goggles, and respiratory protection that is at least as protective as a NIOSH certified fit-tested N95 filtering facepiece respirator or higher (e.g., powered air purifying respiratory or elastomeric respirator) during aerosol generating procedures. • Conduct environmental surface cleaning following procedures (see section below on environmental infection control). • If re-usable equipment or PPE (e.g. Powered air purifying respirator, elastomeric respirator, etc.) are used, they should be cleaned and disinfected according to manufacturer instructions and hospital policies. • Collection and handling of soiled re-usable respirators must be done by trained individuals using PPE as described above for routine patient care	• Although there are limited data available to definitively define a list of AGPs, procedures that are usually included are Bilevel Positive Airway Pressure (BiPAP), bronchoscopy, sputum induction, intubation and extubation, and open suctioning of airways. • Because of the potential risk to individuals reprocessing reusable respirators, disposable filtering face piece respirators are preferred.

Hand Hygiene	• HCP should perform hand hygiene frequently, including before and after all patient contact, contact with potentially infectious material, and before putting on and upon removal of PPE, including gloves. • Healthcare facilities should ensure that supplies for performing hand hygiene are available.	• Hand hygiene in healthcare settings can be performed by washing with soap and water or using alcohol-based hand rubs. If hands are visibly soiled, use soap and water, not alcohol-based hand rubs.
Environmental Infection Control	Interim Guidance for Environmental Infection Control in Hospitals for Ebola Virus	Interim Guidance for Environmental Infection Control in Hospitals for Ebola Virus
Safe Injection practices	• Facilities should follow safe injection practices as specified under Standard Precautions.	• Any injection equipment or parenteral medication container that enters the patient treatment area should be dedicated to that patient and disposed of at the point of use.
Duration of Infection Control Precautions	• Duration of precautions should be determined on a case-by-case basis, in conjunction with local, state, and federal health authorities.	• Factors that should be considered include, but are not limited to: presence of symptoms related to Ebola HF, date symptoms resolved, other conditions that would require specific precautions (e.g., tuberculosis, *Clostridium difficile*) and available laboratory information

Monitoring and Management of Potentially Exposed Personnel	• Facilities should develop policies for monitoring and management of potentially exposed HCP
	• Facilities should develop sick leave policies for HCP that are non-punitive, flexible and consistent with public health guidance
	  ▫ Ensure that all HCP, including staff who are not directly employed by the healthcare facility but provide essential daily services, are aware of the sick leave policies.
	• Persons with percutaneous or mucocutaneous exposures to blood, body fluids, secretions, or excretions from a patient with suspected Ebola HF should
	  ▫ Stop working and immediately wash the affected skin surfaces with soap and water. Mucous membranes (e.g., conjunctiva) should be irrigated with copious amounts of water or eyewash solution
	  ▫ Immediately contact occupational health/supervisor for assessment and access to postexposure management services for all appropriate pathogens (e.g., Human Immunodeficiency Virus, Hepatitis C, etc.)	

	• HCP who develop sudden onset of fever, intense weakness or muscle pains, vomiting, diarrhea, or any signs of hemorrhage after an unprotected exposure (i.e. not wearing recommended PPE at the time of patient contact or through direct contact to blood or body fluids) to a patient with Ebola HF should
	  ▫ Not report to work or should immediately stop working
	  ▫ Notify their supervisor
	  ▫ Seek prompt medical evaluation and testing
	  ▫ Notify local and state health departments
	  ▫ Comply with work exclusion until they are deemed no longer infectious to others	

	• For asymptomatic HCP who had an unprotected exposure (i.e. not wearing recommended PPE at the time of patient contact or through direct contact to blood or body fluids) to a patient with Ebola HF
	  ▫ Should receive medical evaluation and follow-up care including fever monitoring twice daily for 21 days after the last known exposure.
	  ▫ Hospitals should consider policies ensuring twice daily contact with exposed personnel to discuss potential symptoms and document fever checks
	  ▫ May continue to work while receiving twice daily fever checks, based upon hospital policy and discussion with local, state, and federal public health authorities.	

Monitoring, Management, and Training of Visitors	• Avoid entry of visitors into the patient's room
	  ▫ Exceptions may be considered on a case by case basis for those who are essential for the patient's wellbeing.
	• Establish procedures for monitoring managing and training visitors.
	• Visits should be scheduled and controlled to allow for:
	  ▫ Screening for Ebola HF (e.g., fever and other symptoms) before entering or upon arrival to the hospital
	  ▫ Evaluating risk to the health of the visitor and ability to comply with precautions
		• Visitors who have been in contact with the Ebola HF patient before and during hospitalization are a possible source of EHF for other patients, visitors, and staff.

- providing instruction, before entry into the patient care area on hand hygiene, limiting surfaces touched, and use of PPE according to the current facility policy while in the patient's room
- Visitor movement within the facility should be restricted to the patient care area and an immediately adjacent waiting area.

Page last reviewed: August 5, 2014

Page last updated: August 19, 2014

Content source: Centers for Disease Control and Prevention

National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)

Division of High-Consequence Pathogens and Pathology (DHCPP)

Viral Special Pathogens Branch (VSPB)

Vector-Borne Work Instruction

1.1 Notify Infection Control, Administration and the Public Health Department.
- 1.1.1 House Supervisor or Administrator will initiate the Emergency Operations Plan EOC-00213
- 1.1.2 Potential Vector-Borne Diseases:
  - 1.1.2.1 Chikungunya
  - 1.1.2.2 Dengue Fever
  - 1.1.2.3 Rift Valley Fever
  - 1.1.2.4 Yellow Fever
  - 1.1.2.5 Zika
  - 1.1.2.6 Malaria
  - 1.1.2.7 Japanese Encephalitis
  - 1.1.2.8 Lymphatic Filariasis
  - 1.1.2.9 West Nile Fever
  - 1.1.2.10 Leishmaniasis
  - 1.1.2.11 Sandfly Fever (Phelebotomus Fever)
  - 1.1.2.12 Crimean-Congo Haemorrhagic Fever
  - 1.1.2.13 Lyme Disease
  - 1.1.2.14 Relapsing Fever (borreliosis)
  - 1.1.2.15 Rickettsial Diseases (Spotted fever and Q fever)
  - 1.1.2.16 Tick-borne encephalitis
  - 1.1.2.17 Tularemia
  - 1.1.2.18 Chagas Disease (American Trypanosomiasis)
  - 1.1.2.19 Sleeping Sickness (African Trypanosomiasis)
  - 1.1.2.20 Plague (Transmitted by fleas from rats to humans)
  - 1.1.2.21 Rickettsiosis
  - 1.1.2.22 Onchocerciasis (River blindness)
  - 1.1.2.23 Schistosomiasis (bilharziasis)

1.2 *Precautions:* All patients should be treated with Standard Precautions unless otherwise directed by Public Health or CDC.

1.3 Hand-Hygiene, PPE, and other Precautions
- 1.3.1 Ensure that all staff, patients and visitors use PPE and perform hand hygiene.
- 1.3.2 Ensure that all HCWs (including aides and housekeeping) wear PPE according to the expected level of risk before entering the isolation rooms/areas and having contacts with the patients and/or the environment.

HEALTHCARE-ASSOCIATED INFECTION (HAI) OUTBREAK INVESTIGATION ABSTRACTION FORM

Name: _____

Medical Record Number: _____

ID Number: _____

Facility Name: _____

ID Number: _____
Chart Abstraction Dates (Exposure Period): _____to _____

Today's Date:	**Abstractor Initials:**

Date of Illness Onset: _____/_____/_____

For Case/Control Study

Patient is a: ☐ Case ☐ Control – Linked to Case ID#: (_____)

Demographics

Gender: ☐ Male ☐ Female	**DOB:** _____/_____/_____

Race/Ethnicity:

☐ African American
☐ White
☐ Asian/PI
☐ Native American
☐ Hispanic
☐ Non-Hispanic
☐ Other:

Inpatient Admission Information

Admit Date: _____/_____/_____	**Admit Room #:**

Facility Room (Entire Admission)

Unit	Room #	Date In	Date Out

Admit Service:	**Admit Unit:** ☐ ICU – Type of ICU: MICU_____ CCU_____ SICU_____ ☐ Med/Surg Floor ☐ Step-down/Telemetry ☐ Other _____

Admit Diagnoses:

Admit Source:
☐ Home
☐ Long-term Acute Care Hospital (LTACH)
☐ Nursing Home
☐ Rehabilitation Facility
☐ Other Facility – In any ICU prior to this ICU admit?: ☐ Y ☐ N
☐ Other _____

Admit to this facility in last 30 days: ☐ Yes ☐ No	**Admit to other facility in last 30 days:** ☐ Yes ☐ No **Date:** _____/_____/_____ **Facility Name:** _____

ID Number: _____
Chart Abstraction Dates (Exposure Period): _____to _____

Status of Hospitalization:

☐ Still Inpatient

☐ Discharged Home: _____/_____/_____

☐ Transfer to other facility – Name: _____ Date: _____/_____/_____

☐ Deceased – Date of Death: _____/_____/_____ Cause of Death: _____

If deceased, was autopsy performed? ☐ Yes ☐ No If yes, Autopsy Date: _____/_____/_____

Autopsy Findings:_____
_____
_____
_____

Diagnoses at Discharge: (List all diagnoses appearing in the chart)

_____
_____
_____
_____
_____

Outpatient

Date started in clinic: _____/_____/_____

Date	Procedure or Infusion	Additional Visit Information
		☐ Neutropenia ☐ Vascular access Site/Type: _____
		☐ Neutropenia ☐ Vascular access Site/Type: _____
		☐ Neutropenia ☐ Vascular access Site/Type: _____
		☐ Neutropenia ☐ Vascular access Site/Type: _____

ID Number: _____
Chart Abstraction Dates (Exposure Period): _____to _____

Clinical History

History of Present Illness (Give a brief summary of the patient's illness and include any other relevant information not otherwise collected on this form):

_____
_____
_____
_____
_____

Past Medical History:

- ☐ Chronic Lung Disease
- ☐ Coronary Artery Disease
- ☐ Congestive Heart Failure (EF_____)
- ☐ Diabetes (AIC_____)
- ☐ Peripheral Vascular Disease
- ☐ Gastrointestinal disease/bleeding
- ☐ Liver Disease/Cirrhosis
- ☐ Chronic kidney disease (creatinine _____)
  - ☐ Dialysis Dependent
- ☐ Other Immunosuppression (specify: _____)
- ☐ HIV/AIDS (CD4 _____)
- ☐ Major Trauma (30d PTA)
- ☐ Previous Surgery (30d PTA)
- ☐ Obesity
- ☐ Malignancy (type_____)
- ☐ Cerebrovascular Disease
- ☐ Hypertension
- ☐ Other: _____
- ☐ Other: _____

ID Number: _____
Chart Abstraction Dates (Exposure Period): _____to _____

Clinical Course

Site of Infection (check all that apply): ☐ Respiratory ☐ Blood ☐ Surgical/Wound ☐ Urine ☐
Other:_____

Date of Illness Onset: _____/_____/_____ | **Date of positive culture (if applicable):** _____/_____/_____

Previous history of this infection in last 30 days? (Specify:_____)

Did patient receive antimicrobial therapy for this illness? ☐ Yes ☐ No ☐ N/A Date: _____/_____/_____

Abnormal Vital Signs (within 48 hours of illness onset):

☐ Fever >38℃ or 100.4℉ ☐ Hypoxia (O2Sat < 92% on room air) ☐ Hypotension (BP <(90/60))
☐ Tachypnea (RR > 25) ☐ Tachycardia (HR > 100)

Clinical signs and symptoms (within 48 hours of illness onset)

General:
☐ Altered Mental Status ☐ Loss of appetite
☐ Chills ☐ Weight Loss

Respiratory:
☐ Dyspnea (i.e., difficulty breathing)
☐ Hemoptysis (i.e., coughing up blood)
☐ New Increased Sputum:
  ☐ Purulent
  ☐ Change in character (e.g., color, quantity, etc.)
☐ New onset cough
☐ Rales/Crackles
☐ Rhinorrhea (i.e., runny nose)
☐ Sore throat
☐ Wheezing
☐ Worsening gas exchange (e.g., increased O2, PEEP, TV)

GI:
☐ Abdominal Pain ☐ Diarrhea ☐ Nausea/Vomiting
☐ Bloating ☐ Hematochezia (i.e., red blood in stool)
☐ Constipation ☐ Melena (i.e., black, tarry stool)

Urinary:
☐ Dysuria
☐ Suprapubic Tenderness
☐ Urinary urgency

Skin:
☐ Abscess
☐ Cellulitis
☐ Furuncle (i.e., skin boil)
☐ Rash
☐ Wound – Description (include # of wounds, sites, draining and other characteristics)

_____
_____

Laboratory: List abnormal labs within 48 hours of illness onset (if more than one, list the value closest to illness onset)

1. Creatinine _____
2. HCO3 _____
3. Hematocrit _____
4. INR _____
5. pH _____
6. Platelets _____
7. PTT _____
8. WBC _____

ID Number: _____

Chart Abstraction Dates (Exposure Period): _____to _____

Microbiology: (7 days prior to illness onset until end of abstraction period)

Date	Specimen Source (e.g., blood, urine)	Site (e.g., catheter, peripheral)	Result (e.g., organism)
			`

Radiology (e.g., X rays, CTs, U/S, etc.): (7 days prior to illness onset until end of abstraction period)

Date	Type of Study	Location (e.g., bedside, radiology)	Result

ID Number: _____
Chart Abstraction Dates (Exposure Period): _____to _____

ANTIMICROBIALS

Name	Dose/Route	Start Date	End Date

IV MEDICATIONS

Name	Dose/Route	Start Date	End Date

OTHER MEDICATIONS (e.g., immunosuppressives or inhaled/nebulized medications)

Name	Dose/Route	Start Date	End Date

Blood Products (7 days prior to end of abstraction period)

Type of Blood Product	Volume Transfused	Date

Mechanical Ventilation (7 days prior to end of abstraction period)

Type: (Endotracheal, Tracheostomy)	Start Date	End Date
CPAP/BIPAP: ☐ Yes ☐ No	Start Date: _____/_____/_____	End Date: _____/_____/_____

ID Number: _____

Chart Abstraction Dates (Exposure Period): _____to _____

Devices (7 days prior to end of abstraction period)

Device	Site	Date Inserted	Date Removed
☐ Central Venous Catheter			
☐ Central Venous Catheter			
☐ Central Venous Catheter			
☐ Condom Catheter			
☐ Foley Catheter			
Feeding Tube: ☐ Nasogastric/Nasoduodenal ☐ PEG/PEJ (stomach)			
☐ Other			

Point of care testing/injections/infusions (7 days prior to end of abstraction period)

Procedure	Dates
☐ Blood Glucose Monitoring	

Invasive Procedures (7 days prior to end of abstraction period)

Date	Type of procedure	Location (e.g., Bedside, OR, Radiology)

ID Number: _____

Chart Abstraction Dates (Exposure Period): _____to _____

Consult Services (7 days prior to end of abstraction period): ☐ Yes ☐ No

Service	Start Date	End Date
☐ Occupational Therapy		
☐ Physical Therapy		
☐ Speech Therapy/Language		
☐ Respiratory Therapy		
☐ Wound Care Team		
☐ Other: _____		
☐ Other: _____		
☐ Other: _____		

Pioneers Memorial Healthcare District

Title: **Hazardous Drugs Communication Program**	Policy No. CLN-02989
	Page 1 of 8
Current Author: John P. Teague & Violeta Pedernal	Effective: 11/26/2012
Latest Review/Revision Date: 8/2023	Manual: Clinical Pharmacy

Collaborating Departments: Nursing; Material Management; Environmental Services, Human Resource		Keywords: Hazardous Drug storage; waste; MSDS; OSHA; Chemical; Hazard	
Approval Route: List all required approval			
MARCC 9/19/2023	PSQC	Other: P&T Subcommittee; Safety 10/2023	
Clinical Service _____		MSQC 11/2023	MEC 11/2023	BOD 11/2023

Note: *If any of the sections of your final layout are not needed do not delete them, write "not applicable".*

1.0 Purpose:

1.1 To ensure that hazardous chemicals and medications within the facility are evaluated and identified, and that information concerning their hazards is communicated to the employees who transport, distribute, receive, store, prepare, administer, waste, and repair or maintain equipment used for hazardous chemicals or medications

1.2 Background:

1.2.1 The Hazards Communication Standard (HCS) 1994 has been revised to align with the *United Nations Globally Harmonized System of Classification and Labeling of Chemicals* (GHS). The update to the Hazards Communication Standard (HCS), HazCom 2012, provides a common and coherent approach to classifying chemicals and communicating hazard information on labels and safety data sheets. Additionally some minor changes to terminology have been made in order to align with the language used in the GHS. For example, the term "hazard determination" has been changed to "hazard classification" and "material safety data sheet" has been changed to "safety data sheet."

2.0 Scope:

2.1 Pharmacy staff

2.2 Nursing staff

2.3 Clinical and non-clinical staff with potential exposure to hazardous chemicals

2.4 Environmental services staff

3.0 Policy:

3.1 It is the policy of Pioneers Memorial Hospital to develop, maintain and implement a comprehensive written Hazards Communication Program(s) which includes container labeling and other forms of warning, Safety Data Sheets (SDS) and employee training.

3.2 The written Hazard Communication Program is available for review by any employee or their representative or a representative of a Federal or State agency. The program complies with the requirement of the Occupational Safety and Health Administration (OSHA) Hazard Communication Standard (HCS) (29 CFR, 1910.1200) and with the hospital's policy on hazardous materials.

3.3 The Hazard Communication Program includes the following components:

3.3.1 Maintaining a list(s) of hazardous substances present in the workplace

3.3.2 Maintaining Safety Data Sheets (SDSs) for all hazardous substances

Pioneers Memorial Healthcare District

Title: **Hazardous Drugs Communication Program**	Policy No. CLN-02989
	Page 2 of 8
Current Author: John P. Teague & Violeta Pedernal	Effective: 11/26/2012
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3.3.3 Providing employees who may be in contact with hazardous chemicals, or products containing hazardous substances, information and training about the Hazard Communication Program including; the list(s) of hazardous chemicals, container labeling, pictograms and warnings and interpreting Safety Data Sheets.
3.3.4 Documenting training and employee exposure

4.0 Definitions:

4.1 Global Harmonizing System (GHS) – *The Globally Harmonized System of Classification and Labeling of Chemicals* is a system for standardizing and harmonizing the classification and labeling of chemicals.
4.2 Hazard Classification – For each chemical, the chemical manufacturer or importer determines the hazard classes, and where appropriate, the category of each class that apply to the chemical being classified. Employers are not required to classify chemicals unless they choose not to rely on the classification performed by the chemical manufacturer or importer.
4.3 Hazardous Chemical – Any chemical which is classified as a physical hazard or a health hazard
4.4 Health Hazard – A chemical which is classified as posing one of the following hazardous effects: acute toxicity (any route of exposure); skin corrosion or irritation; serious eye damage or eye irritation; respiratory or skin sensitization; germ cell mutagenicity; carcinogenicity; reproductive toxicity; specific target organ toxicity (single or repeated exposure); or aspiration hazard.
4.5 Physical Hazard – A chemical that is classified as posing one of the following hazardous effects: explosive; flammable (gases, aerosols, liquids, or solids); oxidizer (liquid, solid or gas); self-reactive; pyrophoric (liquid or solid); self-heating; organic peroxide; corrosive to metal; gas under pressure; or in contact with water emits flammable gas.
4.6 Pictogram – A composition that may include a symbol plus other graphic elements, such as a border, background pattern, or color, that is intended to convey specific information about the hazards of a chemical. Eight pictograms are designated under this standard for application to a hazard category.
4.7 Precautionary Statement – A phrase that describes recommended measures that should be taken to minimize or prevent adverse effects resulting from exposure to a hazardous chemical or improper storage or handling
4.8 Safety Data Sheet (SDS) – Written or printed material concerning a hazardous chemical that is prepared in accordance with the HCSs.
4.9 Hazardous Drug – As defined by the NIOAH Working Group, drugs considered hazardous include those that exhibit one or more of the following six characteristics in humans or animals:
4.9.1 Carcinogenicity
4.9.2 Teratogenicity or other developmental toxicity
4.9.3 Reproductive toxicity
4.9.4 Organ toxicity at low doses
4.9.5 Genotoxicity

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4.9.6 Structure and toxicity profiles of new drugs that mimic existing drugs determined hazardous by the above criteria.

5.0 Procedure:

5.1 Identification of Hazardous Chemicals in the Workplace

5.1.1 A list of hazardous substances present in the workplace is maintained. The list is compared to the NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings 2016 https://www.cdc.gov/niosh/topics/antineoplastic/pdf/hazardous-drugs-list_2016-161.pdf (Accessed June 2017)

5.1.2 The hazard classification of new or investigational medications entering the workplace is considered during the formulary management process. If classified as posing a health hazard, they are added to the organization's hazardous medication list.

5.2 Safety Data Sheets (SDSs)

5.2.1 A Safety Data Sheet is available in the workplace for each classified hazardous substance present in the workplace.

5.2.2 The SDS may be a hard copy and/or accessed on-line from various sources including facility subscribed SDS vendors and wholesale drug distributors.

5.2.3 The information provided on the SDS is standardized using a 16 section uniform format:

5.2.3.1 *Section 1: Identification* – includes product identifier; manufacturer or distributor name, address, phone number; emergency phone number; recommended use; restrictions on use.

5.2.3.2 *Section 2: Hazard(s) identification* – includes all hazards regarding the chemical; required label elements.

5.2.3.3 *Section 3: Composition/information on ingredients* – includes information on chemical ingredients; trade secret claims.

5.2.3.4 *Section 4: First-aid measures* – includes important symptoms/effects, acute, delayed; required treatment.

5.2.3.5 *Section 5: Fire-fighting measures* – lists suitable extinguishing techniques, equipment; chemical hazards from fire.

5.2.3.6 *Section 6: Accidental release measures* – lists emergency procedures; protective equipment; proper methods of containment and cleanup.

5.2.3.7 *Section 7: Handling and storage* – lists precautions for safe handling and storage, including incompatibilities.

5.2.3.8 *Section 8: Exposure controls/personal protection* – lists OSHAs Permissible Exposure Limits (PELs); Threshold Limit Values (TLVs); appropriate engineering controls; personal protective equipment (PPE).

5.2.3.9 *Section 9: Physical and chemical properties* – lists the chemical's characteristics.

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5.2.3.10 Section 10: Stability and *reactivity* – lists chemical stability and possibility of hazardous reactions.
5.2.3.11 *Section 11: Toxicological information* – includes routes of exposure; related symptoms, acute and chronic effects; numerical measures of toxicity
5.2.3.12 *Section 12: Ecological information* *
5.2.3.13 *Section 13: Disposal considerations**
5.2.3.14 *Section 14: Transport information**
5.2.3.15 *Section 15: Regulatory information**
5.2.3.16 *Section 16: Other information* – including date of preparation or last revision.
*Note: OSHA will not be enforcing Sections 12 through 15 (29 CFR 1910.1200(g)(2)) as these sections are enforced by other agencies.

5.2.4 Safety Data Sheets are provided by the supplier with (or prior to) the initial shipment of a classified hazardous substance and with the first shipment after a SDS is updated. If the SDS is not provided with a shipment that has been labeled as a hazardous chemical, one must be obtained as soon as possible.
5.2.5 If it is determined that a SDS is missing for one or more hazardous substances in the inventory, a request is forwarded to the supplier or the sheet is obtained from an on-line SDS data base.
5.2.6 Employees may not use any hazardous chemicals or medications if the SDS is not readily available.
5.2.7 Understanding the SDS format and information as well as accessing the SDSs is addressed in the employee training section below.

5.3 Container Labeling – Labels are intended to provide an immediate visual warning to employees of the potential hazard.
5.3.1 Labels on Shipped Containers
5.3.1.1 The chemical manufacturer or distributor ensures that each container of classified hazardous chemicals is labeled or marked with the HCS required labeling elements.
5.3.1.2 The following are the required HCS label elements:
5.3.1.2.1 *Product identifier* is how the hazardous chemical is identified. This can be (but is not limited to) the chemical name, code number or batch number. The manufacturer, importer or distributor can decide the appropriate product identifier. The same product identifier must be both on the label and in section 1 of the SDS;
5.3.1.2.2 A *Signal word* is used to indicate the relative level of severity of the hazard and alert the reader to a potential hazard on the label. There are only two words used as signal words within a specific hazard class, “Danger” is used for the more severe hazards and “Warning” is used for the less severe hazards.

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5.3.1.2.3 *Pictogram(s)* are graphic symbols used to communicate specific information about the hazards of a chemical.

5.3.1.2.4 *Hazard Statements* describe the nature of the hazard(s) of a chemical, including, where appropriate, the degree of hazard. The hazard statements are specific to the hazard classification categories, and chemical users should always see the same statement for the same hazards no matter what the chemical is or who produces it.

5.3.1.2.5 *Precautionary statement(s)* describe recommended measures that should be taken to minimize or prevent adverse effects resulting from exposure to the hazardous chemical or improper storage or handling. There are four types of precautionary statements: prevention (to minimize exposure); response (in case of accidental spillage or exposure emergency response, and first-aid); storage; and disposal.

5.3.1.2.6 *Name, address, and telephone number* of the chemical manufacturer, importer, or other responsible party.

5.3.2 Workplace Labeling

5.3.2.1 Labels on containers of hazardous chemicals provided by the manufacturer/distributor may not be removed or defaced.

5.3.2.2 Medications dispensed by the pharmacy to a health care provider for direct administration to a patient are *exempted* from the above HCS labeling requirement; however cautionary statements related to safe handling and disposition of the product should be included on the patient specific product label.

5.3.2.3 Product identifiers and words, pictures, symbols, or combination thereof, which provide at least general information regarding the hazards of the chemicals, and which, in conjunction with the other information immediately available to employees under the hazard communication program, provide employees with the specific information regarding the physical and health hazards of the hazardous chemical.

5.4 Employee Information and Training

5.4.1 Employees are provided information and training on hazardous chemicals in their work area at the time of their initial employment, and whenever a new chemical hazard is introduced into the work area.

5.4.2 The information and training provided may cover categories of hazards (e.g., flammability, carcinogenicity) or specific chemicals.

5.4.3 Chemical specific information must always be available through labels and Safety Data Sheets.

5.4.4 Employees are informed of:

5.4.4.1 Any operations in the work area where hazardous chemicals are present; and

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5.4.4.2 The location and availability of the written hazard communication program, including the required list(s) of hazardous chemicals and safety data sheets

5.4.5 Employee Training

5.4.5.1 New employees who may potentially be exposed to hazardous chemicals are provided information and training during the hospital's orientation program.

5.4.5.2 Refresher training is provided to employees at least annually.

5.4.5.3 Employee training includes but is not limited to:

5.4.5.3.1 Location and availability of the written Hazard Communication Program and OSHA Hazards Communication Standards (HCS)

5.4.5.3.2 The list of hazardous chemicals present in their work area and the physical and health hazards of these products

5.4.5.3.3 Explanation of the information contained on the labels received on shipped containers and the workplace labeling system when applicable.

5.4.5.3.4 The location of the Safety Data Sheets. How to obtain, interpret and use the information on the SDSs including the order of information

5.4.5.3.5 Methods and observations that may be used to detect the presence or release of a hazardous chemical in the work area such as visual appearance or odor of hazardous chemicals when being released

5.4.5.3.6 Measures employees can take to protect themselves from these hazards, including specific procedures implemented to protect employees from exposure to hazardous chemicals, such as appropriate work practices, emergency procedures, and the use of personal protective equipment

5.4.5.3.7 Procedures to follow if exposed to the hazardous chemicals.

5.4.5.4 Training records include the following:

5.4.5.4.1 Date(s) of the training session

5.4.5.4.2 Training session contents or summary

5.4.5.4.3 Names and qualifications of the person conducting the training

5.4.5.4.4 Names and job titles of all persons attending the training

5.4.6 Competency Assessment

5.4.6.1 Knowledge and competency is assessed for each employee after the initial training, the annual refresher training, or more often as needed.

5.5 Reporting and Recordkeeping

5.5.1 In the event of accidental contact or exposure to a hazardous chemical, employees should notify their manager, if appropriate, and seek immediate medical attention. The incident is reported to Employee Health, the department director, and Risk Management and an events report is filed per hospital policy.

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5.5.2 OSHA recommends that workplace exposure records be maintained for all employees who have handled hazardous drugs. This record and the employee's medical records should be maintained for the duration of employment plus 30 years. (Access to Employee Exposure and Medical Records Standard (29 CFR 1910.1020)

5.5.3 Training records should be maintained for three years from the date the training occurred.

6.0 References:

6.1 Joint Commission Standards MM.01.01.03 and EC.02.02.01:EP:8

6.2 CMS Interpretive Guidelines A-0326 §482.41(b)(2)

6.3 Healthcare Facilities Accreditation Program (HFAP) 25.00.00

6.4 DNV National Integrated Accreditation for Healthcare Organizations (NIAHO –DNV) MM.1, PE.5

6.5 Occupational Safety and Health Administration (OSHA) Hazardous Communication 2012 Aligns with the United Nations Globally Harmonized System of Classification and Labeling of Chemicals https://www.osha.gov/dsg/hazcom/ (Accessed March 2014)

6.6 OSHA, Regulation Standards CFR 29 Toxic and Hazardous Substances 1910.1200 Hazardous Communication http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10099 (Accessed March 2014)

6.7 OSHA Brief on Labels and Pictograms https://www.osha.gov/Publications/OSHA3636.pdf (Accessed March 2014)

6.8 OSHA Hospital e Tool Pharmacy Hazardous Communication Standard http://www.osha.gov/SLTC/etools/hospital/pharmacy/pharmacy.html#HazardCommunicationStandard (Accessed March 2014)

6.9 OSHA Technical Manual Section VI – Chapter 2. Controlling Occupational Exposure to Hazardous Drugs. http://www.osha.gov/dts/osta/otm/otm_vi/otm_vi_2.html#3 (Accessed March 2014)

6.10 National Institute for Occupational Safety and Health (NIOSH) List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings 2012 http://www.cdc.gov/niosh/docs/2012-150/pdfs/2012-150.pdf (Accessed March 2014)

6.11 NIOSH list of hazardous drugs updated annually at URL www.cdc.gov/niosh (Accessed March 2014)

6.12 MSDS Solutions Center http://www.msds.com/index.asp?open=/protected_public/loginsuccessful.asp (Accessed 2014)

7.0 Attachment List:

7.1 Attachment A – National Institute for Occupational Safety and Health (NIOSH) List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings 2016 https://www.cdc.gov/niosh/topics/antineoplastic/pdf/hazardous-drugs-list_2016-161.pdf (Accessed June 2017)

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7.2 Attachment B – Hazard Communication Standard Pictograms https://www.osha.gov/Publications/HazComm_QuickCard_Pictogram.html (Accessed June 2017)

7.3 Attachment C – OSHA Brief Hazard Communication Standard Safety Data Sheets https://www.osha.gov/Publications/OSHA3514.html (Accessed June 2017)

8.0 Summary of Revisions:

8.1 N/A

NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, 2016

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention
National Institute for Occupational Safety and Health

NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, 2016

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CDC-INFO: http://wwwn.cdc.gov/dcs/RequestForm.aspx

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Suggested Citation

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NIOSH evaluation of hazardous drugs does not cover NIOSH classification of chemical carcinogens. Although NIOSH hazardous drug evaluation includes consideration of carcinogenicity and genotoxicity, this evaluation is tailored to identify and evaluate data from human toxicity profiles, animal studies and in vitro studies unique to evaluating therapeutic agents. For example, NIOSH consults a variety of resources including, but not limited to, safety data sheets, product labeling approved by the U.S. Food and Drug Administration and databases such as DailyMed and DrugBank. For more information on NIOSH classification of chemical carcinogens see "NIOSH Chemical Carcinogen Policy," http://www.cdc.gov/niosh/index.htm.

DHHS (NIOSH) Publication No. 2016-161

September 2016

List of Acronyms

AHFS	American Hospital Formulary Service
ASHP	American Society of Health-System Pharmacists (formerly, American Society of Hospital Pharmacy)
BCG	Bacillus Calmette–Guérin
BSC	Biological safety cabinet
CACI	Compounding aseptic containment isolator
CFR	Code of Federal Regulations
CSTD	Closed system drug-transfer device
DPI	Drug package insert
EPA	Environmental Protection Agency
FDA	Food and Drug Administration
HEPA	High-efficiency particulate air
HIPEC	Heated intraperitoneal chemotherapy
IARC	International Agency for Research on Cancer
IV	Intravenous
MRHD	Maximum Recommended Human Dose
MSHG	Manufacturer's safe handling guidance
NIOSH	National Institute for Occupational Safety and Health
OEL	Occupational exposure limit
OSHA	Occupational Safety and Health Administration
ONS	Oncology Nursing Society
PPE	Personal protective equipment
SC	Subcutaneous
SDS	Safety Data Sheet (formerly Material Safety Data Sheet)
USP	United States Pharmacopeial Convention

Preamble: The *National Institute for Occupational Safety and Health (NIOSH) Alert: Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Healthcare Settings* was published in September 2004 (http://www.cdc.gov/niosh/docs/2004-165/). In Appendix A of the Alert, NIOSH identified a sample list of hazardous drugs. The list was compiled from information provided by four institutions that had generated lists of hazardous drugs for their respective institutions, as well as a list from the Pharmaceutical Research and Manufacturers of America (PhRMA). The 2004 list was updated in 2010, 2012, and 2014. The current update (2016) adds 34 drugs, five of which have safe-handling recommendations from the manufacturers. In 2014, a new format was developed for the list of hazardous drugs, as described below. The review process for the addition of the new listings is described in the Federal Register: http://www.cdc.gov/niosh/docket/review/docket233a/pdfs/233a_2015-12857.pdf.

Drugs Considered Hazardous

I. General Approach to Handling Hazardous Drugs

Early concerns about occupational exposure to antineoplastic drugs first appeared in the 1970s. Although the antineoplastic drugs remain the principal focus of the Alert, other drugs may also be considered hazardous because they are potent (small quantities produce a physiological effect) or cause irreversible effects. As the use and number of these potent drugs increase, so do opportunities for hazardous exposures among healthcare workers. For example, antineoplastic drugs such as cyclophosphamide and methotrexate have proved beneficial for treating nonmalignant diseases such as rheumatoid arthritis and multiple sclerosis.

In the Alert (NIOSH 2004) and updates to the hazardous drug list (NIOSH 2010 and 2012), NIOSH had previously recommended standard precautions (universal precautions) be taken in handling hazardous drugs. Given the addition of new drug formulations and drugs in tablet and/or capsule form to the list, no single approach can cover the diverse potential occupational exposures to the drugs. All listed drugs are considered hazardous, but safe-handling precautions can vary with the activity and the formulation of the drug. Table 5 provides some guidance on engineering controls and personal protective equipment (PPE) that applies to all listed drugs. The current NIOSH approach involves three groups of drugs:

- Group 1: Antineoplastic drugs (AHFS Classification 10:00) [ASHP/AHFS DI 2016]. Note that many of these drugs may also pose a reproductive risk for susceptible populations (Table 1).
- Group 2: Non-antineoplastic drugs that meet one or more of the NIOSH criteria for a hazardous drug. Note that some of these drugs may also pose a reproductive risk for susceptible populations (Table 2).
- Group 3: Drugs that primarily pose a reproductive risk to men and women who are actively trying to conceive and women who are pregnant or breast feeding, because some of these drugs may be present in breast milk (Table 3).

All hazardous drugs, regardless of the formulation, should be labeled as such to prevent improper handling. The majority of the reproductive risks associated with the drugs listed in Table 3 apply to women, but some can apply to men only (such as reduced fertility or sperm count) or to both men and women. Although all hazardous drugs should be handled according to recommended procedures, especially if they must be prepared aseptically, some populations of workers may not be at reproductive risk from handling drugs in Group 3. These include workers who are excluded from the susceptible populations for specific reasons such as age or infertility. In addition, drugs for which the manufacturer includes safe-handling guidance in the DPI are indicated. NIOSH carries out a hazard identification on each drug on the basis of the NIOSH criteria for a hazardous drug. No attempt has been made to perform risk assessments on each drug or to propose exposure limits. NIOSH has provided guidance for personal protective equipment and ventilated engineering controls for some of the various scenarios in which a drug may be handled in healthcare settings (Table 5). This guidance does not cover all possible situations but provides general recommendations for the typical handling situations in healthcare.

With the increased availability of oral antineoplastic and other hazardous drugs, additional precautions are required in order to prevent worker exposure to these formulations. Some drugs defined as hazardous may not pose a significant risk of direct occupational exposure because of their dosage formulation (for example, coated tablets or capsules—solid, intact medications that are administered to patients without modification of the formulation). However, they may pose a risk if the formulations are altered, such as by crushing tablets or making solutions from them outside a ventilated cabinet [Simmons 2010; Goodin et al. 2011]. Uncoated tablets may present a risk of exposure from dust by skin contact and/or inhalation when the tablets are counted [Shahsavarani et al. 1993; Ahmad et al. 2014]. Tablet and capsule forms of hazardous drugs should not be placed in automated counting machines, which subject them to stress and may introduce powdered contaminants into the work area [Fent et al. 2014]. Counting and pouring of hazardous drugs should be done carefully, and clean equipment should be dedicated for use with these drugs. Crushing tablets or opening capsules should be avoided and liquid formulations should be used whenever possible.

During the compounding of hazardous drugs (e.g., crushing, dissolving, or preparing a solution or an ointment), workers should wear nonpermeable gowns and double gloves (Table 5). Guidelines for the safe compounding, administration, and disposal of hazardous drugs have been developed by several organizations [NIOSH 2004; ASHP 2006; ONS 2011; USP 2016, OSHA 2016]. However, the lack of proper training for handling antineoplastic drugs in other specialty areas may be an issue that needs to be addressed [Abel 2000; Polovich and Giesker 2011; Menonna-Quinn et al. 2013].

II. Defining Hazardous Drugs

Hazardous drugs include those used for cancer chemotherapy, antiviral drugs, hormones, some bioengineered drugs, and other miscellaneous drugs. The NIOSH definition of hazardous drugs used in the Alert is based on a definition originally developed in 1990 by the American Society of Hospital Pharmacists [ASHP 1990], currently known as the American Society of Health-System Pharmacists. Thus, the NIOSH definition may not accurately indicate the potential toxicity criteria associated with some of the newer-generation pharmaceuticals used in healthcare. For example, bioengineered drugs target specific sites in the body, and although they may or may not pose a risk to healthcare workers, some may pose a risk to patients.

NIOSH and other organizations are still gathering data on the potential toxicity and health effects related to highly potent drugs and bioengineered drugs. Therefore, when working with any hazardous drug, healthcare workers should follow the approaches described in Table 5, along with any recommendations included in the manufacturer's Safety Data Sheet (SDS) or the drug package inserts (DPIs).

A. ASHP Definition of Hazardous Drugs

ASHP defines hazardous drugs in its 1990 revision of the Technical Assistance Bulletin on Handling

Hazardous Drugs* [ASHP 1990]. The bulletin gives criteria for identifying potentially hazardous drugs that should be handled in accordance with an established safety program [ASHP 2006; Massoomi et al. 2008; Eisenberg 2009; ONS 2011]. The criteria are prioritized to reflect the hierarchy of potential toxicity described below. Since the hazardous drugs covered by the Alert were designed as therapeutic agents for humans, human toxicity profiles should be given more weight than data from animal models or in vitro systems. Additional guidance for defining hazardous drugs is available from the following sources: carcinogenicity [61 Fed Register 17960–18011 (1996b); IARC 2014], teratogenicity [56 Fed Register 63798–63826 (1991)], developmental toxicity [56 Fed Register 63798–63826 (1991)], and reproductive toxicity [61 Fed Register 56274–56322 (1996a)].

B. NIOSH Revision of ASHP Definition

1. The 1990 ASHP definition of hazardous drugs was revised by the NIOSH Working Group on Hazardous Drugs for the Alert. Drugs considered hazardous include those that exhibit one or more of the following six characteristics in humans or animals:

   - Carcinogenicity
   - Teratogenicity or other developmental toxicity†
   - Reproductive toxicity†
   - Organ toxicity at low doses†
   - Genotoxicity‡
   - Structure and toxicity profiles of new drugs that mimic existing drugs determined hazardous by the above criteria

2. Determining Whether a Drug is Hazardous

Many hazardous drugs used to treat cancer (for example, alkylating agents) bind to or damage DNA. Other antineoplastic drugs, some antivirals, antibiotics, and bioengineered drugs interfere with cell growth or proliferation, or with DNA synthesis. In some cases, the nonselective actions of these drugs disrupt the growth and function of both healthy and diseased cells, resulting in toxic side effects for treated patients and their offspring. These nonselective actions can also cause adverse effects in healthcare workers who are inadvertently exposed to hazardous drugs. However, drugs other than those used to treat cancer may have toxic properties similar to those of the antineoplastic drugs. For some other drugs, adverse reproductive effects are the primary characteristic of concern for occupational exposure. NIOSH evaluates the potential of proposed additions to the list on the basis of these and other characteristics of the drugs.

This document presents criteria and sources of information for determining whether a drug is hazardous. When a drug has been judged to be hazardous, the various precautions outlined in the Alert should be applied when handling that drug. Also included is a list of drugs that should be handled as hazardous. When applying the criteria for a hazardous drug as outlined above, NIOSH takes the following approach.

*ASHP [1990] definition of hazardous drugs:
1. Genotoxicity (i.e., mutagenicity and clastogenicity in short-term test systems)
2. Carcinogenicity in animal models, in the patient population, or both, as reported by the International Agency for Research on Cancer (IARC)
3. Teratogenicity or fertility impairment in animal studies or in treated patients
4. Evidence of serious organ or other toxicity at low doses in animal models or treated patients.

†All drugs have toxic side effects, but some exhibit toxicity at low doses. The level of toxicity reflects a continuum from relatively nontoxic to production of toxic effects in patients at low doses (for example, a few milligrams or less). For example, a daily therapeutic dose of 10 mg/day or a dose of 1 mg/ kg per day in laboratory animals that produces serious organ toxicity, developmental toxicity, or reproductive toxicity has been used by the pharmaceutical industry to develop occupational exposure limits (OELs) of less than 10 µg/ m^3 after applying appropriate uncertainty factors [Sargent and Kirk 1988; Naumann and Sargent 1997; Sargent et al. 2002]. OELs in this range are typically established for potent or toxic drugs in the pharmaceutical industry. Under all circumstances, an evaluation of all available data should be conducted to protect healthcare workers.

‡In evaluating mutagenicity for potentially hazardous drugs, responses from multiple test systems are needed before precautions can be required for handling such agents. The EPA evaluations include the type of cells affected and in vitro versus in vivo testing [51 Fed Register 34006–34012 (1986)].

Reproductive and Developmental Toxicity

NIOSH takes into account the dose for animal testing of reproductive and developmental toxicity. If adverse effects are observed in animal testing near, at, or below the maximum recommended human dose (MRHD), NIOSH considers it to be highly relevant. If doses producing an adverse effect are many times the MRHD, usually NIOSH does not consider them in its evaluation.

For reproductive and developmental effects, NIOSH notes if there was maternal toxicity, in addition to the dose. Effects on the fetus in the absence of maternal toxicity are considered relevant. Many drugs with an FDA pregnancy category X rating meet the criteria for a hazardous drug and are listed, but each drug is evaluated individually. Similarly, for Category D, these drugs are often listed because many meet the criteria for being hazardous. Any available human data are considered significant. In June 2015, the FDA removed the pregnancy letter categories (A, B, C, D, and X) in prescription drug labeling. The new labeling was renamed "Pregnancy," "Lactation," and "Females and Males of Reproductive Potential" [FDA 2015]. The plan for the new labeling is to be phased in gradually for drugs approved on or after June 2001, but it went into effect immediately for drugs and biologic products submitted after June 2015. Therefore, the pregnancy letter categories are still in effect for most of the drugs described in this document, for the immediate future.

Carcinogenicity

In addition to dose, for carcinogenicity testing NIOSH looks for tumors in more than one species and sex. It looks for tumors in multiple organs and for tumors that are not rodent-specific. Any available human data are considered significant.

Genotoxicity

For effects of genotoxicity, NIOSH gives greater weight to in vivo testing than in vitro testing. However, adverse outcomes in several in vitro tests will be considered in its evaluation.

Organ Toxicity

For organ toxicity, the low-dose criterion in the definition (a daily therapeutic dose of 10 mg/day or a dose of 1 mg/kg per day in laboratory animals) is used as a benchmark.

Other

Drugs with safe-handling guidelines from the manufacturer are automatically put on the list because the manufacturer has determined their properties warrant special handling.

A NIOSH internal committee performs an initial review of all new FDA drug approvals and new warnings on existing drugs for a two-year period. Following this review, an expert panel consisting of peer reviewers and stakeholders reviews the proposed additions (and deletions, when applicable), using information in DrugBank, DailyMed, and the DPIs and SDSs. Additionally, a Federal Register Notice is published requesting comments on the proposed changes to the list. A final review of all information is performed by NIOSH, and the updated list is published on the NIOSH Hazardous Drug Topic Page (http://www.cdc.gov/niosh/topics/hazdrug/) and in the Federal Register.

In addition to using the list of hazardous drugs presented here, each organization should create its own list of drugs considered to be hazardous, based on drugs in its formulary. This document presents guidance for making such a facility-specific list (see section entitled How to Generate Your Own List of Hazardous Drugs). Subsequently, newly purchased drugs should be evaluated against the organization's hazardous drug criteria and added to the list if they are deemed hazardous. Organizations have developed various approaches to identifying and classifying hazardous drugs [Chaffee et al. 2010; Badry et al. 2013; Kaestli et al. 2013]. Although the classification schemes may differ somewhat, the drugs listed as hazardous are quite similar.

Individual organizations may not have adequate resources for determining their own list of hazardous drugs. If so, the list of hazardous drugs in this document will help employers and workers to determine when precautions are needed. However, reliance on such a published list is a concern because it quickly becomes outdated as new drugs continually enter the market or listed drugs are removed when additional information becomes available. NIOSH will update this list periodically by adding

drugs that meet its criteria and removing those that no longer meet its criteria. This hazardous drug list will be posted on the NIOSH website at www.cdc.gov/niosh/topics/hazdrug/. In addition, drugs that have safe-handling guidance from the manufacturers in the DPIs will be posted on this website after they are approved by the FDA.

III. How to Generate Your Own List of Hazardous Drugs

A. OSHA Hazard Communication

The OSHA hazard communication standard [29 CFR 1910.1200] requires employers to develop a hazard communication program appropriate for their unique workplaces. An essential part of the program is the identification of all hazardous chemicals a worker may encounter in the facility. Compliance with the OSHA hazard communication standard entails developing a list of hazardous chemicals (in this case, drugs) as part of the written hazardous communication program and informing workers where that list can be obtained. The criteria OSHA uses to identify hazardous chemicals, including hazardous drugs, are provided in that standard. Institutions may wish to compare their lists to the listing in this document or on the NIOSH website.

It is not likely that every healthcare provider or facility will use all drugs that have received U.S. Food and Drug Administration (FDA) approval. Instead, compliance requires practice-specific assessments for drugs used at any one time by a facility. However, hazardous drug evaluation is a continual process. Each facility must assess each new drug that enters its workplace to determine if it needs to be included in the Hazard Communication program and, when appropriate, reassess its list of hazardous drugs when new toxicological data become available. Toxicological data are often incomplete or unavailable for investigational drugs. However, if their mechanism of action suggests that there may be a concern, it is prudent to handle them as hazardous drugs until adequate information becomes available to exclude them.

B. NIOSH List of Hazardous Drugs

The following list (Tables 1–3) contains those drugs that NIOSH has reviewed according to the criteria in the NIOSH definition of a hazardous drug. The list was compiled from the following:

- the 2014 NIOSH update to the list
- the NIOSH 2016 update to the list, for which 34 drugs were added (including five with the manufacturers' safe-handling warnings).

The OSHA hazard communication standard requires a written program including a list of chemicals that meet the Hazard Communication definitions for hazardous, labelling, and employee training. The mandate applies not only to healthcare professionals who provide direct patient care but also to others who support patient care by participating in product acquisition, storage, transportation, housekeeping, and waste disposal. Institutions may want to adopt this list or compare theirs with the list on the NIOSH website.

CAUTION: Drugs purchased and used by a facility may have entered the marketplace after the list below was assembled. Therefore, this list may not be all-inclusive.

If you use a drug that is not included in the list of hazardous drugs, check the available literature to see whether the unlisted drug should be treated as hazardous. Check the SDS from the manufacturer or the DPI. You may also check with other institutions that might be using the same drug. If any of the documents mention carcinogenicity, genotoxicity, teratogenicity (Section 13 in the DPI), or reproductive or developmental toxicity (Section 8), or if the DPI contains safe-handling warnings (Section 16), then use the precautions stipulated in the Alert. If the drug meets one or more of the criteria for hazardous drugs in the NIOSH definition, handle it as hazardous.

The list of hazardous drugs will be updated periodically on the website http://www.cdc.gov/niosh/topics/hazdrug/.

This list supersedes the lists from 2004 (http://www.cdc.gov/niosh/docs/2004-165/), 2010, 2012, and 2014 (http://www.cdc.gov/niosh/docs/2014-138/).

C. Where to Find Information Related to Drug Toxicity

Practice-specific lists of hazardous drugs (usually developed by pharmacy or nursing departments) should be comprehensive, including all hazardous medications routinely used or very likely to be used by a local practice. Here are some of the resources that employers can use to evaluate the hazard potential of a drug:

- Safety Data Sheets (SDSs, formerly Material Safety Data Sheets)
- Product labeling approved by the U.S. FDA (DPIs)
- International Agency for Research on Cancer (IARC): http://www.iarc.fr
- DrugBank: http://www.drugbank.ca/
- DailyMed: http://dailymed.nlm.nih.gov/dailymed/
- Special health warnings from drug manufacturers, FDA, and other professional groups and organizations
- Reports and case studies published in medical and other healthcare profession journals
- Evidence-based recommendations from other facilities that meet the criteria defining hazardous drugs

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NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, 2016

NIOSH performs a hazard identification for each of the drugs in the following tables, based on its criteria as described above. The actual risk to healthcare workers depends on toxicity of the drugs, how the drugs can enter the body (e.g., dermal, inhalation, or ingestion), and how the drugs are handled—how they are manipulated, how often they are handled, and the exposure controls in place, such as the type of engineering controls and personal protective equipment (PPE) (see Table 5). For example,

- Dispensing a single tablet to a patient may pose a relatively low risk to the healthcare worker. A single pair of gloves may be adequate.
- Repeatedly counting, cutting, or crushing tablets may pose a higher risk for worker exposure than dispensing a single tablet and contamination to the workplace if exposure controls are not in place. If a containment device such as a BSC (Class II biological safety cabinet) or CACI (compounding aseptic containment isolator) is not available, then double gloves, a protective gown, respiratory protection, and a disposable pad to protect the work surface should be used.
- Preparing several intravenous doses of an antineoplastic drug typically poses a higher potential risk to the worker. In addition to double gloving and a protective gown, an engineering control such as a BSC or CACI, possibly supplemented with a CSTD (closed system drug-transfer device), is necessary to protect the drug, environment, and healthcare worker.

The drugs in **Table 1** meet one or more of the NIOSH criteria for a hazardous drug. In addition to many of these drugs being cytotoxic, the majority are hazardous to males or females who are actively trying to conceive, women who are pregnant or may become pregnant, and women who are breast feeding, because they may be present in breast milk.

These drugs represent an occupational hazard to healthcare workers and should always be handled with use of recommended engineering controls and personal protective equipment (PPE), regardless of their formulation (IV [intravenous], SC [subcutaneous], topical, tablet, or capsule). Unopened, intact tablets and capsules may not pose the same degree of occupational exposure risk as injectable drugs, which usually require extensive preparation. Cutting, crushing, or otherwise manipulating tablets and capsules will increase the risk of exposure to workers. The manufacturer's safe-handling guidance (MSHG) is typically in Section 16 of the DPI. See Table 5 for safe-handling recommendations.

Abbreviations and footnotes. AHFS = American Hospital Formulary Service; MRHD = maximum recommended human dose.

*Drugs in red font were added in 2016.

National Toxicology Program classifications (http://ntp.niehs.nih.gov/pubhealth/roc/index.html): **Known To Be Human Carcinogens; ***Reasonably Anticipated To Be Human Carcinogens.

†International Agency for Research on Cancer (www.iarc.fr): Group 1, Carcinogenic to Humans; Group 2A, Probably Carcinogenic to Humans; Group 2B, Possibly Carcinogenic to Humans.

‡BCG, although classified as a vaccine, is used in the treatment of certain cancers. BCG should be prepared with aseptic techniques. To avoid cross-contamination, parenteral drugs should not be prepared in areas where BCG has been prepared. A separate area for the preparation of BCG suspension is recommended. All equipment, supplies, and receptacles in contact with BCG should be handled and disposed of as biohazardous. If preparation cannot be performed in a containment device, then respiratory protection, gloves, and a gown should be worn to avoid inhalation or contact with BCG organisms.

‡‡MSHG was removed in 2015 by the manufacturer.

Table 1. Group 1: Antineoplastic drugs, including those with the manufacturer's safe-handling guidance (MSHG)

Drug	AHFS classification	MSHG	Supplemental information	Links
abiraterone	10:00 antineoplastic agents		Women who are pregnant or may be pregnant should not handle without protection (e.g., gloves); FDA Pregnancy Category X	DailyMed; DrugBank
ado-trastuzumab emtansine	10:00 antineoplastic agents	yes	Conjugated monoclonal antibody; FDA Pregnancy Category D	DailyMed; DrugBank
afatinib*	10:00 antineoplastic agents		Special warnings on contraception for females while taking and 2 weeks post-treatment; FDA Pregnancy Category D	DailyMed; DrugBank

(Continued)

Table 1 (Continued). Group 1: Antineoplastic drugs, including those with the manufacturer's safe-handling guidance (MSHG)

Drug	AHFS classification	MSHG	Supplemental information	Links
altretamine	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; DrugBank
amsacrine	NA antineoplastic agents	yes	IARC Group 2B†	DrugBank
anastrozole	10:00 antineoplastic agents		FDA Pregnancy Category X	DailyMed; DrugBank
arsenic trioxide	10:00 antineoplastic agents	yes	IARC Group 1 carcinogen; NTP**; FDA Pregnancy Category D	DailyMed; DrugBank
axitinib	10:00 antineoplastic agents		Teratogenic, embryotoxic and fetotoxic in mice at exposures lower than human exposures; FDA Pregnancy category D	DailyMed; DrugBank
azacitidine	10:00 antineoplastic agents	yes	IARC Group 2A carcinogen; NTP***; FDA Pregnancy Category D	DailyMed; DrugBank
Bacillus Calmette Guerin (BCG)	80:12 vaccines	yes	See special handling requirements‡; FDA Pregnancy Category C	DailyMed
belinostat	10:00 antineoplastic agents	yes	May cause teratogenicity and/or embryo-fetal lethality because it is a genotoxic drug and targets actively dividing cells; FDA Pregnancy Category D	DailyMed; DrugBank
bendamustine	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; DrugBank
bexarotene	10:00 antineoplastic agents		FDA Pregnancy Category X	DailyMed; DrugBank
bicalutimide	10:00 antineoplastic agents		FDA Pregnancy Category X	DailyMed; DrugBank
bleomycin	10:00 antineoplastic agents	yes	IARC Group 2B; FDA Pregnancy Category D	DailyMed; DrugBank
bortezomib	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; DrugBank

(Continued)

Table 1 (Continued) Group 1: Antineoplastic drugs, including those with the manufacturer's safe-handling guidance (MSHG)

Drug	AHFS classification	MSHG	Supplemental information	Links
bosutinib	10:00 antineoplastic agents		FDA Pregnancy Category D	DailyMed; DrugBank
brentuximab vedotin	10:00 antineoplastic agents	yes	Conjugated monoclonal antibody; FDA Pregnancy Category D	DailyMed; DrugBank
busulfan	10:00 antineoplastic agents	yes	IARC Group 1 carcinogen; FDA Pregnancy Category D	DailyMed; DrugBank
cabazitaxel	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; DrugBank
cabozantinib	10:00 antineoplastic agents		Embryolethal in rats at exposures below the recommended human dose; FDA Pregnancy category D	DailyMed; DrugBank
capecitabine	10:00 antineoplastic agents	yes	Metabolized to 5-fluorouracil; FDA Pregnancy Category D	DailyMed; DrugBank
carboplatin	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; DrugBank
carfilzomib	10:00 antineoplastic agents		Special warnings on contraception while taking and 2 weeks post- treatment; FDA Pregnancy category D	DailyMed; DrugBank
carmustine	10:00 antineoplastic agents	yes	IARC Group 2A carcinogen; NTP***; FDA Pregnancy Category D	DailyMed; DrugBank
chlorambucil	10:00 antineoplastic agents	yes	IARC Group 1 carcinogen; NTP**; FDA Pregnancy Category D	DailyMed; DrugBank
cisplatin	10:00 antineoplastic agents	yes	IARC Group 2A carcinogen; NTP***; FDA Pregnancy Category D	DailyMed; DrugBank
cladribine	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; DrugBank
clofarabine	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; DrugBank

(Continued)

Table 1 (Continued). Group 1: Antineoplastic drugs, including those with the manufacturer's safe-handling guidance (MSHG)

Drug	AHFS classification	MSHG	Supplemental information	Links
crizotinib	10:00 antineoplastic agents		FDA Pregnancy Category D	DailyMed; DrugBank
cyclophospha-mide	10:00 antineoplastic agents	yes	IARC Group 1 carcinogen; NTP**; FDA Pregnancy Category D	DailyMed; Drugbank
cytarabine	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; DrugBank
dabrafenib	10:00 antineoplastic agents		Special warnings on contraception for females while taking and 2 weeks post-treatment; FDA Pregnancy Category D	DailyMed; DrugBank
dacarbazine	10:00 antineoplastic agents	yes	NTP***; FDA Pregnancy Category C	DailyMed; Drugbank
dactinomycin	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; DrugBank
dasatinib	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; Drugbank
daunorubicin	10:00 antineoplastic agents	yes	IARC Group 2B, AKA daunomycin; FDA Pregnancy Category D	DailyMed; Drugbank
decitabine	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; Drugbank
degarelix	10:00 antineoplastic agents	-‡‡	FDA Pregnancy Category X	DailyMed; Drugbank
docetaxel	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; DrugBank
doxorubicin	10:00 antineoplastic agents	yes	IARC Group 2A carcinogen; NTP***; FDA Pregnancy Category D	DailyMed; DrugBank
enzalutamide	10:00 antineoplastic agents		Embryo-fetal toxicity in mice at exposures that were lower than in patients receiving the recommended dose; FDA Pregnancy Category X	DailyMed; DrugBank

(Continued)

Table 1 (Continued). Group 1: Antineoplastic drugs, including those with the manufacturer's safe-handling guidance (MSHG)

Drug	AHFS classification	MSHG	Supplemental information	Links
epirubicin	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; Drugbank
eribulin	10:00 antineoplastic agents		FDA Pregnancy Category D	DailyMed; DrugBank
erlotinib	10:00 antineoplastic agents		FDA Pregnancy Category D	DailyMed; DrugBank
estramustine	10:00 antineoplastic agents	yes	FDA Pregnancy Category X	DailyMed; Drugbank
etoposide	10:00 antineoplastic agents	yes	IARC Group 1 carcinogen; FDA Pregnancy Category D	DailyMed; DrugBank
everolimus	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; Drugbank
exemestane	10:00 antineoplastic agents		FDA Pregnancy Category X	DailyMed; DrugBank
floxuridine	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; DrugBank
fludarabine	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; DrugBank
fluorouracil	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; DrugBank
flutamide	10:00 antineoplastic agents		Indicated only for men; FDA Pregnancy Category D	DailyMed; DrugBank
fulvestrant	10:00 antineoplastic agents		FDA Pregnancy Category D	DailyMed; DrugBank
gemcitabine	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; DrugBank
gemtuzumab ozogamicin	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; DrugBank
goserelin	10:00 antineoplastic agents		FDA Pregnancy Category X	DailyMed; Drugbank
histrelin	10:00 antineoplastic agents		Can cause fetal harm when administered to a pregnant patient, with the possibility of spontaneous abortion; FDA Pregnancy Category X	DailyMed; DrugBank

(Continued)

Table 1 (Continued). Group 1: Antineoplastic drugs, including those with the manufacturer's safe-handling guidance (MSHG)

Drug	AHFS classification	MSHG	Supplemental information	Links
hydroxyurea	10:00 antineoplastic agents	yes	Special warning on handling bottles and capsules; FDA Pregnancy Category D	DailyMed; DrugBank
idarubicin	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; DrugBank
ifosfamide	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; DrugBank
imatinib	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; DrugBank
irinotecan	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; DrugBank
ixazomib	10:00 antineoplastic agents	yes	Male and female patients of childbearing potential must use effective contraceptive measures during and for 3 months following treatment	DailyMed; DrugBank
ixabepilone	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; DrugBank
letrozole	10:00 antineoplastic agents		FDA Pregnancy Category X	DailyMed; DrugBank
leuprolide	10:00 antineoplastic agents	yes	FDA Pregnancy Category X	DailyMed; DrugBank
lomustine	10:00 antineoplastic agents	yes	IARC Group 2A carcinogen; NTP***; FDA Pregnancy Category D	DailyMed; DrugBank
mechlorethamine	10:00 antineoplastic agents	yes	NTP***; FDA Pregnancy Category D	DailyMed; DrugBank
megestrol	10:00 antineoplastic agents	yes	Nursing should be discontinued if megestrol is required; women at risk of pregnancy should avoid exposure; FDA Pregnancy Category X	DailyMed; DrugBank
melphalan	10:00 antineoplastic agents	yes	IARC Group 1 carcinogen; NTP**; FDA Pregnancy Category D	DailyMed; DrugBank

(Continued)

Table 1 (Continued). Group 1: Antineoplastic drugs, including those with the manufacturer's safe-handling guidance (MSHG)

Drug	AHFS classification	MSHG	Supplemental information	Links
mercaptopurine	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; DrugBank
methotrexate	10:00 antineoplastic agents	yes	FDA Pregnancy Category X	DailyMed; DrugBank
mitomycin	10:00 antineoplastic agents	yes	IARC Group 2B; FDA Pregnancy Category D	DailyMed; DrugBank
mitotane	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; DrugBank
mitoxantrone	10:00 antineoplastic agents	yes	IARC Group 2B; FDA Pregnancy Category D	DailyMed; DrugBank
nelarabine	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; DrugBank
nilotinib	10:00 antineoplastic agents		FDA Pregnancy Category D	DailyMed; DrugBank
omacetaxin	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; DrugBank
oxaliplatin	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; DrugBank
paclitaxel	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; DrugBank
panobinostat	10:00 antineoplastic agents	yes	Special warnings on contraception for females while taking and 1 month post-treatment;	DailyMed; DrugBank
pazopanib	10:00 antineoplastic agents		FDA Pregnancy Category D	DailyMed; DrugBank
pemetrexed	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; DrugBank
pentostatin	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; DrugBank
pertuzumab	10:00 antineoplastic agents		Black Box warning on embryo-fetal death and birth defects; FDA Pregnancy Category D	DailyMed; DrugBank

(Continued)

Table 1 (Continued). Group 1: Antineoplastic drugs, including those with the manufacturer's safe-handling guidance (MSHG)

Drug	AHFS classification	MSHG	Supplemental information	Links
pomalidomide	10:00 antineoplastic agents	yes	Females of reproductive potential must use two forms of contraception or continuously abstain from heterosexual sex during and for 4 weeks after stopping treatment; FDA Pregnancy Category X	DailyMed; DrugBank
ponatinib	10:00 antineoplastic agents		FDA Pregnancy Category D	DailyMed; DrugBank
pralatrexate	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; DrugBank
procarbazine	10:00 antineoplastic agents	yes	IARC Group 2A carcinogen; NTP***; FDA Pregnancy Category D	DailyMed; DrugBank
regorafenib	10:00 antineoplastic agents		Black Box warning on severe and sometimes fatal hepatotoxicity; total loss of pregnancy at doses lower than recommended human dose; FDA Pregnancy Category D	DailyMed; DrugBank
romidepsin	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; DrugBank
sorafenib	10:00 antineoplastic agents		FDA Pregnancy Category D	DailyMed; DrugBank
streptozocin	10:00 antineoplastic agents	yes	IARC Group 2B; NTP***; FDA Pregnancy Category D	DailyMed; DrugBank
sunitinib	10:00 antineoplastic agents		FDA Pregnancy Category D	DailyMed; DrugBank
tamoxifen	10:00 antineoplastic agents		IARC Group 1 carcinogen; NTP**; FDA Pregnancy Category D	DailyMed; DrugBank
temozolomide	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; DrugBank
temsirolimus	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; DrugBank

(Continued)

Table 1 (Continued). Group 1: Antineoplastic drugs, including those with the manufacturer's safe-handling guidance (MSHG)

Drug	AHFS classification	MSHG	Supplemental information	Links
teniposide	10:00 antineoplastic agents	yes	IARC Group 2A carcinogen; FDA Pregnancy Category D	DailyMed; DrugBank
thioguanine	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; DrugBank
thiotepa	10:00 antineoplastic agents	yes	IARC Group 1 carcinogen; NTP**; FDA Pregnancy Category D	DailyMed; DrugBank
topotecan	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; DrugBank
toremifene	10:00 antineoplastic agents		FDA Pregnancy Category D	DailyMed; DrugBank
trametinib	10:00 antineoplastic agents		Embryotoxic and abortifacient at doses less than recommended human dose; FDA Pregnancy Category D	DailyMed; DrugBank
trifluridine/tipiracil (combination only)	10:00 antineoplastic agents	yes	Embryo-fetal lethality and embryo-fetal toxicity at doses lower than or similar to exposures at the recommended human dose	DailyMed; DrugBank; DrugBank
triptorelin	10:00 antineoplastic agents		FDA Pregnancy Category X	DailyMed; DrugBank
valrubicin	10:00 antineoplastic agents	yes	FDA Pregnancy Category C	DailyMed; DrugBank
vandetanib	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; DrugBank
vemurafenib	10:00 antineoplastic agents		FDA Pregnancy Category D	DailyMed; DrugBank
vinblastine	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; DrugBank
vincristine	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; DrugBank
vinorelbine	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; DrugBank

(Continued)

Table 1 (Continued). Group 1: Antineoplastic drugs, including those with the manufacturer's safe-handling guidance (MSHG)

Drug	AHFS classification	MSHG	Supplemental information	Links
vismodegib	10:00 antineoplastic agents		Black Box warning on embryo-fetal death or severe birth defects; recommend effective contraception for females during therapy and for 7 months after treatment; present in semen; no sperm donation during and 3 months post-treatment; FDA Pregnancy Category D	DailyMed; DrugBank
vorinostat	10:00 antineoplastic agents	yes	Adverse embryo-fetal effects at less than the recommended human dose; FDA Pregnancy Category D	DailyMed; DrugBank
ziv-aflibercept	10:00 antineoplastic agents		Embryotoxic and teratogenic in rabbits at exposure levels lower than human exposures at the recommended dose, with increased incidences of external, visceral, and skeletal fetal malformations; FDA Pregnancy Category C	DailyMed; DrugBank

The drugs in **Table 2** meet one or more of the NIOSH criteria for a hazardous drug. Some of these drugs may represent an occupational hazard to males or females who are actively trying to conceive, women who are pregnant or may become pregnant, and women who are breast feeding, because they may be present in breast milk.

Unopened, intact tablets and capsules may not pose the same degree of occupational exposure risk as injectable drugs, which usually require extensive preparation. Cutting, crushing, or otherwise manipulating tablets and capsules will increase the risk of exposure to workers. The manufacturer's safe-handling guidance (MSHG) is typically in Section 16 of the DPI. See Table 5 for safe-handling recommendations.

Abbreviations and footnotes. AHFS = American Hospital Formulary Service; MRHD = maximum recommended human dose.

*Drugs in blue font meet one or more criteria for a hazardous drug and also pose a potential reproductive hazard.

National Toxicology Program (http://ntp.niehs.nih.gov/pubhealth/roc/index.html): **Known To Be Human Carcinogens; ***Reasonably Anticipated To Be Human Carcinogens.

†International Agency for Research on Cancer (www.iarc.fr): Group 1, Carcinogenic to Humans; Group 2A, Probably Carcinogenic to Humans; Group 2B, Possibly Carcinogenic to Humans.

‡Drugs in red font were added in 2016.

Table 2. Group 2: Non-antineoplastic drugs that meet one or more of the NIOSH criteria for a hazardous drug, including those with the manufacturer's safe-handling guidance (MSHG)

Drug	AHFS classification	MSHG	Supplemental information	Links
abacavir	8:18.08.20 nucleoside and reverse transcriptase inhibitors		FDA Pregnancy Category C; malignant tumors observed in male and female mice and rats; genotoxic in in vivo micronucleus test	DailyMed; DrugBank
alefacept	84:92 skin and mucous membrane agents, miscellaneous		Increased frequency of malignancies observed in treated patients; FDA Pregnancy Category B	DailyMed; DrugBank
carbamazepine	28:12:92 anticonvulsants, miscellaneous		Black Box warning for aplastic anemia; congenital malformations in offspring of mothers who took drug; rapid transplacental passage; FDA Pregnancy Category D*	DailyMed; DrugBank
apomorphine	28:36.20.08 non-ergot-derivative dopamine receptor agonists		FDA Pregnancy Category C; genotoxic in several in vitro assays	DailyMed; DrugBank

(Continued)

Table 2 (Continued). Group 2: Non-antineoplastic drugs that meet one or more of the NIOSH criteria for a hazardous drug, including those with the manufacturer's safe-handling guidance (MSHG)

Drug	AHFS classification	MSHG	Supplemental information	Links
azathioprine	92:44 immunosuppressants	yes	IARC Group 1 carcinogen†; NTP**; FDA Pregnancy Category D	DailyMed; DrugBank
chloramphenicol	8:12:08 chloramphenicols		IARC Group 2A carcinogen; NTP***; FDA Pregnancy Category C	DailyMed; DrugBank
cidofovir	8:18:32 nucleosides and nucleotides	yes	FDA Pregnancy Category C	DailyMed; DrugBank
cyclosporine	92:44 immunosuppressive agents		IARC Group 1 carcinogen; NTP**; FDA Pregnancy Category C	DailyMed; DrugBank
deferiprone	64:00 heavy metal antagonists		Genotoxic in vitro and in vivo; FDA Pregnancy Category D	DailyMed; DrugBank
dexrazoxane	92:56 protective agents	yes	FDA Pregnancy Category C; secondary malignancies observed in patients treated long term with Razoxane (a racemic mixture containing dexrazoxane); genotoxic in vitro and in vivo; in laboratory studies, testicular atrophy observed at or below the human dose	DailyMed; DrugBank
diethylstilbestrol	NA		IARC Group 1 carcinogen; NTP**; FDA Pregnancy Category X	DrugBank
divalproex	28:12:92 anticonvulsants, miscellaneous		Black Box warning for teratogenicity; FDA Pregnancy Category D; tumors seen in laboratory studies at doses below MRHD	DailyMed; DrugBank
entecavir	8:18:32 nucleosides and nucleotides		FDA Pregnancy Category C	DailyMed; DrugBank

(Continued)

Table 2 (Continued). Group 2: Non-antineoplastic drugs that meet one or more of the NIOSH criteria for a hazardous drug, including those with the manufacturer's safe-handling guidance (MSHG)

Drug	AHFS classification	MSHG	Supplemental information	Links
estradiol	68:16:04 estrogens		Black Box warning for malignant neoplasms; increased risk of endometrial cancer, breast cancer, and ovarian cancer; in laboratory studies, increased frequency of carcinomas of the breast, uterus, cervix, vagina, testis, and liver; present in breast milk; FDA Pregnancy Category X	DailyMed; DrugBank
estrogen/ progesterone combinations	68:12 contraceptives		IARC Group 1 carcinogen; NTP**; FDA Pregnancy Category X	DailyMed
estrogens, conjugated	68:16:04 estrogens		Black Box warning for endometrial cancer and cardiovascular risks; long-term use in women and laboratory studies increases frequency of several cancers; NTP**; FDA Pregnancy Category X	DailyMed; DrugBank
estrogens, esterified	68:16:04 estrogens		Black Box warning for endometrial cancer and cardiovascular risks; NTP**; FDA Pregnancy Category X	DailyMed; DrugBank
estropipate	68:16:04 estrogens		Black Box warning for endometrial carcinoma in postmenopausal women and use during pregnancy; FDA Pregnancy Category X	DailyMed; DrugBank
fingolimod	92:20 biologic response modifiers		FDA Pregnancy Category C; in laboratory studies, increased malformations and embryofetal deaths at less than the recommended human dose; malignant lymphomas observed in male and female mice	DailyMed; DrugBank
fluoxymesterone	68:08 androgens		Tumors in mice and rats and possibly humans; FDA Pregnancy Category X	DailyMed; DrugBank

(Continued)

Table 2 (Continued). Group 2: Non-antineoplastic drugs that meet one or more of the NIOSH criteria for a hazardous drug, including those with the manufacturer's safe-handling guidance (MSHG)

Drug	AHFS classification	MSHG	Supplemental information	Links
fosphenytoin	28:12.12 hydantoins		Metabolized to phenytoin; FDA Pregnancy Category D	DailyMed; DrugBank
ganciclovir	8:18:32 nucleosides and nucleotides	yes	FDA Pregnancy Category C	DailyMed; DrugBank
leflunomide	92:36 disease-modifying antirheumatic agents		Teratogenic in laboratory studies at 1/10 human dose (HD); marked postnatal survival at 1/100 HD; FDA Pregnancy Category X; severe liver injury reported in patients; carcinogenicity observed at doses below HD	DailyMed; DrugBank
lenalidomide	92:20 biologic response modulators	yes	Analog of thalidomide; FDA Black Box warnings for limb abnormalities; Pregnancy Category X; in laboratory studies, caused thalidomide-type limb defects in monkey offspring	DailyMed; DrugBank
liraglutide recombinant	68:20.06 incretin mimetics		FDA Pregnancy Category C; Black Box warning for thyroid C-cell tumors, with supporting evidence in laboratory studies; also in laboratory studies, teratogenic at or below the MRHD	DailyMed; DrugBank
medroxyprogesterone acetate	68:32 progestins	yes	IARC Group 2B; FDA Pregnancy Category X	DailyMed; DrugBank
methimazole‡	68:36:08 antithyroid agents		Appears in human breast milk; FDA Pregnancy Category D	DailyMed; DrugBank
mipomersen	24:06:92 antilipemic agents, miscellaneous		Black Box warning on hepatotoxicity; FDA Pregnancy Category B	DailyMed; DrugBank

(Continued)

Table 2 (Continued). Group 2: Non-antineoplastic drugs that meet one or more of the NIOSH criteria for a hazardous drug, including those with the manufacturer's safe-handling guidance (MSHG)

Drug	AHFS classification	MSHG	Supplemental information	Links
mycophenolate mofetil	92:44 immunosuppressive agents		Black Box warning for embryo fetal toxicity, malignancies, and serious infections; increased risk of first-trimester pregnancy loss and increased risk of congenital malformations; FDA Pregnancy Category D; Special warning: Tablets should not be crushed and capsules should not be opened or crushed. Avoid inhalation or direct contact with skin or mucous membranes of the powder contained in capsules and oral suspension (before or after constitution). If such contact occurs, wash thoroughly with soap and water; rinse eyes with plain water.	DailyMed; DrugBank
mycophenolic acid	92:44 immunosuppressive agents		Black Box warning for first trimester pregnancy loss and an increased risk of congenital malformations; FDA Pregnancy Category D; Black Box warning for lymphomas and other malignancies; genotoxic in vitro and in vivo	DailyMed; DrugBank
nevirapine	8:18.08.16 nonnucleoside reverse transcriptase inhibitors		FDA Pregnancy Category B; in laboratory studies, hepatocellular adenomas and carcinomas at doses lower than human dose	DailyMed; DrugBank
ospemifene	68:16:12 estrogen agonists-antagonists		Black Box warning on increased risk of endometrial cancer in certain populations; risk of adverse outcomes during pregnancy and labor; FDA Pregnancy Category X	DailyMed; DrugBank
oxcarbazepine	28:12:92 anticonvulsants, miscellaneous		Tumors observed in laboratory studies at 1/10 MRHD; FDA Pregnancy Category C	DailyMed; DrugBank

(Continued)

Table 2 (Continued). Group 2: Non-antineoplastic drugs that meet one or more of the NIOSH criteria for a hazardous drug, including those with the manufacturer's safe-handling guidance (MSHG)

Drug	AHFS classification	MSHG	Supplemental information	Links
palifermin	84:16 cell stimulants and proliferants		FDA Pregnancy Category C; potential for stimulation of tumor growth	DailyMed; DrugBank
paliperidone	28:16:08:04 atypical antipsychotics		Metabolite of risperidone; excreted in human breast milk; FDA Pregnancy Category C	DailyMed; DrugBank
phenoxybenzamine	12:16:04:04 non-selective alpha-andrenergic blocking agents		IARC Group 2B; FDA Pregnancy Category C	DailyMed; DrugBank
phenytoin	28:12.12 hydantoins		IARC Group 2B; NTP***; FDA Pregnancy Category D	DailyMed; DrugBank
pipobroman	NA		FDA Pregnancy Category D	DrugBank
progesterone	68:32 progestins		IARC Group 2B; NTP***	DailyMed; DrugBank
progestins	68:12 contraceptives		FDA Pregnancy Category X	DailyMed
propylthiouracil	68:36.08 antithyroid agents		IARC Group 2B; NTP***; FDA Pregnancy Category D	DailyMed; DrugBank
raloxifene	68:16:12 estrogen agonists-antagonists		Abortion and developmental abnormalities seen at low doses in laboratory studies; evidence of tumors at low doses in laboratory studies; FDA Pregnancy Category X	DailyMed; DrugBank
rasagiline	28:36 antiparkinsonian agents		FDA Pregnancy Category C	DailyMed; DrugBank
risperidone	28:16:08:04 atypical anti-psychotics		Evidence of tumors at low doses in laboratory studies; may be prolactin-mediated; FDA Pregnancy Category C	DailyMed; DrugBank
sirolimus	92:44 immunosuppressive agents		AKA rapamycin; increased risk of lymphomas and other malignancies; embryotoxic and fetotoxic at 0.2 human dose; FDA Pregnancy Category C	DailyMed; DrugBank

(Continued)

Table 2 (Continued). Group 2: Non-antineoplastic drugs that meet one or more of the NIOSH criteria for a hazardous drug, including those with the manufacturer's safe-handling guidance (MSHG)

Drug	AHFS classification	MSHG	Supplemental information	Links
spironolactone	24:32.20 mineralocorticoid receptor antagonists		FDA Pregnancy Category C; Black Box warning for tumorogenicity in laboratory studies	DailyMed; DrugBank
tacrolimus	92:44 immunosuppressive agents		Increased risk of lymphomas and other malignancies; reproductive effects seen in laboratory studies below the MRHD; excreted in breast milk; FDA Pregnancy Category C	DailyMed; DrugBank
teriflunomide	92:20 immunomodulatory agents		Black Box warning on severe hepatotoxicity and teratogenicity, including major birth defects; FDA Pregnancy Category X	DailyMed; DrugBank
thalidomide	92:20 biologic response modulators	yes	FDA Pregnancy Category X	DailyMed; DrugBank
tofacitinib	92:36 disease modifying antirheumatic drugs		Black Box warning for lymphoma and other malignancies; FDA Pregnancy Category C	DailyMed; DrugBank
uracil mustard	NA	yes	FDA Pregnancy Category D	DrugBank
valganciclovir	8:18:32 nucleosides and nucleotides	yes	FDA Pregnancy Category C	DailyMed; DrugBank
zidovudine	8:18:08 antiretroviral agents		IARC Group 2B; FDA Pregnancy Category C	DailyMed; DrugBank

The drugs in **Table 3** primarily meet the NIOSH criteria for reproductive hazards. They represent a potential occupational hazard to males or females who are actively trying to conceive, women who are pregnant or may become pregnant, and women who are breast feeding, as they may be present in breast milk. Unopened, intact tablets and capsules may not pose the same degree of occupational risk as injectable drugs that usually require extensive preparation. Cutting, crushing, or otherwise manipulating tablets and capsules will increase the risk of exposure to workers. The manufacturer's safe-handling guidance (MSHG) is typically in Section 16 of the DPI. See Table 5 for safe handling recommendations.

*Drugs in red font were added in 2016.

Table 3. Group 3: Non-antineoplastic drugs that primarily have adverse reproductive effects

Drug	AHFS classification	Supplemental information	Links
acitretin	88:04 vitamin A	Black Box warning on adverse reproductive effects; FDA Pregnancy Category X	DailyMed; DrugBank
alitretinoin	84:92 skin and mucous membrane agents, miscellaneous	FDA Pregnancy Category D	DailyMed; DrugBank
ambrisentan	24:12:92 vasodilating agents, miscellaneous	Black Box warning on adverse reproductive effects; reduced sperm counts in patients; FDA Pregnancy Category X	DailyMed; DrugBank
bosentan	24:12:92 vasodilating agents, miscellaneous	Black Box warning on adverse reproductive effects; Pregnancy Category X	DailyMed; DrugBank
cabergoline	28:36:20:04 ergot-derivative dopamine receptor agonists	Inhibition of conception and embryo fetal effects at doses below recommended human dose; FDA Pregnancy Category B	DailyMed; DrugBank
cetrorelix	92:40 gonadotropin-releasing hormone antagonists	FDA Pregnancy Category X	DailyMed; DrugBank
choriogonadotropin	68:18 gonadotropins	FDA Pregnancy Category X; may cause fetal harm when administered to a pregnant woman	DailyMed; DrugBank
clomiphene*	68:16:12 estrogen agonist-antagonists	FDA Pregnancy Category X	DailyMed; DrugBank
clonazepam	28:12:08 benzodiazepines	Increased risk of congenital abnormalities when taken in first trimester; FDA Pregnancy Category D	DailyMed; DrugBank

(Continued)

Table 3 (Continued). Group 3: Non-antineoplastic drugs that primarily have adverse reproductive effects

Drug	AHFS classification	Supplemental information	Links
colchicine	92:16 anti-gout agents	FDA Pregnancy Category C; published animal reproduction and development studies indicate it causes embryofetal toxicity, teratogenicity, and altered postnatal development at exposures within or above the clinical therapeutic range	DailyMed; DrugBank
dinoprostone	76:00 oxytocics	Hazardous only for women in late pregnancy; FDA Pregnancy Category C	DailyMed; DrugBank
dronedarone	24:04:04 antiarrythmics	Teratogenic in laboratory studies at ½ MRHD; FDA Pregnancy Category X	DailyMed; DrugBank
dutasteride	92:08 5-alpha reductase inhibitors	Women warned not to handle; FDA Pregnancy Category X	DailyMed; DrugBank
eslicarbazepine	28:12:92 anticonvulsants, miscellaneous	Fetal malformations, fetal growth retardation, embryolethality, and reduced body weights observed in animal studies; excreted in human breast milk; FDA Pregnancy Category C	DailyMed; DrugBank
ergonovine/methylergonovine	76:00 oxytocics	Use is contraindicated during pregnancy because of its uterotonic effects; FDA Pregnancy Category C	DailyMed; DrugBank; DrugBank
finasteride	92:08 5-alpha reductase inhibitors	Women should not handle crushed or broken finasteride tablets when they are pregnant or may potentially be pregnant, due to potential risk to a male fetus; FDA Pregnancy Category X	DailyMed; DrugBank
fluconazole	8:18.08 azoles	FDA Pregnancy Category C; case reports describe congenital anomalies in infants exposed in utero to maternal fluconazole (400–800 mg/ day) during most or all of the first trimester, similar to those seen in animal studies	DailyMed; DrugBank

(Continued)

Table 3 (Continued). Group 3: Non-antineoplastic drugs that primarily have adverse reproductive effects

Drug	AHFS classification	Supplemental information	Links
ganirelix	92:40 gonadotropin-releasing hormone antagonists	FDA Pregnancy Category X	DailyMed; DrugBank
gonadotropin, chorionic	68:18 gonadotropins	Defects of forelimbs and central nervous system and alterations in sex ratio have been reported in laboratory studies; FDA Pregnancy Category C	DailyMed; DrugBank
icatibant	92:32 complement inhibitors	FDA Pregnancy Category C; in laboratory studies, premature birth and abortion rates increased at a dose that was less than 1/40th the MRHD, and delayed parturition and fetal death occurred at 0.5 and 2-fold, respectively, the MRHD	DailyMed; DrugBank
lomitapide	24:06:92 antilipemic agents, miscellaneous	FDA Pregnancy Category X	DailyMed; DrugBank
macitentan	48:48 vasodilating agents	Black Box warning for embryo-fetal toxicity; special warnings on contraception for females while taking and 1 month post-treatment; FDA Pregnancy Category X	DailyMed; DrugBank
mentropins	68:18 gonadotropins	FDA Pregnancy Category X	DrugBank
methyltestosterone	68:08 androgens	FDA Pregnancy Category X	DailyMed; DrugBank
mifepristone	76:00 oxytocics	When given to pregnant women, results in termination of pregnancy; FDA Pregnancy Category X	DailyMed; DrugBank
misoprostol	56:28.28 prostaglandins	FDA Pregnancy Category X	DailyMed; DrugBank
nafarelin	68:18 gonadotropins	Note: Given only as nasal spray; no potential for occupational exposure; FDA Pregnancy Category X	DailyMed; DrugBank
oxytocin	76:00 oxytocics	Hazardous only for women in 3rd trimester; FDA Pregnancy Category C	DailyMed; DrugBank

(Continued)

Table 3 (Continued). Group 3: Non-antineoplastic drugs that primarily have adverse reproductive effects

Drug	AHFS classification	Supplemental information	Links
pamidronate	92:24 bone resorption inhibitors	Embryo-fetal toxicities at doses below the recommended human dose; FDA Pregnancy Category D	DailyMed; DrugBank
paroxetine	28:16:04:20 selective serotonin uptake inhibitors	Increased risk of congenital abnormalities when taken in first trimester; complications in pregnancy when taken in third trimester; FDA Pregnancy Category D	DailyMed; DrugBank
pasireotide	68:29:04 somostatin agonists	Increased implantation loss and decreased viable fetuses, corpora lutea, and implantation sites at doses less than the human recommended dose; FDA Pregnancy Category C	DailyMed; DrugBank
pentetate calcium trisodium	NA	Severe teratogenic effects in laboratory studies in dogs; supplied in ampule, which can lead to occupational exposure; FDA Pregnancy Category C	DailyMed
peginesatide	20:16 hematopoietic agents	Adverse embryo-fetal effects, including reduced fetal weight, increased resorption, embryo-fetal lethality, and cleft palate, observed in doses below the recommended human dose; FDA Pregnancy Category C	DailyMed; DrugBank
plerixafor	20:16 hematopoietic agents	Teratogenic in laboratory studies; FDA Pregnancy Category D	DailyMed; DrugBank
ribavirin	8:18:32 nucleosides and nucleotides	Teratogenic and embryotoxic effects in several laboratory studies; contraindicated in women who are pregnant and in the male partners of women who are pregnant; FDA Pregnancy Category X	DailyMed; DrugBank

(Continued)

Table 3 (Continued). Group 3: Non-antineoplastic drugs that primarily have adverse reproductive effects

Drug	AHFS classification	Supplemental information	Links
riociguat	48:48 vasodilating agents	Exclude pregnancy before the start of treatment, monthly during treatment, and 1 month after stopping treatment; FDA Pregnancy Category X	DailyMed; DrugBank
telavancin	8:12:28 glycopeptides	Black Box warning for potential risk to fetus and adverse reproductive outcomes; reduced fetal weights and increased rates of digit and limb malformations in three species at clinical doses; FDA Pregnancy Category C	DailyMed; DrugBank
temazepam	28:24:08 benzodiazepines	Increased risk of congenital malformations associated with treatment during the first trimester of pregnancy; FDA Pregnancy Category X	DailyMed; DrugBank
testosterone	68:08 androgens	Children should avoid contact with unwashed or unclothed application sites on skin; FDA Pregnancy Category X	DailyMed; DrugBank
topiramate	28:12.92 anticonvulsants, miscellaneous	FDA Pregnancy Category D	DailyMed; DrugBank
tretinoin	84:16 cell stimulants and proliferants	Black Box warning for severe birth defects; Special FDA distribution system; FDA Pregnancy Category X	DailyMed; DrugBank
ulipristal	68:12 contraceptives	FDA Pregnancy Category X	DailyMed
valproate/valproic acid	28:12:92 anticonvulsants, miscellaneous	Black Box warning for teratogenicity; congenital malformations, including neural tube defects; teratogenic in multiple species; FDA Pregnancy Category D	DailyMed; DailyMed; DrugBank
vigabatrin	28:12:92 anticonvulsants, miscellaneous	Malformations seen in laboratory studies below the MRHD; FDA Pregnancy Category C	DailyMed; Drugbank
voriconazole	8:14.08 azoles	FDA Pregnancy Category D	DailyMed; DrugBank

(Continued)

Table 3 (Continued). Group 3: Non-antineoplastic drugs that primarily have adverse reproductive effects

Drug	AHFS classification	Supplemental information	Links
warfarin	20:12.04.08 coumarin derivatives	FDA Pregnancy Category D	DailyMed; DrugBank
ziprasidone	28:16:08:04 atypical antipsychotics	Developmental toxicity, including possible teratogenic effects at doses similar to human therapeutic doses; an increase in the number of pups born dead and a decrease in postnatal survival at less than MRHD; FDA Pregnancy Category C*	DailyMed; DrugBank
zoledronic acid	92:24 bone resorption inhibitors	Number of stillbirths increased and survival of neonates decreased in laboratory studies at low doses; FDA Pregnancy Category D	DailyMed; DrugBank
zonisamide	28:12:92 anticonvulsants, miscellaneous	Teratogenic in multiple miscellaneous animal species; FDA Pregnancy Category D	DailyMed; DrugBank

Table 4 would list drugs that were deleted from the 2014 NIOSH hazardous drug list for the 2016 update; however, there are no deletions to report.

Table 5 provides general guidance for some of the possible scenarios that may be encountered in healthcare settings where hazardous drugs are handled, but it cannot cover all possible situations.

Abbreviations and footnotes. BSC = Class II biological safety cabinet; CACI = compounding aseptic containment isolator; CSTD = closed system drug-transfer device; HIPEC = hyperthermic intraperitoneal chemotherapy.

*This guidance applies to the drugs in Tables 1–3. For more detailed information on safe-handling practices, see the reference list [NIOSH 2004; ASHP 2006; ONS 2011; USP 2016; OSHA 2016].

†For nonsterile preparations, a ventilated engineering control such as a fume hood or Class I BSC or a HEPA-filtered enclosure (such as a powder hood) is sufficient if the control device exhaust is HEPA filtered or appropriately exhausted to the outside of the building. It is recommended that these activities be carried out in a control device, but it is recognized that under some circumstances, it is not possible. If the activity is performed in a ventilated engineering control that is used for sterile intravenous preparations, a thorough cleaning is required following the activity.

‡Required if patient may resist (infant, unruly patient, patient pre-disposed to spitting out, patient who has difficulty swallowing, veterinary patient) or if the formulation is hard to swallow.

§Sterile gloves are required for aseptic drug preparation in BSC or CACI.

¶Intravenous tubing already attached and primed.

Table 5. Personal protective equipment and engineering controls for working with hazardous drugs in healthcare settings*

Formulation	Activity	Double chemo-therapy gloves	Protective gown	Eye/face protection	Respiratory protection	Ventilated engineering control
All types of hazardous drugs	Receiving, unpacking, and placing in storage	no (single glove can be used, unless spills occur)	yes, when spills and leaks occur	no	yes, when spills and leaks occur	no
Intact tablet or capsule	Administration from unit-dose package	no (single glove can be used)	no	no	no	N/A
Tablets or capsules	Cutting, crushing, or manipulating tablets or capsules; handling uncoated tablets	yes	yes	no	yes, if not done in a control device	yes†
	Administration	no (single glove can be used)	no	yes, if vomit or potential to spit up‡	no	N/A

(Continued)

Table 5 (Continued). Personal protective equipment and engineering controls for working with hazardous drugs in healthcare settings*

Formulation	Activity	Double chemo-therapy gloves	Protective gown	Eye/face protection	Respiratory protection	Ventilated engineering control
Oral liquid drug or feeding tube	Compounding	yes	yes	yes, if not done in a control device	yes, if not done in a control device	yes†
	Administration	yes	yes	yes, if vomit or potential to spit up‡	no	N/A
Topical drug	Compounding	yes	yes	yes, if not done in a control device	yes, if not done in a control device	yes†, BSC or CACI (Note: carmustine and mustargen are volatile)
	Administration	yes	yes	yes, if liquid that could splash‡	yes, if inhalation potential	N/A
Subcutaneous/ intra-muscular injection from a vial	Preparation (withdrawing from vial)	yes	yes	yes, if not done in a control device	yes, if not done in a control device	yes, BSC or CACI
	Administration from prepared syringe	yes	yes	yes, if liquid that could splash‡	no	N/A
Withdrawing and/or mixing intravenous or intramuscular solution from a vial or ampoule	Compounding	yes§	yes	no	no	yes, BSC or CACI; use of CSTD recommended
	Administration of prepared solution	yes	yes	yes; if liquid that could splash‡	no	N/A; CSTD required per USP 800 if the dosage form allows

(Continued)

Table 5 (Continued). Personal protective equipment and engineering controls for working with hazardous drugs in healthcare settings*

Formulation	Activity	Double chemo-therapy gloves	Protective gown	Eye/face protection	Respiratory protection	Ventilated engineering control
Solution for irrigation	Compounding	yes	yes	yes, if not done in a control device	yes, if not done in a control device	yes, BSC or CACI; use of CSTD recommended
	Administration (bladder, HIPEC, limb perfusion, etc.)	yes	yes	yes	yes	N/A
Powder/solution for inhalation/ aerosol treatment	Compounding	yes	yes	yes, if not done in a control device	yes, if not done in a control device	yes, BSC or CACI
	Aerosol administration	yes	yes	yes	yes	yes, when applicable
	Administration	yes	yes	yes, if liquid that could splash‡	yes, if inhalation potential	N/A
Drugs and metabolites in body fluids	Disposal and cleaning	yes	yes	yes, if liquid that could splash	yes, if inhalation potential	N/A
Drug-contaminated waste	Disposal and cleaning	yes	yes	yes, if liquid that could splash	yes, if inhalation potential	N/A
Spills	Cleaning	yes	yes	yes	yes	N/A

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DHHS (NIOSH) Publication No. 2016–161 (Supersedes 2014-138)

Pioneers Memorial Healthcare District

Title: **Influenza Vaccination Program**	Policy No. HRD-00100
	Page 1 of 2
Current Author: Lizbette Cordova, MSN	Effective: 3/5/2008
Latest Review/Revision Date: 08/10/23	Manual: HR / Employee Health

Collaborating Departments: Infection Control, Employee Health	Keywords: Flu shots

Approval Route: List all required approval				
MARCC 9/19/2023	PSQC	Other:		
Clinical Service _____		MSQC 10/2023	MEC 10/2023	BOD 10/2023

Note: *If any of the sections of your final layout are not needed do not delete them, write "not applicable".*

1.0 Purpose:

1.1 Minimizing the transmission of influenza between healthcare workers and patients is a major component of patient and healthcare worker safety. To help protect staff, non-employees, patients, and families of Pioneers Memorial Healthcare District from acquiring seasonal influenza and to help prevent the unnecessary spread of the influenza virus between employees, non-employees, patients, and families the influenza vaccination is offered annually. The virus is spread from person to person through coughing and sneezing.

2.0 Scope:

2.1 The program is available to all District Employees, Physicians, Adult Volunteers, Contract Employees, Students, Job Shadows, Nursing Instructors, and Board of Directors.

3.0 Policy:

3.1 Immunization against influenza is offered at no cost.

3.2 Healthcare Workers (HCW) are offered the influenza (flu) vaccine each year. The program will generally begin in the fall and extend through the winter, prior to the expected "flu season".

3.3 Employees must consent or decline to influenza vaccine each year.

3.4 All staff (employees, contracted employees and volunteers) who refuse or are not able to take the flu vaccination will be required to wear a mask (regardless of reason) while working in the organization, with the exception of restrooms, staff lounges (while on a designated break), cafeteria and all off-site non-clinical buildings.

3.5 A legible, written record of current flu vaccination from outside providers will be accepted as proof of vaccination.

3.6 Acceptable proof of vaccination (from another facility) for medical staff, is either a signed PMHD consent form (checking the box stating that this year's flu vaccine was already received), written record of current flu vaccination from outside providers or a signed letter stating that they have completed the flu shot requirement, elsewhere.

3.7 Staff without documentation of the flu vaccination will be required to wear a mask during the influenza season to be determined by the Centers of Disease Control, the California Department of Public Health and/or the Infectious Disease Physician.

4.0 Definitions: Not applicable

Pioneers Memorial Healthcare District

Title: **Influenza Vaccination Program**	Policy No. HRD-00100
	Page 2 of 2
Current Author: Lizbette Cordova, MSN	Effective: 3/5/2008
Latest Review/Revision Date: 08/10/23	Manual: HR / Employee Health

5.0 Procedure:

5.1 The program will be coordinated by the Human Resources/Employee Health and Infection Control Departments.

5.2 Administration of the vaccine will begin each year as recommended by the Centers of Disease Control and the California Department of Public Health.

5.3 Administration of vaccinations will be coordinated by Employee Health and Infection Control.

5.4 Vaccination administration schedules will be announced by department managers, PMHD e-mail and posted flyers.

5.5 HCWs who receive the flu vaccine will receive a sticker for their name badge.

5.6 HCWs who do not receive the flu vaccine and who do not wear a mask while working in the acute care environment will be considered non-compliant and will be removed from duty without pay until they comply with these requirements.

6.0 References:

6.1 Aerosol Transmission Plan (Employee Health Services: 5199 ATD (h) page 8)

6.2 Aerosol Transmissible Disease Standard

6.3 California Department of Public Health

6.4 American Hospital Association Quality Advisory – July, 2011

7.0 Attachment List:

7.1 Attachment A – Consent Mandatory Decline Influenza

8.0 Summary of Revisions

8.1 Annual review; no changes

PIONEERS MEMORIAL HEALTHCARE DISTRICT

Declination of Influenza Vaccination 2023-2024

Name:	**Date of Birth:**
Department:	**Position/Title:**
□ Hospital □ SNF □ Physician/Midlevel Provider □ Student □ Volunteer □ Traveler/Contract	

My employer or affiliated health facility, **Pioneers Memorial Healthcare District**, has recommended that I receive influenza vaccination to protect the patients I serve.
I acknowledge that I am aware of the following facts:

- Influenza is a serious respiratory disease that kills thousands of people in the United States each year.
- Influenza vaccination is recommended for me and all other healthcare workers to protect this facility's patients from influenza, its complications, and death.
- If I contract influenza, I can shed the virus for 24 hours before influenza symptoms appear. My shedding the virus can spread influenza to patients in this facility.
- If I become infected with influenza, I can spread severe illness to others even when my symptoms are mild or non-existent.
- I understand that the strains of virus that cause influenza infection change almost every year and, even if they don't change, my immunity declines over time. This is why vaccination against influenza is recommended each year.
- I understand that I cannot get influenza from the influenza vaccine.
- The consequences of my refusing to be vaccinated could have life-threatening consequences to my health and the health of those with whom I have contact, including
  - all patients in this healthcare facility
  - my coworkers
  - my family
  - my community

Despite these facts, I am choosing to decline influenza vaccination right now for the following reasons:

If NO, please check all the following that apply:

☐ a. Fear of injection (sore arm, tenderness)

☐ b. Fear of getting influenza from the vaccine

☐ d. Medical Contraindication

☐ e. Other, specify:

_____

_____

I understand that due to my occupational exposure to aerosol transmissible diseases, I may be at risk of acquiring **seasonal influenza**. I have been given the opportunity to be vaccinated against this infection at no charge to me. However, I decline this vaccination at this time. I understand that by declining this vaccine, I continue to be at increased risk of acquiring **influenza.** If, during the season for which the CDC recommends administration of the influenza vaccine, I continue to have occupational exposure to aerosol transmissible diseases and want to be vaccinated, I can receive the vaccination at no charge to me.. **I also understand that if I decline to receive the influenza vaccine (regardless of the reason) that I will be required to wear a mask while working in the organization, with the exception of restrooms, staff lounges (while on a designated break), and the cafeteria.**
I have read and fully understand the information on this declination form.

Signature: _____

Date: _____

Reference: CDC. Prevention and Control of Influenza with Vaccines—

Recommendations of ACIP at www.cdc.gov/flu/professionals/acip/index.htm

www.immunize.org/catg.d/p4068.pdf • Item #P4068 (10/11)

Technical content reviewed by the Centers for Disease Control and Prevention, October 2011.
Immunization Action Coalition • 1573 Selby Ave. • St. Paul, MN 55104 • (651) 647-9009 • www.immunize.org • www.vaccineinformation.org

PIONEERS MEMORIAL HEALTHCARE DISTRICT

2023-2024 Influenza Vaccine Consent

(Please Print Clearly)

Return form to Human Resources/Employee Health

(Please Print Clearly)

Return form to Human Resources/Employee Health

Name:	**Date of Birth:**
Department:	**Position/Title:**
□ Hospital □ SNF □ Physician/Midlevel Provider □ Student □ Volunteer □ Traveler/Contract	

Yes	No	(1-3 Permanent Contra-indications)
☐	☐	1. Are you allergic to eggs or egg products?
☐	☐	2. Have you ever had Guillian-Barre Syndrome?
☐	☐	3. Have you ever had an anaphylactic reaction to the influenza vaccine?

☐ **Yes, I would like to have the influenza vaccination given to me**

☐ *I have had the flu shot already this year.* (Must provide proof)*

☐ I am not able to receive the flu shot due to permanent contraindication 1 – 3 above.

X _____

Signature **Date**

For Healthcare Provider Use Only

Vaccine Manufacturer: Lot #: Expires:

Site: ☐ Left deltoid ☐ Right deltoid Dose: 0.5ml VIS:

Signature: (**RN / LVN**) Date:

Pioneers Memorial Healthcare District

Title: **ISO Preventive Action**	Policy No. ADM-00076
	Page 1 of 3
Current Author: Carol Bojorquez	Effective: 1/1/2014
Latest Review/Revision Date: 11/06/2023	Manual: Administrative / Quality

Collaborating Departments: Audit Team		Keywords: ISO, documented procedures, 8.5.3, management review		
Approval Route: List all required approval				
MARCC 11/9/2023	PSQC 12/2023	Other:		
Clinical Service _____		MSQC	MEC	BOD 1/2024

Note: *If any of the sections of your final layout are not needed do not delete them, write "not applicable".*

1.0 Purpose:

1.1 To define the proactive processes and methods to be used to identify potential non-conformances within the organization

1.2 To determine and implement actions to prevent occurrence of potential non-conformances

2.0 Scope: District wide

3.0 Policy:

3.1 The District shall employ proactive processes and methods to prevent non-conformities in the services and physical products provided to its customers.

3.2 All District personnel are responsible to:

3.2.1 Identify and report potential non-conforming conditions, products and/or services.

3.2.1.1 Reporting can be completed via a Quality Review Report (QRR) or active reporting to the department leaders as appropriate and should be immediate.

3.3 Department leaders, Quality Department (Management Representative or designee) are responsible to:

3.3.1 Review information generated from data analysis actives such as, but not limited to QRR reporting, rounding, drills, surveillance, scorecards, and lessons learned to determine if potential non-conformities exist and action is required.

3.3.2 Review any new or changed processes to determine if potential non-conformities exist and action is required.

3.3.3 Initiate an investigation and determine if potential non-conformities exist and action is required.

3.3.4 Determine root cause and implement action if required.

3.3.5 Document actions taken to prevent occurrence and review the effectiveness of the preventive actions taken.

3.3.6 Communicate preventive action activities via various modalities and committees as appropriate.

3.4 Management Representative is responsible to:

3.4.1 Report to senior leadership, at the Management Review, the status and effectiveness of preventive actions taken.

3.5 Examples of preventive action activities include but are not limited to:

3.5.1 Surveillance Rounds (Environment of Care Rounds)

Pioneers Memorial Healthcare District

Title: **ISO Preventive Action**	Policy No. ADM-00076
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3.5.2 Internal Audits/Surveys/Tracers
3.5.3 Employee Training/Education Programs
3.5.4 Preventive Maintenance and Equipment Calibration
3.5.5 Fire Drills
3.5.6 Disaster Planning
3.5.7 Use of Statistical Tool Analysis (i.e., Pareto Chart, Histograms, Bar Charts)
3.5.8 Vendor/Supplier Monitoring
3.5.9 Benchmarking
3.5.10 Failure Modes Effects Analysis
3.5.11 Root Cause Analysis

4.0 Definitions:

4.1 Preventive Action – Proactive action to prevent potential non-conformities from occurring

5.0 Procedure:

5.1 Determining potential nonconformities and their causes
- 5.1.1 All staff is responsible for identifying and reporting potential non conformities and their causes if known.
  - 5.1.1.1 Reporting can be completed via a Quality Review Report (QRR) or active reporting to the department leaders as appropriate.

5.2 Department leaders will evaluate the need for action to prevent occurrence of non-conformities based on the investigation.

5.3 Department leaders will determine and implement appropriate action needed to prevent potential non-conformities.
- 5.3.1 If necessary a team will be established to determine potential causes and mitigating strategies to prevent occurrence.
- 5.3.2 The best quality technique, statistical tool and documentation format will be determined by the department leader/team/quality facilitator.

5.4 Recording results of actions taken
- 5.4.1 An appropriate record will be created and maintained of the process by the department or team leader.

5.5 Effectiveness of preventive actions
- 5.5.1 Effectiveness of the action(s) taken can be verified through the following processes including, but not limited to:
  - 5.5.1.1 Internal Audit process (see Policy # ADM-00060 Internal Audit)
  - 5.5.1.2 After action plans
  - 5.5.1.3 Rounding
  - 5.5.1.4 Records
  - 5.5.1.5 Evaluations

5.6 Preventive actions are communicated and reviewed at various committees and during management review.

6.0 References:

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6.1 ISO 9001:2015 6.1 Actions to Address Risks and Opportunities
6.2 NIAHO Standards QM.2; SR.3b
6.3 Policy # ADM-00481 Quality Review Reporting
6.4 Policy # ADM-00060 Internal Audit

7.0 Attachment List:

7.1 Attachment A: FMEA procedure tool http://app.ihi.org/Workspace/tools/fmea/ (electronic)

8.0 Summary of Revisions:

8.1 Submitted without revisions

Pioneers Memorial Healthcare District **Annual Review**

Title: **Medication Error Reduction and Prevention Performance Improvement Plan**	Policy No. CLN-02811
	Page 1 of 8
Current Author: John P. Teague	Effective: 2/25/2002
Latest Review/Revision Date: 06/30/2023	Manual: Clinical / Pharmacy

Collaborating Departments: Hospital-Wide		Keywords: medication, error, reporting, definition, MERP	
Approval Route: List all required approval			
MARCC **7/11/2023**	PSQC **8/2023**	Other: P&T Subcommittee	
Clinical Service _____		MSQC **9/2023**	MEC **9/2023**	BOD **10/2023**

Note: *If any of the sections of your final layout are not needed do not delete them, write "not applicable".*

1.0 Purpose:

1.1 The purpose of the Medication Error Reduction and Prevention Performance Improvement Plan (MERP PIP) is to promote safe and effective medication use through the reduction of preventable medication-related errors and adverse events.

1.2 Medication error reduction and prevention strategies focus on the core procedures and systems of the medication management process; prescribing; prescription order communication; product labeling, packaging and nomenclature; compounding; dispensing; distribution; administration; education; monitoring and medication use.

1.3 The Medication Error Reduction and Prevention PI Plan (MERP PIP) is updated on an ongoing basis in consideration of the changing needs of patients, staff, quality management and performance improvement, and risk management processes. Modifications to the plan are assessed for effectiveness.

1.4 The effectiveness of the Medication Error Reduction and Prevention Performance Improvement Plan (MERP PIP) is reviewed annually. The methodology used to assess the effectiveness of the plan should provide objective and relevant evidence that informs policy decision makers in the evaluation and development of corrective actions to effectively prevent and reduce medication errors.

1.5 The (MERP PIP) includes:

1.5.1 Creating and embracing an accountable non-punitive culture for identifying and reporting medication errors and near miss events;

1.5.2 Utilizing a "systems" approach to understanding and eliminating medication errors through multidisciplinary involvement;

1.5.3 Using organization-wide quality assurance and performance improvement (QAPI) data to identify and analyze medication errors and, near miss events;

1.5.4 Implementing system changes to minimize the likelihood of future medication errors and near misses;

1.5.5 Involvement of multidisciplinary teams and committees to direct and monitor the medication safety and performance improvement effort. The Medication Safety Team/Subcommittee is a function of the Pharmacy and Therapeutics Subcommittee which oversees and coordinates the plan.

2.0 Scope:

2.1 The Medication Error Reduction and Prevention Performance Improvement Plan (MERP PIP) is applicable to all patients receiving care within the facility or under the licensure of the facility, including both inpatients and outpatients. The MERP PIP

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pertains to all areas in which medications are prescribed, prescription orders are communicated, products are labeled, packaged and nomenclature used, compounded, dispensed, stored, distributed, administered, monitored and used.

3.0 Policy:

3.1 Leadership – Hospital leadership is committed to maintaining an environment that emphasizes patient safety and supports ongoing error prevention and reduction activities. Hospital leaders actively encourage medication error identification and reporting by all staff. Preventing and reducing medication errors is a high priority. Errors are analyzed and processes, functions and services are established or; procedures and systems are changed to prevent recurrence and reduce risk to patients.

3.1.1 Medical Executive Committee – The Medical Executive Committee is responsible for reviewing the progress and effectiveness of the medication-related error reduction and prevention plan as reported by the Pharmacy and Therapeutics Subcommittee, and to take action when necessary based on report findings, making recommendations to the Board of Directors in matters of quality improvement and providing the Board of Directors with quarterly updates/reports.

3.1.2 Pharmacy and Therapeutics Subcommittee – The Pharmacy and Therapeutics Subcommittee reports to and acts as a subcommittee of the Medical Staff Quality Council (MSQC). The P&T Subcommittee will also act as the Medication Safety Team/Subcommittee reporting as a subcommittee to MSQC and will advise and review activities for progress and effectiveness. The P&T Chairperson &/or designee reports progress and effectiveness of the MERP PIP to the Medical Executive Committee.

3.2 Developmental Considerations – The following are the fundamental components considered in the development of the MERP PIP:

3.2.1 Create, communicate, and demonstrate a leadership-driven culture of medication safety.

3.2.2 Maintain an organization-wide Quality Assurance and Performance Improvement (QAPI) program that addresses key components of medication safety.

3.2.3 Encourage reporting with a non-punitive reporting process that minimizes individual blame or retribution for involvement in a medication error or near miss event.

3.2.4 Maintain simple, consistent reporting procedures throughout the organization for reporting both actual and potential medication errors.

3.2.5 Use internal and external sources to identify and acknowledge risks to medication safety issues that contribute to medication errors.

3.2.6 Assess measure and implement risk reduction processes designed to improve the safety of medication use.

3.2.7 Recommend indicators that monitor medication safety and identify areas for improvement.

3.2.8 Facilitate multidisciplinary teams and committees to address identified medication safety issues.

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3.2.9 Use preventative measures to reduce the risk of medication errors, near miss occurrences and sentinel events.
3.2.10 Design a data driven medication error reduction process that incorporates comparative data over time.
3.2.11 Promote education of staff, vendors, providers, patients' families, and volunteers.
3.2.12 Incorporate improvements consistent with organization-wide and department specific quality assurance and process improvement goals.

3.3 Objectives
3.3.1 Improve error detection, reporting and analysis of data and use of information to improve medication safety.
3.3.1.1 Evaluate on-line reporting and enhance active reporting.
3.3.1.2 Enhance awareness of on-line reporting tools and methodologies for capturing data and tracking medication related events.
3.3.1.3 Orient and educate staff on processes for reporting medication events. Re-orient staff on a regular basis.
3.3.1.4 Establish a system to encourage staff to report medication errors, participate in identifying system-based causes, make recommendations to improve the system, and facilitate necessary changes.
3.3.1.5 Create methods to enhance error detection by capturing medication errors and near misses through computer surveillance and trigger events, Medication Administration Records (MAR) reconciliation, pharmacy interventions and competency assessment processes. Use the data to identify additional opportunities to improve medication processes.
3.3.2 Emphasize an accountable, non-punitive reporting process that encourages staff to report potential or actual medication safety risks.
3.3.2.1 Widely communicate the organization's commitment to medication safety in specific terms and with concrete examples in staff newsletters and educational programs.
3.3.2.2 Develop methods to obtain frontline staff feedback about medication/patient safety issues.
3.3.2.3 Review *ISMP Medication Safety Alert* and disseminate information to all staff involved in the medication management process.
3.3.2.4 Establish a blame-free environment for responding to errors.
3.3.2.5 Involve staff in Root Cause Analysis and Failure Mode Effect Analysis to assist in evaluation of systems and procedures that have or may contribute to errors.
3.3.2.6 Incorporate patient safety tenets in evaluation of employee competence and performance evaluations. (Do not include the absence or presence of errors as a criterion.)
3.3.3 Evaluate and utilize technology to reduce the risk of medication errors.
3.3.3.1 Maintain an up-to-date compendium of system capabilities and

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reporting functionalities. Set standards for medication safety alerts and educate staff on functionality.

3.3.3.2 Collect and analyze data to identify areas needing improvement and implement appropriate strategies for medication error reduction.

3.3.4 Reduce the risk of errors with high-alert medications prescribed and administered to high-risk patient populations or at vulnerable periods of transfer through the health care system.

3.3.4.1 Evaluate medication management processes for high-risk patients and patients receiving high-alert medications (e.g. pediatric and chemotherapy) to include the following indicators:

3.3.4.1.1 Establish maximum safe doses for high-alert medications and enter them into the order entry system to electronically alert staff to potentially toxic doses.

3.3.4.1.2 Evaluate the storage and safe use of high-alert medications and look-alike/sound-alike medications in the hospital and initiate safe practice recommendations.

3.3.4.1.3 Establish standard order sets for the use of high-alert medications, as appropriate.

3.3.4.1.4 Standardize drug concentrations of high alert medications and medications used in high risk patient populations such as pediatrics and ICU.

3.3.4.1.5 Establish a consistent process for a cognitive, independent double check for defined high-alert medications.

3.3.5 Implement safe practice recommendations from nationally recognized organizations such as ISMP, Joint Commission Sentinel Event Alerts and California Institute for Health Systems Performance.

3.3.6 Ensure continuous compliance with medication management safety strategies recognized by professional and accreditation standards. Compliance measures may include:

3.3.6.1 Self assessment tools and gap analysis

3.3.6.2 Survey preparation assessments

3.3.6.3 Medication Safety Checklist

4.0 Definitions:

4.1 Adverse Event – An event that has resulted in an unanticipated death or major permanent loss of function, not related to the natural course of the patient's illness or underlying condition or the risk thereof

4.2 Adverse Drug Event (ADE) – An injury resulting from a medical intervention related to a medication, including harm from an adverse drug reaction or a medication error.

4.3 Adverse Drug Reaction (ADR) – A response to a medicinal product that is noxious and unintended and that occurs at doses normally used in humans for the prophylaxis, diagnosis or treatment of disease or for the restoration, correction , or modification of physiological or psychological function.

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

4.5 Medication Incompatibility [2] – Incompatibility is an undesirable reaction that occurs between the drug and the solution, container or another drug. The two types of incompatibilities associated with intravenous administration are physical and chemical.

4.6 Near Miss Event – Any variation during the provision of care, treatment, or services that did not affect an outcome, but for which a recurrence carries a significant risk of an adverse outcome.

4.7 Sentinel Event – An unexpected occurrence involving death or serious physical or psychological injury or the risk thereof. The phrase “or the risk thereof” includes any process variation for which a recurrence would carry a significant chance of serious adverse outcome.

4.8 Root Cause Analysis (RCA) – A process for identifying the basic or causal factor(s) that underlying variation in performance, including the occurrence or possible occurrence of a sentinel event.

4.9 Failure Mode and Effects Analysis (FMEA) – is a systematic, proactive method for evaluating a process to identify where and how it might fail, and to assess the relative impact of different failures in order to identify the parts of the process that are most in need of change and/or additional safeguards.

4.10 MERP PIP – Medication Error Reduction and Prevention Performance Improvement Plan

4.11 QAPI – quality assurance and performance improvement. PMHD uses Quality Review Reports (QRR) generated & stored in the MIDAS system to report & track QAPI.

5.0 Procedure:

5.1 Plan Development

5.1.1 A multidisciplinary group comprised of core team members from the Medication Safety Team/Subcommittee is responsible for development of the Medication Error Reduction and Prevention Performance Improvement Plan (MERP PIP). The core team is also responsible for recommending the MERP PIP’s approval through the Pharmacy and Therapeutics Subcommittee which reports to and functions as a subcommittee of the Medical Staff Quality Council, Patient Safety Quality Council, Medical Executive Committee and the Board or Directors.

5.1.2 Membership of the MERP PIP core team includes:

5.1.2.1 Director of Pharmacy

[1] NCC MERP definition http://www.nccmerp.org/aboutMedErrors.html

[2] Josephson 2006, RCN 2005, Douglas et al. 2001

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5.1.2.2 Director of Quality Management
5.1.2.3 Director of Risk Management
5.1.2.4 Chief Nursing Officer
5.1.2.5 Medical Staff representative(s)

5.2 Plan Implementation and Assessment

5.2.1 The Medication Safety Team/Subcommittee provides primary oversight of MERP PIP). The subcommittee's role is to guide and direct others within the organization towards; the provision of safe medication use; the prevention and reduction of medication errors and the improvement of medication management processes /procedures and systems.

5.2.2 The Medication Safety Team/Subcommittee works collaboratively with the hospital and medical staff leadership, medical staff, and hospital staff; working across interdepartmental boundaries as needed, to address medication safety issues and to assess the effectiveness of the MERP PIP.

5.2.3 Methodology used to evaluate each of the eleven medication management procedures or systems to identify weakness or deficiencies which could contribute to medication errors may include but are not limited to:

5.2.3.1 Evaluation of external alerts (e.g. ISMP Alert, FDA Alerts, etc)
5.2.3.2 Observation of medication pass
5.2.3.3 QAPI studies
5.2.3.4 FMEA studies
5.2.3.5 Medication Use Evaluations
5.2.3.6 Analysis of medication error reports to identify system vulnerabilities
5.2.3.7 Root Cause Analysis
5.2.3.8 Monitoring and adjusting implementations of practices/process changes to evaluate and enhance effectiveness
5.2.3.9 Technology upgrade feasibility is reviewed when needed, but at least annually.
5.2.3.10 GAP analysis of the plan is performed and priorities are established annually.

5.3 Improvement Strategies

5.3.1 Current literature is reviewed on an ongoing basis for the development and ongoing review and revision of the Medication Error Reduction and Prevention Plan's improvement strategies. The literature includes publications from the Institute of Medicine (IOM), Institute for Safe Medication Practices (ISMP), American Society of Health System Pharmacists (ASHP), the Joint Commission and other publications/organizations as appropriate.

5.3.2 Medication use systems and procedures are identified to include both current and future improvement strategies.

5.4 Implementation Strategies – Annually, improvement strategies are evaluated and resultant implementation strategies are identified. Strategies include both technology and non-technology approaches.

5.4.1 Review the effectiveness of the existing plan, and make adjustments, when

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needed, to improve the plan.

5.4.2 Implement medication use safe practice recommendations

5.4.3 Optimize medication error prevention and reduction potential of technology systems

5.4.4 Respond rapidly and effectively to potential errors of, and errors caused by workflow processes

5.5 Education and Awareness – Entity specific core curriculums are created to support the MERP PIP initiative. The following methodology will be used to assist with identifying and reporting medication errors with the goal of reducing their incidence:

5.5.1 An annual medication safety assessment will be used to identify needs.

5.5.2 Systems will be reviewed to identify current practice and compared to nationally recognized safe medication practices to identify gaps.

5.5.3 Expected outcomes and measures of success will be defined for identification and reporting of medication errors and to identify process changes for error reduction and prevention.

5.5.4 Clinical education will include medication safety core curriculum during orientation and annual competency reviews for pharmacy, nursing and other allied health professionals.

5.5.5 The medical staff will be informed of MERP PIP progress via committee presentations and Pharmacy and Therapeutics Subcommittee (P&T) newsletters.

5.6 Monitoring – The Medication Safety Team/Subcommittee will monitor multiple data sources which may include:

5.6.1 Adverse drug event reporting (medication errors, near misses, adverse drug reaction and incompatibilities)

5.6.2 Concurrent chart reviews and audits (e.g. Medication Use Evaluations)

5.6.3 Computerized surveillance (e.g., Trigger drug utilization, Automated Dispensing Cabinet (ADC) Reports, Bar-Code Medication Verification (BMV) data reports, etc.)

5.7 Reporting

5.7.1 Findings and recommendations from the Medication Safety Team/Subcommittee are first reported to the P&T Subcommittee as a function of the P&T, which through its representative reports to the Medical Executive Committee

5.7.2 The Medication Safety Team/Subcommittee also presents its findings to the Patient Safety Quality Council, which are comprised of leadership from the facility's functional departments.

5.7.3 The Medication Safety Team/Subcommittee publishes quarterly newsletters to update patient care staff of MERP PIP's progress.

5.7.4 If findings or recommendations have an *immediate* impact on patient safety, focused memos and direct communication to affected functional areas is utilized.

5.8 Annual Review

5.8.1 The Medication Error Reduction and Prevention Performance Improvement Plan (MERP PIP) is reviewed annually and modified as needed to focus efforts to reduce medication related errors. The analysis will consist of both concurrent and

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retrospective review of patterns and trends of clinical care, weakness and deficiencies, and focus on procedure and system related opportunities for improvement. Individual performance issues will not be addressed during an annual review.

5.8.2 The annual assessment of the effectiveness of the MERP PIP will include, but not be limited to, a comprehensive review of prescribing, prescription order communication, labeling, packaging, nomenclature, compounding, dispensing, distribution, administration, patient and staff education, monitoring tools and overall medication use.

5.8.3 Annual review of the MERP PIP will be a function of the Medication Safety Team/Subcommittee as a function of the Pharmacy and Therapeutics Subcommittee which reports to and functions as a subcommittee of the Medical Staff Quality Council and will be reported to the Patient Safety Quality Council, the Medical Executive Committee and the Board of Directors.

6.0 References:

6.1 The Joint Commission MM.08.01.01
6.2 Healthcare Facilities Accreditation Program (HFAP) 25.03.06
6.3 Center The Centers for Medicare and Medicaid Services (CMS)§482.25(b)(6)
6.4 DNV National Integrated Accreditation for Healthcare Organizations (NIAHO –DNV) MM.1, QM.8
6.5 The National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) http://www.nccmerp.org/aboutMedErrors.html
6.6 The California Board of Pharmacy B&P, Chapter 9, Division 2; 4125
6.7 The California Code of Regulations Division 17, Title 16; 1711; 1716
6.8 The California Code of Regulations, Title 22, Health and Safety Code Section 1339.63
6.9 Josephson 2006, RCN 2005, Douglas et al. 2001

7.0 Attachment List:

7.1 Attachment A – Computer Surveillance Methodology
7.2 Attachment B – Medication Error Reduction and Prevention Strategies by Medication Use Process/Procedure/System
7.3 Attachment C – Medication Safety Subcommittee
7.4 Attachment D – MERP 2022 Annual
7.5 Attachment E – Performance Improvement 2022 Evaluation

8.0 Summary of Revisions:

8.1 Attachment E update PI 2022 Eval
8.2 Attachment D updated to 2022 review with a reformat of this attachment to ease reading and understanding

PIONEERS
MEMORIAL HEALTHCARE DISTRICT

ATTACHMENT A – COMPUTER SURVEILLANCE METHODOLOGY

Rescue Medications and Trigger Drugs

Rescue medications and trigger drugs are agents which, when used, may indicate adverse medication events. Using the reporting functions of the automated dispensing cabinets (ADC) and the medication order entry system, utilizations of the following medications may be monitored.

Utilization of these medications is investigated by a pharmacist to identify adverse drug related events. Adverse Drug Event (ADE) data is trended and analyzed to identify opportunities for improvement. ADEs are reported to, and recommendations (if any) are made and reported quarterly to the P&T Subcommittee.

Medication	Possible Adverse Medication Event
Acetylcysteine (Acetadote, Mucomyst)	Acetaminophen overdose
Argatroban	Heparin induced thrombocytopenia
Dextrose 50%	Hypoglycemic agent overdose
Digoxin Immune Fab (Digibind)	Digoxin toxicity
Diphenhydramine (Benadryl)	Drug allergy
Flumazenil (Romazicon)	Benzodiazepine overdose
Mephyton (Oral Vit K)	Warfarin Overdose
Methylprednisolone Succinate (Solu-Medrol)	Anaphylaxis, severe drug allergy
Naloxone (Narcan)	Opiate overdose
Phytonadione (Vit K)	Warfarin overdose
Protamine	Heparin overdose
Sodium Polystyrene Sulfonate (Kayexelate)	Potassium overdose

Automated Dispensing Cabinet (ADC) Removal Reports and/or Bedside Medication Verification (BMV) Scanning Report Data

Medications removed and/or administered too early or too late; or medications that are missed or given too close to the previous dose are reviewed by the pharmacy and/or unit managers. Event data is tracked, trended and evaluated. Findings are reported to the P&T Committee quarterly.

Identified missed doses are investigated by the pharmacist and unit manager. Errors of omission are reported immediately to the attending physician.

Qualified events are logged, per hospital policy, in the electronic reporting system.

ADC Override Reports

Overrides are medication removals from an ADC prior to pharmacist order review. Override reports are reviewed by pharmacy and/or nursing services. Each override dispense must be based on a valid order. Unacceptable reasons for overrides may indicate unauthorized medication administration. Identified errors are reported immediately to the attending physician and logged in the electronic reporting system.

Override report data are analyzed and reported to the P&T Committee quarterly.

ADC Discrepancies

Controlled substance discrepancies at the unit based cabinet level are resolved by the end of the shift. Discrepancies may indicate diversion or unintended over dose. Identified errors are reported immediately to the attending physician and logged in the electronic reporting system.

Unresolved controlled substance discrepancies are reported immediately to the pharmacy manager for investigation.

Pharmacy runs an open and closed discrepancy report daily to identify unresolved discrepancies. Unresolved discrepancies are reported to the unit manager for resolution.

Findings are collated, trended and reported to the P&T Committee on a quarterly basis.

Bar-code Verification at Medication Administration

Various report functions can be utilized to promote medication safety: Overall Scanning Rates, Overrides, Administration Time Variance. Utilization of BMV data will be customized based on the organization’s needs and performance.

Audits

ADC utilization data is used to perform random medication administration audits to identify discrepancies between doses removed, dose ordered, dose documented as administered & recorded waste if a controlled substance. Non-controlled substance discrepancies are reported to the unit manager for investigation & resolution. Controlled substance discrepancies are reported to the Director of Pharmacy for investigation & implementation of required notification and reporting procedures, as appropriate.

Utilize automated data management systems for diversion analysis.

Medication Use Evaluation

Utilization reports from automatic dispensing cabinets and electronic medication administration records can be used to obtain data specific to hospital approved medication use evaluation criteria. Deviations may identify adverse drug events or outcomes. Findings are reported to the P&T Committee.

Medication Integrity

Medication storage area (i.e. refrigerators, med rooms, etc.) temperatures are monitored using a remote monitoring system if applicable or daily logs. Deviations beyond acceptable limits are reported to the Director of Pharmacy or designee, who will assess the viability of the affected products, and confirm action for adjustments or repairs. Events should be reported using the electronic reporting system.

Medications stored in an ADC can be readily traced in the event of a drug recall, facilitating the requirements of the drug recall process.

Variances affecting medication integrity & drug recall information is reviewed & reported to the P&T Committee quarterly.

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ATTACHMENT B – MEDICATION ERROR REDUCTION AND PREVENTION STRATEGIES BY MEDICATION USE PROCESS/PROCEDURE/SYSTEM

The following medication use practices have been shown to be effective in reducing medication-related errors.

Medication Use Process	*Safe Practice Recommendations*
Prescribing	▪ Minimize and eliminate symbols and abbreviations ▪ Use of CPOE-Computerized prescriber order entry system ▪ Automatic drug-drug interaction alerts ▪ Minimum/maximum dose alerts ▪ Automatic allergy checking ▪ Automatic duplication alerts ▪ Abnormal laboratory value alerts; e.g., creatinine ▪ Potential antidote orders ▪ Alerts on automatic stop orders ▪ Use of preprinted medication order forms ▪ Do not use trailing zeros; e.g., 20.0 mg ▪ Always use a zero before a decimal point; e.g., 0.5 mg ▪ Make current drug information readily available ▪ Make laboratory information readily available ▪ Minimize verbal - telephone orders ▪ Develop and implement dosing protocols ▪ Require all physician orders to be complete and legible ▪ Use of standardized critical pathways ▪ Digital transmission of orders ▪ Alerts on look alike, sound alike drugs ▪ Include indication for use in the order
Prescription Order Communication	▪ Minimize verbal – telephone orders ▪ Authenticate and verify verbal order by prescriber as soon as possible ▪ Use of CPOE ▪ Use of preprinted order sheets ▪ Simplify and streamline the communication of orders ▪ Clarify all irregular or ambiguous orders ▪ Reduce or eliminate transcription

Product Labeling, Packaging, & Nomenclature	▪ Print trade & generic names on the label ▪ Include indication on label ▪ Ensure all medications are labeled; e.g., procedure medications not prepared in pharmacy, anesthesia medications, first dose of intravenous solutions prepared by nursing staff, etc. ▪ Intravenous fluids have patient specific labels ▪ Use of appropriate warning labels ▪ Attach specific dose instructions if multiple dose vials must be dispensed ▪ Highlight critical parts of the label; e.g., drug concentration, unusual dose, look alike and sound alike names, etc. ▪ Distinctive labeling for similar or sound alike names ▪ Use metric system not apothecary or English units
Compounding	▪ Maintain a pharmacy based intravenous admixture system ▪ Use USP grade ingredients for compounding ▪ Comply with USP <797> and <795> requirements ▪ Implement quality control measures; e.g. personnel competency, surface sample testing ▪ Follow standards of practice for all type of compounding; e.g., ASHP guidelines, USP 797 and 795 requirements
Dispensing	▪ Utilize Rx computer software with clinical screening ▪ Do not stock concentrated, hypertonic electrolyte solutions on nursing units ▪ Computerized Pharmacy system ▪ Automatic drug-drug interaction alerts ▪ Minimum and maximum dose alerts ▪ Automatic allergy checking ▪ Automatic duplication alerts ▪ Automatic stop alerts ▪ Automatic alerts for critical laboratory values; e.g., creatinine ▪ Automatic alerts for clinical contraindication ▪ Unit dose all medications ▪ Pharmacist reviews and verifies all orders before drug is dispensed or administered ▪ Identify and restrict the availability of high risk medications; e.g., o Concentrated Potassium o Neuromuscular blocking agents o Concentrated Opiate Solutions

	○ Look alike, sound alike medications ○ Standardize concentrations of medications ○ Heparin ○ Potassium chloride ▪ Double check system for built in redundancy for high risk, problem prone medications; e.g., chemotherapy, heparin ▪ Dispense drugs in ready to administer dosage form ▪ Bar coding bedside technology ▪ Automatic drug delivery systems ▪ Restrict floor stock to emergency medications
Distribution	▪ Maintain a unit of use distribution system ▪ Remove excess medication floor stock ▪ Identify and restrict the availability of high risk medications ▪ Restrict use of medications to formulary approved items unless clinical circumstances mandate an exception ▪ Remove discontinued medications (from the nursing unit)
Administration	▪ Computer generated e-MAR or daily updated MARs ▪ Periodic & continual staff re-education ▪ Patient education ▪ RN double check for defined high alert medications (before medication is administered) ▪ Print generic and trade names of medication on MAR ▪ All infusion pump settings for high risk medications are double checked ▪ Utilize smart pumps with set guardrails ▪ Standardized administration times ▪ Ensure proper administration times for medications; e.g., 1 hour before meals prints a correct time on the MAR ▪ No medication is unlabeled ▪ All syringes are labeled ▪ Bar coding bedside technology ▪ Electronic charting or medication administration record (MAR) ▪ Ensure the five rights of administration ▪ Use distinctive administrative sets to reduce the risks of medication and nutritional products from being administered by the incorrect route
Education	▪ Develop special procedures for high risk drugs with special guidelines ▪ Complete, current, and accessible drug information for all staff

	▪ Publish Pharmacy newsletter ▪ Provide in-services for professional staff ▪ Administer competency/certification medication exams ▪ Develop and provide nursing with dosing charts ▪ Make drug and Formulary information available on line ▪ Provide training before new drugs or non-formulary drugs are used ▪ Patient, caregiver education, and or family education on the proper use of medication and possible adverse events ▪ Computerized patient education ▪ Alerts on look-alike/sound-alike and High Risk Drugs
Monitoring	▪ Pharmacist available 24 hours a day / on call ▪ Pharmacist based monitoring with problematic or high risk patients and medications ▪ Healthcare professionals' access to laboratory information ▪ Computer tracking of medication related errors for trending and analysis ▪ Direct observation of medication administration ▪ Use of trigger drugs to identify medication error related events; e.g., naloxone, flumazenil, epinephrine etc. ▪ Encourage the reporting of errors by focusing on process and systems problems. Individual blame and involvement should be minimized ▪ Use of protocols for drugs with a narrow therapeutic index
Use	▪ Medication use evaluations- including medications with frequent interventions and/or "near misses" ▪ Assign clear responsibilities for investigation and review ▪ Perform root cause analysis and if applicable, assign a severity grade

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ATTACHMENT C: MEDICATION SAFETY SUBCOMMITTEE

Mission

Medication Safety

- Oversee and maximize the safety of the medication use process throughout the continuum of care by incorporating fail-safe procedures and safety surveillance systems.
- Assure systems are in place to conduct and review root-cause analysis and trends for reported medication errors and preventable adverse drug events. Facilitate implementation and monitoring of procedure or system changes to help prevent similar events in the future.

Medication Error Reporting

- Maintain simple, consistent reporting procedures for both actual and potential medication errors in all areas of the organization.
- Ensure that a non-punitive system exists so that fear of retribution is not a barrier to medication error reporting.

Awareness

- Increase health care practitioner and administrator awareness about medication safety.
- Ensure that employees know how the medication error reporting process works and how to report an adverse drug event, including near misses, using the electronic reporting system.
- Increase patient awareness about medication safety.

Role

The Medication Safety Team/Subcommittee is a component of the Pharmacy & Therapeutics (P&T) Committee and functions as a collaborative forum in which Pharmacy, Quality and Nursing address medication safety issues. The role and function of the Medication Safety Team/Subcommittee should be purposefully structured to achieve the goal of a “culture of safety” with primary oversight of the hospitals Medication Error Reduction and Prevention Performance Improvement Plan (MERP PIP). The subcommittee will guide and direct others within the organization towards process improvements that support the prevention and reduction of adverse drug events and other factors that contribute to unintended adverse patient outcomes.

The committee provides leadership for safety assessments, coordinates the activities of the MERP PIP, educates other practitioners on the system-based causes for medication errors, consults with the Patient Safety Committee and hospital management and communicates literature-based ideas regarding effective patient safety strategies to others.

The committee will establish and maintain direct communication with all accountable functions such as Quality Management, Risk Management, Nursing Services, Pharmacy Services, etc.

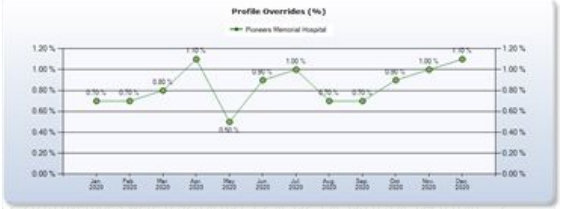
Responsibilities

- Oversees the development, review, and ongoing refinement of the Medication Error Reduction and Prevention Performance Improvement Plan. Reviews the effectiveness of the MERP PIP and sets goals on an annual basis.
- Supports and encourages error reporting through a non-punitive error reporting system.
- Reviews internal error reports and medication use safety issues. Prepares reports and analyses identifying progress and adverse trends with appropriate recommendations or conclusions.
- Promptly investigates medication errors and sentinel events in order to improve staff performance and patient care. Participates in root cause analyses (RCA) and follow-up.
- Collaborates on the development of policy and procedures and medication use safety standards.
- Recommends failure mode effect analysis (FMEA) when developing procedures or implementing systems with a high propensity for adversely affecting patient or medication safety.
- Develops a mechanism for internal communication of medication safety related information.
- Designs and implements educational presentations that facilitate the understanding and implementation of medication use safety initiatives.
- Serves as a resource on issues of safe medication use. Serves as an expert resource for medication safety standards and process improvement strategies.
- Identifies, develops, coordinates and drives medication safety initiatives. Ensure consistent practices across all areas where medications are prescribed, prescription orders are communicated, products are labeled, packaged and nomenclature used, compounded, dispensed, stored, distributed, administered, monitored and used.

Work Performed

- Sets annual goals for medication error reduction and medication use safety improvement, under the direction of the Pharmacy and Therapeutics Subcommittee and in collaboration with the Patient Safety Committee.
- Collaborates on development of tools for effective training, implementation and monitoring of medication safety initiatives.
- Develops safe medication use policies and incorporates safe medication use procedures and safety surveillance systems.
- Reviews trending data on medication errors, near misses and adverse drug events.
- Reviews results of root cause analyses (RCA).
- Reviews results of failure mode effect analyses (FMEA).
- Facilitates implementation and monitoring of system changes to evaluate effectiveness and sustainability.

SUMMARY OF CY 2020 MERP ACTIVITIES AND ACTIONS TAKEN

Procedure or System	Methodology	Weaknesses or Deficiencies Noted	Date Identified	Actions Noted / Plan Modification	Evaluation Frequency	Date last Completed	Outcomes (Data)	Follow Up Assessment by committee	Effective / Not Effective	Annual Review - Continue, Modify, Discontinue
Prescribing	GAP Analysis, Technology Upgrade	Smart pump	Oct-14	1. PCA GAP Analysis reviewed at Med Safety and P&T meetings October 2014. Noted improvements made in 2013 but recommended Smart pump upgrade which is planned to be approved December 2014 with implementation early 2015 2. December Board meeting approved Alaris purchase implementation to start January 2015 3. Alaris Smart Pumps Go-Live March 2015 "One" pump hospital-wide noted P&T April 30, 2015 4. Alaris Guardrails data set updated September 1, 2015 with minimal edits and approved P&T September 25, 2015. 5. Need for #15 Syringe Pumps for Peds noted June 2017 P&T 6. Need to review compliance with the use of the Guardrails system 7. P&T May 2019 J.Teague notes syringe pumps are located in Pediatrics 8. PCA GAP analysis completed by RN Clincal Lead Mgr Educator C. Abubo 09/18/2019	Quarterly P&T	Nov-20	1. Guardrails Data sets updated and reviewed at P&T during the 2018 year 2. 15 Syringe pumps purchased and stored in Peds pending dilution build in systems noted November 2017 P&T 3. No data reported on the use of the Guardrails data set 4. 4th Qtr 2019 P&T February 2020 noted PCA GAP analysis work with RN Clinical Lead Mgr Educator C. Abubo 5. Pending items unresolved by C. Abubo noted by J.Teague P&T 11/05/2020 planned follow-up impeded by Covid-19	Quarterly at P&T/MSQC	Not Effective	Annual Review
Prescription Order Communication / Processing & Handling	Monitoring & Adjusting to evaluate & enhance effectiveness	# of Overrides	May-13	1. Overrides policy reviewed and revised 5/30/13 and approved at P&T August 2013. Reviewed Pyxis policy and adjusted formulary to match approved override list 2. Implemented Night Pharmacy Order Review late Nov. 2013 3. Policy Medication Overrides-Pyxis CLN-02973 Approved by Medical Staff Quality Council August 2015 & P&T September 2015. There was a complete revision of the listed overrides which categorized all of the overrides with listed corresponding clinical conditions, the list was also created as a house-wide override list versus the old list that broke down overrides based on nursing unit. The change in listed overrides resulted in a dramatic reduction of override percentage compared to the previous year and months. 4. Reviewed threshold limit set for Override report	quarterly	Feb-20	 2016 Overrides were 0.7% 3. 2017 Overrides were 0.875% 4. 2018 Overrides were 0.875%. 5. Report limits came standard with Pyxis PMHD limit is <1% which is below Pyxis default noted 2018 P&T 5. Increased review of Overrides has generated an increase in reported Med Errors 6. 4th Qtr 2019 P&T 02/13/2020 notes annual trend below threshold continuing to review and report 7. P&T 11/05/2020 overrides for 2020 continue to be monitored and do not show variance to bring concern, covid pandemic has impacted monitoring	Monitor Overrides Report Quarterly by P&T and MSQC	Effective	Quarterly Review

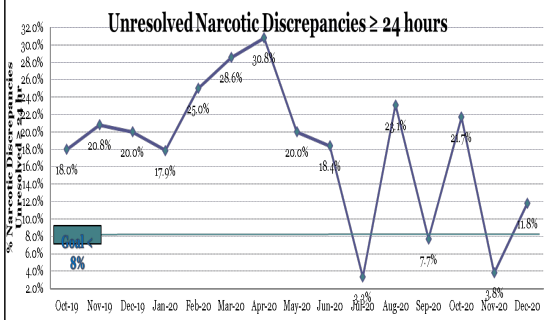
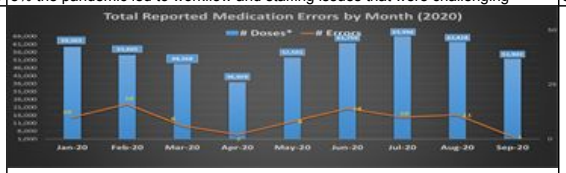
SUMMARY OF CY 2020 MERP ACTIVITIES AND ACTIONS TAKEN

Procedure or System	Methodology	Weaknesses or Deficiencies Noted	Date Identified	Actions Noted / Plan Modification	Evaluation Frequency	Date last Completed	Outcomes (Data)	Follow Up Assessment by committee	Effective / Not Effective	Annual Review - Continue, Modify, Discontinue
Product Labeling	ISMP Alert, Tech Upgrade, Monitoring and adjusting implementations of practices/process changes to evaluate and enhance effectiveness	Multi-Dose Insulin Vials	Oct-19	1. ISMP alert notes Baxter Insulin drip premix now available MYXREDLIN (insulin, human) 100 units per 100 mL (1 unit per mL).	Quarterly P&T	Aug-19	1. P&T August 2019 implemented purchase of premix Insulin bags from Baxter for 24-hour availability, preven compounding, labeling erros, and improves BCMA	Quarterly P&T	Effective	Discontinue
Packaging and Nomenclature	Review of BMVmedication scanning compliance reports, Tech Upgrade	Not all medications scan. Multifaceted problem: lack of barcode entered into system(s), scanners, isolation	Jul-18	1. Ensure medications are scanned when received 2. Follow-up with CNO to discuss steps to improve BCMA rates 3. Baxter Insuli drip premix added P&T August 2019	Quarterly P&T	Feb-20	1. 03/2018 P&T J.Teague notes BCMA % low needs to improve will meet with CNO. 2. P&T reports combined BCMA data of PO/IV meds which decreased rates. 3. 02/2019 P&T MD co-chairs recommended "immediate" pharmacy check of ALL IV/PO meds and IV solutions to ensure bar codes do scan and follow-up with nursing following scanning to ensure compliance improves. 4. P&T August 2019 added Insulin Premix by mfg Baxter 5. 10/31/2019 P&T notes collaborative work to improve Nursing, Pharmacy, IT all making changes to improve data, 4th Qtr 2019 P&T 02/13/2020 noted almost 90% rates overall for December 2019	Quarterly P&T	Effective	Quarterly Review

SUMMARY OF CY 2020 MERP ACTIVITIES AND ACTIONS TAKEN

Procedure or System	Methodology	Weaknesses or Deficiencies Noted	Date Identified	Actions Noted / Plan Modification	Evaluation Frequency	Date last Completed	Outcomes (Data)	Follow Up Assessment by committee	Effective / Not Effective	Annual Review - Continue, Modify, Discontinue
Compounding	Process review, Regulatory Review, GAP Analysis, Tech Upgrade	1. Compounding Policy revision/update 2. Procedure review 3. Master Formulas	Feb-13	1. Policy review annually 2. Master Formulas Review annually 3. Equipment certification every 6-months 4. USP 797 GAP Analysis annually 5. Document and report any issues and corresponsing actions	Quarterly P&T	Feb-20	1. Policy is currently being reviewed annually including master formulas 2. Quarterly reviews of outscourced compounders is being completed at P&T 3. QA being tracked and reported to P&T this includes testing and compliance with cleaning. There was 100% pass of swabs for bacterial growth and potency testing. 4. USP797 Gap performed issues not serious but reparied 5. P&T 4th Qtr 2019 on 02/13/2020 notes completion of New Oncology HD room with new fridge install and Go-Live 12/2019 6. P&T 11/05/2020 reviewed IV cmpd policy on patient care units, covid pandemic impacted reporting but cleaning of compounding rooms was maintained as well as certification.	Yearly Policy Review including Master Formulas P&T Committee	Effective	Annual Review

SUMMARY OF CY 2020 MERP ACTIVITIES AND ACTIONS TAKEN

Procedure or System	Methodology	Weaknesses or Deficiencies Noted	Date Identified	Actions Noted / Plan Modification	Evaluation Frequency	Date last Completed	Outcomes (Data)	Follow Up Assessment by committee	Effective / Not Effective	Annual Review - Continue, Modify, Discontinue
Dispensing	Monitoring & Adjusting to evaluate & enhance effectiveness	1. Controlled Substance Auditing/Monitoring 2. Policy Update/Revision	Feb-13	1. Engaged Leadership and Executive PMHD Team Members 2. Medication Diversion Prevention Coordinator Pharmacist created 3. Diversion Software purchased and Implemented 4. Revised Controlled Substance Policy and Created Diversion Algorithm 5. Held Drug Diversion Conference April 2017	Quarterly P&T	Jun-21	 1.2015 average 40% 2. 2016 average was 20% 3. 2017 average was 17.6% 4. 2017 there were many changes made this year which resulted in a dramatic improvement toward the end of the year, Dec 2017 was 4.3% 5. 2018 ended the year above goal at overall 9.7%, but we still improved significantly from 2017. 6. 2020 ended 15.7% which was lower than 2019 and while 2019 started with support of leadership etc to manage the rates to below 8% the pandemic led to workflow and staffing issues that were challenging	Review medication errors quarterly at P&T/MSQC	Effective	Quarterly Review
Distribution	Med Error Reports, Quarterly Audits	Reporting	Jun-13	1. Adverse Drug Events Policy created 6/18/13 2. Revised the MIDAS QRR reporting system to standardize report capturing throughout PMHD	Daily monitoring, Quarterly reporting at P&T	Nov-20	 1. 2016 Doses Dispensed 657,613 with Med Errors 138; this represents 0.021% med error rate per dispensation 2. 2017 Doses Dispensed 600,705 with Med Errors 174; this represents 0.029% med error rate per dispensation 3. 2018 610,134 doses dispensed wit 124 Med Errors; represents 0.021% Med Error per dispensation. 4. 2019 586,739 doses dispensed with 148 Med Errors; represents 0.025% Med Error per dispensation. 5. 2020 702,800 doses dispensed all time high number of doses and only 100 Med Errors; represents 0.014% Med Error per dispensation 6. There was no trend that was cause for concern we averaged 8.3 Med Errors per month for the year 2020	Review medication errors Quarterly at P&T and Patient Safety Quality Council	Effective	Quarterly Review

SUMMARY OF CY 2020 MERP ACTIVITIES AND ACTIONS TAKEN

Procedure or System	Methodology	Weaknesses or Deficiencies Noted	Date Identified	Actions Noted / Plan Modification	Evaluation Frequency	Date last Completed	Outcomes (Data)	Follow Up Assessment by committee	Effective / Not Effective	Annual Review - Continue, Modify, Discontinue
Administration	Monitoring & Adjusting to evaluate & enhance effectiveness	Personnel Competency	Apr-13	1. Policy updated and revised - 4/13 & 11/13 2. Approved purchase of RX Learning Center at P&T August 2013 3. Jan. 2014 Policy Approved & Implemented Feb. 2014 4. Annual Competency & Sterile compounding training was completed for the year, training started in August 2015 and noted September 25, 2015 at P&T meeting.	annual	Nov-20	1. Compounding Policy Revised and Reviewed with staff, staff meeting on 06/14/2017 focused on cleaning of compounding area including hazardous handling updates 2. All staff members completed annual competency training and annual compounding training 3. Medication Area Inspection policy was updated and training provided at staff meeting 03/07/2017 4. Annual 2018 completed during the summer of 2018 and noted in P&T notes 02/2019 during 3rd &4th Qtr 2018 P&T. 5. 4th Qtr 2019 P&T 02/13/2020 notes training completion 09/30/2019 6. P&T 11/05/2020 notes completion of training 10/30/2020	P&T and MSQC	Effective	Annual Review
Education	Monitoring & Adjusting to evaluate & enhance effectiveness	Formulary Management	Jun-13	1. Formulary policy revised 6/12/13 2. Formulary reviewed/approved & posted on intranet January 2015 3. Med Safety committee March 31, 2015 removed Acetaminophen (Tylenol) drops 80mg/0.8mL to standardize all Acetaminophen oral suspension house-wide to 160mg/5mL 4. OB Emergency Meds: NitroSpray, Methergine, Hemabate, Cytotec, Intralipid, & Magnesium Sulfate. Listed emergency medications were added at the request of OB & Anesthesia Medical Directors Drs. Grewal & Larra, reported to NEC memo given to OR & OB for staff education and noted at Med Safety committee March 31, 2015 5. Emergency Medications Policy revised to include graphs & attachments to educate staff regarding location & contents of all carts, kits & Pyxis kits. Collaborative creation between Pharmacy, Nursing and Medical Staff including Emergency Department. Noted at Med Safety committee April 29, 2015. 6. Drug Use Criteria policy implemented attachments listing specific medications approved by Medical Staff for specific indications or criteria that must be met to allow usage, medications where criteria are not met and restriction is overriden by prescriber will be documented and reported to Medical Staff for review of non-formulary orders overridden noted by P&T September 25, 2015. 7. Formulary policy revised 9/2015 at both Medical Staff Quality Council and P&T, added section 4.7 on Biosimilars and added attachment C "2015 PMHD Formulary".	annual	Nov-20	1. Medication requests reviewed quarterly at P&T for formulary approval 2. Formulary reviewed 3. P&T 11/05/2020 reviewed and approved the formulary for the year 2020	P&T and MSQC	Effective	Annual Review

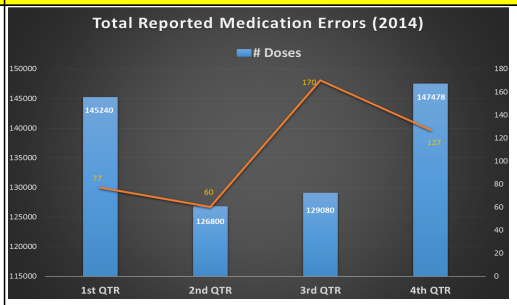
SUMMARY OF CY 2020 MERP ACTIVITIES AND ACTIONS TAKEN

Procedure or System	Methodology	Weaknesses or Deficiencies Noted	Date Identified	Actions Noted / Plan Modification	Evaluation Frequency	Date last Completed	Outcomes (Data)	Follow Up Assessment by committee	Effective / Not Effective	Annual Review - Continue, Modify, Discontinue
Monitoring	Monitoring & Adjusting to evaluate & enhance effectiveness	Medication Observation Audits low in volume and Nursing not following Infection Control Processes	Feb-15	1. Assigned project to A.Vandiver RN to complete audits 2. Rate established 2 per unit per week 3. Paper audits moved to electronic system MIDAS for ease of reporting etc 4. 2017 Noted lack of audits and Infx Control poor %, PSQC recommended end of month report to CNO & Infx Control noted at P&T that they would be completing rounding & more training	Weekly documentation and quarterly monitor/reporting	Jun-21	1. 2016 there were 194 total Med Obs Admin Audits completed for the year which was an increase from 2015, but there was a decrease in Infx Control measures when preparing a medication 58.9% (more data 2016 = more statistically significance) 2. 2017 noted improvement in total Med Obs Admin Audits with 287 for the year, there was also an Increase in Infx Control measures when preparing meds 64.5% 3. 2018 increase Med Obs audits to 446 for the year, still low results with Infx Control at 60.5% 4. 2019 Increassed Med Obs Audits to 981 for the year, also Infx Control measures increased to 84% and were statistically significant can adjust from not effective to effective. 5. 2020 Med Obs Audits declined to 253 for the year due to the covid pandemic related issues.	Review Med Admin Audits quarterly at P&T/MSQC	Effective	Quarterly Review

SUMMARY OF CY 2020 MERP ACTIVITIES AND ACTIONS TAKEN

Procedure or System	Methodology	Weaknesses or Deficiencies Noted	Date Identified	Actions Noted / Plan Modification	Evaluation Frequency	Date last Completed	Outcomes (Data)	Follow Up Assessment by committee	Effective / Not Effective	Annual Review - Continue, Modify, Discontinue
Use	MUE (concurrent)	Failure to prevent a Med Error when heparin was not administered in accordance to physician's orders and hospital protocol	Feb-15	1. Anticoagulation monitoring, Heparin Continuous Infusion monitor for 100% compliance 2. Go-Live date June 01, 2016 new updated Heparin Infusion Protocol 3. P&T reviewed quarterly there was discussion between ED Medical Staff & RN director and adjustments made by Information Systems to the protocol order that is in the ED eMAR 4. Reviewed ALL Heparin ordering in ED eHR system as requested by Dr. Gomez at MSQC meeting 2017	Daily monitor and quarterly reporting	Nov-20	1. 100% of the Heparin patients were monitored by Pharmacy 2. There was an improvement in protocol usage for 2016 3. Following the implementation of the new protocol in June Incorrect Protocol usage improved to 0%, but then jumped to 12% 4th quarter 4. Incorrect Protocol Usage Improved throughout the year following discussions at MSQC & P&T meetings with input and involvment from Medical Staff, Nursing, Information Systems and Pharmacy Department 5. P&T 4th Qtr 2019 02/13/2020 reviewed sample update to Heparin protocol with MedStaff and Nursing discussion with Dr. Krutzik and H. Munger 2017 Incorrect Protocol Usage: 1st Qtr. 2017 13% 2nd Qtr. 2017 3% 3rd Qtr. 2017 0% 4th Qtr. 2017 0% 2018 Incorrect Protocol Usage: 1st Qtr. 2018 0% 2nd Qtr. 2018 0% 3rd Qtr. 2018 0% 4th Qtr. 2018 0% Incorrect Protocol Usage: 2019 5% 0% 4th Qtr. 2019 0% Incorrect Protocol Usage: 2020 0% 0% 4th Qtr. 2020 0% 2019 1st Qtr. 2nd Qtr. 2019 3rd Qtr. 2019 2% 2020 1st Qtr. 2nd Qtr. 2020 3rd Qtr. 2020 0%	Review medication errors at monthly Medication Safety meeings and quarterly at P&T/MSQC	Effective	Quarterly Review

Procedure or System	Methodology	Weaknesses or Deficiencies Noted	Date Identified	Actions Noted / Plan Modification	Evaluation Frequency	Date last Completed	Data	Follow Up Assessment by committee	Effective / Not Effective	Annual Review - Continue, Modify, Discontinue
Prescribing	Monitoring & Adjusting to evaluate & enhance effectiveness	1. Controlled Substance Auditing/Monitoring 2. Policy Update/Revision	Feb-13	1. Operational Audit and Controlled Substance Policy Feb-13 P&T 2. Controlled Substance Continuous Infusion Flow Sheet monitored 100% P&T July 2014 3. Approved Narc Discrepancy document Med Safety July 2014	Daily monitor and quarterly reporting	Jan-15	**see P&T & MedSafety January 2015**	Review medication errors at monthly Medication Safety meeings and quarterly at P&T/MSQC	Effective	Quarterly Review
Prescribing	GAP Analysis, Technology Upgrade	Smart pump	Oct-14	1. PCA GAP Analysis reviewed at Med Safety and P&T meetings October 2014. Noted improvements made in 2013 but recommended Smart pump upgrade which is planned to be approved December 2014 with implementation early 2015 2. December Board meeting approved Alaris purchase implementation to start January 2015	Monthly Med Safety and Quarterly P&T	Jan-15	see Med Safety & P&T minutes January 2015	Review monthly Medication Safety meeings and quarterly at P&T/MSQC	Effective	Annual Review

Procedure or System	Methodology	Weaknesses or Deficiencies Noted	Date Identified	Actions Noted / Plan Modification	Evaluation Frequency	Date last Completed	Data	Follow Up Assessment by committee	Effective / Not Effective	Annual Review - Continue, Modify, Discontinue
Prescribing	Med Error Reports, Quarterly Audits	Reporting	Jun-13	1. Adverse Drug Events Policy created 6/18/13 2. Revised the MIDAS QRR reporting system to standardize report capturing throughout PMHD	Daily monitoring and quarterly reporting at P&T	Jan-15		Review medication errors at quarterly P&T and Patient Safety Quality Council	Effective	Quarterly Review
Prescription Order Communication / Processing & Handling	Monitoring & Adjusting to evaluate & enhance effectiveness	# of Overrides	May-13	1. Overrides policy reviewed and revised 5/30/13 and approved at P&T August 2013. Reviewed Pyxis policy and adjusted formulary to match approved override list 2. Implemented Night Pharmacy Order Review late Nov. 2013	quarterly	Jan-14		Quarterly by P&T and MSQC	Effective	Quarterly Review
Packaging and Nomenclature	ISMP Alert, FMEA, Tech Upgrade	Multi-Dose Insulin Vials	Jan-14	1. P&T January 2014 reviewed ISMP article from October 2013 and agreed to move toward pt. specific vials. 2. MILT unit dosing software purchased & approved P&T April 2014 to assist in labeling vials. 3. FMEA started January 7, 2015 with Quality Director	Monthly Med Safety and Quarterly P&T	Jan-15	see P&T January 2014 & April 2014 purchased MILT. See FMEA pending results	Monthly Med Safety and Quarterly P&T	Effective	Annual Review

Procedure or System	Methodology	Weaknesses or Deficiencies Noted	Date Identified	Actions Noted / Plan Modification	Evaluation Frequency	Date last Completed	Data	Follow Up Assessment by committee	Effective / Not Effective	Annual Review - Continue, Modify, Discontinue
Packaging and Nomenclature	Process review, Regulatory Review, GAP Analysis, Tech Upgrade	1. Compounding Policy revision/update 2. Procedure review 3. Master Formulas	Feb-13	1. Policy updated and revised - 2/13 & 7/13 2. Review of procedures and Master Forumulae - 7/13 3. Purchased new CAI - 9/13 4. RN IV training & annual competency - 10/13 5. USP 797 GAP Analysis P&T April 2014 6. Dose Edge IV Cmpd. Management Software planned Jan. 2014 & Implemented June 2014	Monthly	Jan-14	100% Compliance	P&T Committee	Effective	Annual Review
Compounding	Monitoring & Adjusting to evaluate & enhance effectiveness	Personnel Competency	Apr-13	1. Policy updated and revised - 4/13 & 11/13 2. Approved purchase of RX Learning Center at P&T August 2013 3. Jan. 2014 Policy Approved & Implemented Feb. 2014	annual	Jan-14	100% Compliance	P&T and MSQC	Effective	Annual Review
Education	Monitoring & Adjusting to evaluate & enhance effectiveness	Formulary Management	Jun-13	1. Formulary policy revised 6/12/13 2. Formulary reviewed/approved & posted on intranet January 2015	annual	Jan-15	see P&T minutes January 2015	P&T and MSQC	Effective	Annual Review

Performance Improvement Annual Evaluation

Departmental Evaluation

YEAR 2020

Annually we must review each of the formally selected PI projects and each Project Leader is asked to give a brief overview/summary of activity (5 minutes maximum).

Below is a list of questions that should be addressed in your presentation.

Overview (**"P"** plan)

1. What was your project to improve?
   a. Reduction of Narcotic Discrepancies outstanding >24 hrs. to ≤8% of the total number of discrepancies.

2. Who was involved on your team?
   a. Pharmacy Department Staff - Cyrus Laborde, Violeta Pedernal, LizBeth Reyes, Ray G., Donnell Lu, Edward Padilla, Michele Gandia, Lori Dubois, Elvira Martinez, Danielle Hewett, Lourdes Guillen, Ivan Romero, Daniel Zanetti, Steven Campos, Jessica Oliveras

Data (**"D"** do)

3. What were your quarterly averages?
   a. Our average for the year was 15.7%

4. What was your target/goal?
   a. ≤8%

5. Did you meet it?
   a. No

Analysis (**"C"** Check)

6. If goals were not achieved or were modified, list reasons why.
   a. Narcotic Discrepancy Reports were being left unresolved past 24 hours.
   b. Covid-19 Pandemic led to workflow and staffing issues.

7. What were your greatest accomplishments over the year?
   a. Engagement from Leadership and Executive PMHD Team Members.
   b. Engagement from Medical Staff including supported desire to improve.
   c. Increase in leadership oversight.

Performance Improvement Annual Evaluation

Departmental Evaluation

YEAR 2020

8. What were your weaknesses?
   a. Lack of timely response.
   b. Staff availability and pandemic related priorities.

9. Where did you report your findings? How often?
   a. Using the MIDAS system and PMHD email when issues were discovered
   b. P&T Committee on a regular basis; meetings are scheduled to occur normally on a quarterly basis

Action (**"A"** Act to maintain the improvement or Act to increase the improvement)

10. What actions did you put into place to make a change?
    a. Engaged Leadership and Executive PMHD Team Members.
    b. Regular consistent reporting.
11. What will you do different in the future to meet goal (if not reached) or improve further?
    a. Continue current practice and monitor.
    b. Allow Discrepancy Resolution Documents to be completed via remote communication as long as completed and signed by department manager/director.

12. Who/what do you need to succeed?
    a. Increase in Pharmacy staff that are trained and able to extract and review document data to review for completeness and/or discrepancies.

……..……...Internal Use Only……..……

Reason of Importance: Patient Safety / Regulatory / Financial Impact / Strategic Goals

HWPI Project for Future? Yes / No

Priority 1 2 3 4 (1 highest priority – 4 lowest)

Pioneers Memorial Healthcare District

Title: **Pain Assessment in Children**	Policy: CLN-00310
	Page 1 of 2
Current Author: Yolanda Smith	Effective: 1/28/2002
Latest Review/Revision Date:06 06 2023	Manual: Clinical / Pediatric

Collaborating Departments: ER, Nursing Admin		Keywords: assessment, pain	
Approval Route: List all required approval			
MARCC 7/11/2023	PSQC	Other:	
Clinical Service Pediatrics 10/2023	MSQC 11/2023	MEC 11/2023	BOD

Note: *If any of the sections of your final layout are not needed do not delete them, write "not applicable".*

1.0 Purpose:

1.1 Pain is assessed to understand how much pain a child is experiencing and to understand if what is being done to relieve pain is working.

2.0 Scope: Pediatric Unit, ER

3.0 Policy:

3.1 Pain in infants, children and adolescents will be assessed and reassessed.

4.0 Definitions: Not applicable

5.0 Procedure:

5.1 Infants and children less than 1 year

5.1.1 For Neonatal and Children less than the age of 1 year we utilize the Neonatal Infant Pain Scale (NIPS) Attachment A

5.1.2 A Score greater than 3 indicates pain

5.2 Children over 1 year and children under 3 years of age:

5.1.3 Children that experience pain, in which the intensity may be difficult to measure are sometimes a challenge to nurses doing the assessment. The "FLACC Score is a practical approach to assessing pain in the infants or small children. (See attached FLACC Scoring Grid on Page)

5.1.4 0 = relaxed and comfortable

5.1.5 1-3 = mild discomfort

5.1.6 4-6 = moderate pain

5.1.7 7-10 = severe discomfort or pain or both

5.2 Children 3 or 4 years of age:

5.2.1 May become quiet and inactive; May become hyperactive; May only be able to express pain using single words.

5.2.2 Parents recognize pain through changes in behavior and communicate what word is used at home for pain.

5.2.3 Depending on the developmental/cognitive abilities of the individual, it may require the use of the FLACC Score to assess pain.

5.3 Children 5 to 10 years of age:

5.3.1 Can tell you more about pain and express their pain.

5.3.2 Can use Whaley & Wong faces or other pain scale (0-5 or 0-10 least pain to worst pain) for units of measure in assessing pain; (See attached pain scale

Pioneers Memorial Healthcare District

Title: **Pain Assessment in Children**	Policy: CLN-00310
	Page 2 of 2
Current Author: Yolanda Smith	Effective: 1/28/2002
Latest Review/Revision Date:06 06 2023	Manual: Clinical / Pediatric

examples) Can draw pain location on a body diagram.

5.4 Adolescents: Age of 10 years and up.
- 5.4.1 Can explain pain more clearly.
- 5.4.2 Are able to use descriptive words like, shooting, aching or burning.

6.0 References:

6.1 Current Pediatric Research (2017) Volume 21, Issue 1, Assessment and treatment of pain in pediatric children.

6.2 Nursing Reference Center Plus (Policy CLN-00287)

7.0 Attachment List:

7.1 Attachment A – NIPS

7.2 Attachment B – Pain Scale Examples

8.0 Summary of Revisions:

8.1 Added 5.1, 5.1.1 and 5.1.2

8.2 Added 5.1.4, 5.1.5, 5.1.6 and 5.1.7

I. Neonatal Infant Pain Scale (NIPS)

Variable	*Finding*	*Points*
Facial Expression	*Relaxed (Restful face, neutral expression)*	*0*
	Grimace (Tight facial muscles, furrowed brow, chin, jaw)	*1*
Cry	*No cry (Quiet, not crying)*	*0*
	Whimper (Mild, moaning, intermittent)	*1*
	Vigorous crying (Loud scream, shrill, continuous). If infant is intubated, score silent cry based on facial movement.	*2*
Breathing pattern	*Relaxed, (Usual pattern for this infant)*	*0*
	Change in breathing (Irregular, faster than usual, gagging, breath holding)	*1*
Arms	*Relaxed (No muscular rigidity, occasional random movements of arms)*	*0*
	Flexed/extended (Tense, straight arms, rigid and/or rapid extension, flexion)	*1*
Legs	*Relaxed (No muscular rigidity, occasional random leg movements)*	*0*
	Flexed/extended (Tense, straight legs, rigid and/or rapid extension, flexion)	*1*
State of Arousal	*Sleeping/Awake (Quiet, peaceful, sleeping or alert and settles)*	*0*
	Fussy (Alert, restless and thrashing	*1*

PAIN SCALE EXAMPLES

Numerical Pain Scale:

0 1 2 3 4 5 6 7 8 9 10

0-10, Zero equals no pain, 10 equals worst possible pain.

Categorical or Descriptive Pain Intensity Scale:

None Mild Moderate Severe Worst Possible

Analog Scale:

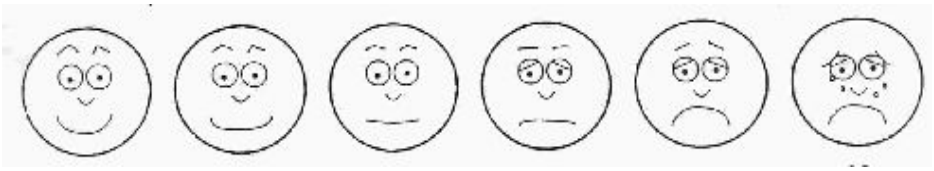
No Pain Worst Possible Pain

The patient marks on the line the spot for the pain intensity which is then measured. Non-written versions can be used for very sick patients by having an attendant run a pencil along the line while the patient confirms the point corresponding to the current pain.

Pain Relief Scale:

No Relief Complete Relief

Pain Affect Faces Scale



0 2 4 6 8 10

No pain **Mild** **Moderate** **Severe** **Unbearable**
No dolor ***Leve*** ***Moderado*** ***Severo*** ***Insoportable***

Children are presented with face drawings representing the happiest feeling possible to the saddest feeling possible. The faces are assigned numbers for quantifying children's responses.

Pioneers Memorial Healthcare District ***REVIEWED ANNUALLY***

Title: **Risk Management Plan**	Policy No. ADM-00476
	Page 1 of 2
Current Author: Merlina Esparza	Effective: 4/23/1993
Latest Review/Revision Date: 09/07/2023	Manual: Administration / Risk

Collaborating Departments: Quality, Compliance, Administration		Keywords:	
Approval Route: List all required approval			
MARCC 9/19/2023	PSQC 10/2023	Other: Safety Committee 10/2023	
Clinical Service _____		MSQC 11/2023	MEC 11/2023	BOD 12/2023

Note: *If any of the sections of your final layout are not needed do not delete them, write "not applicable".*

1.0 Purpose:

1.1 The Risk Management Plan is designed to identify actual and potential situations, which could put the organization, employees, or customers at risk.

1.2 All employees and medical staff are to support and participate in the risk management plan by working safely and identifying, reporting and/or alleviating conditions and practices that may cause injury to patients, guests, and staff, as well as organizational loss.

2.0 Scope: District wide

3.0 Policy:

3.1 The Risk Manager is responsible for the implementation and operation of the Risk Management Plan for Pioneers Memorial Healthcare District (PMHD).

3.2 The Risk Manager reports directly to the Quality Director.

4.0 Definitions: Not applicable

5.0 Procedure:

5.1 Plan Components

5.1.1 Loss prevention, consisting of identification of potentially compensable events, medical-malpractice claims, risk assessment and occurrence reporting from Quality Review Reports (QRR's)

5.1.2 Facilitation of Root Cause Analysis (RCA's)

5.1.3 Participation of Failure Modes and Effect Analysis

5.1.4 Educational program development, organization-wide and department specific as needed

5.1.5 Event reporting to California Department of Public Health (CDPH) or other regulatory/accreditation bodies as required.

5.1.6 Reporting to organizational committees

5.2 Plan Activities

5.2.1 Loss control and prevention

5.2.1.1 Identify notices of intention, claims, quality reviews, risk assessments, incident reports and survey findings.

5.2.1.2 Conduct a thorough investigation on all claims and provide essential case information to the facility's counsel and liability insurance carrier.

Pioneers Memorial Healthcare District ***REVIEWED ANNUALLY***

Title: **Risk Management Plan**	Policy No. ADM-00476
	Page 2 of 2
Current Author: Merlina Esparza	Effective: 4/23/1993
Latest Review/Revision Date: 09/07/2023	Manual: Administration / Risk

5.2.1.3 Submit recorded occurrences, quantified and trended quarterly and annually to the Patient Safety and Quality Council (PSQC) and other committees as appropriate.

5.2.1.4 Utilize sources to assess risks inherent to the environment, including, but not limited to quality review reports, potential compensable events and medical-malpractice claims.

5.2.2 Root Cause Analysis

5.2.2.1 Risk Management is responsible to facilitate a credible and thorough RCA on events when there is a suspected deviation from a known standard of care and/or an internal/external policy.

5.2.2.2 Risk Management will collaborate with appropriate hospital personnel to complete the RCA process. (*See policy Sentinel Event; ADM-00480*)

5.2.2.3 Risk Management will assist in coordinating and participating in the development of a Corrective Action Plan (CAR) when the need for one is identified during a RCA.

5.2.3 Failure Mode and Effects Analysis

5.2.3.1 Risk Management is responsible to participate in at least one Failure Mode and Effects Analysis annually in an effort to proactively address patient safety, risk reduction and loss prevention.

5.2.4 Education

5.2.4.1 Risk Management conducts orientation education monthly to new employees to include Quality Review Reporting, Loss Prevention, and Risk Services.

5.2.4.2 Risk Management conducts department specific and individual training during departmental rounds, in-services and/or staff meetings as needed.

5.2.5 Risk Management Reporting

5.2.5.1 Reporting to Governing Board, Medical Staff, PSQC, Safety Committee, Chief Executive Officer (CEO), Chief Financial Officer (CFO) and other organizational committees as requested.

5.2.5.2 At a minimum a Quarterly report to PSQC

5.2.5.3 Lesson Learned when appropriate.

5.2.5.4 Safety Committee as requested.

5.2.5.5 Department Leaders as requested.

5.2.5.6 Claims will go directly to Governing Board's legal counsel for reporting.

5.2.5.6.1 All claims will be presented to the Governing Board.

6.0 References:

6.1 PMHD policy Sentinel Event; ADM-00480

6.2 20-1 National Integrated Accreditation for Healthcare Organizations (NIAHO) Standards: Quality Management

7.0 Attachment List: Not applicable

8.0 Summary of Revisions: 5.2.5.5 changed to Department Leaders, from Leadership Counsel

PIONEERS MEMORIAL HEALTHCARE DISTRICT
207 West Legion Road, Brawley, CA 92227
REGULAR MEETING OF THE BOARD OF DIRECTORS

Tuesday, November 28, 2023
PMH Auditorium
5:00 pm

Minutes

PMHD MISSION: Quality healthcare and compassionate service for families of the Imperial Valley

In compliance with the Americans with Disabilities Act, if you require special accommodations to participate in a board meeting, please contact the District at (760) 351-3250 at least 47 hours prior to the meeting.

I. CALL TO ORDER (*time: 5:00 pm – 5:15 pm)*

President Santillan called the meeting to order at 5:03 pm in the PMH Auditorium.

A. Roll Call

BOARD MEMBERS:
Katy Santillan, President
Enola Berker, Vice President
Rachel Fonseca, Secretary
Linda Rubin, Treasurer
Nick Aguirre, Asst. Secretary/Treasurer

STAFF:
Damon Sorensen, Interim CEO
Carly Loper, CFO
Sally Nguyen, General Counsel
Carol Bojorquez, CNO

GUEST:
Carly Zamora, CCO
Charity Dale, CHRO
Carrie Teague, Director of Information Systems
Melissa Ramirez, Director of Marketing

B. Approval of Agenda

A motion was made to approve the agenda by Director Aguirre, seconded by Director Berker. **The motion was unanimously carried.**

II. BOARD MEMBER COMMENTS

Director Rubin reported that yesterday's meeting with all the healthcare stakeholders was more of the same. An invitation had been extended to PMHD's new CEO, but not Mr. Sorensen who has been involved in this process since September of 2022. It was noted that there was a "pre-meeting" and only one representative from Brawley was at that meeting. It is unclear who else was at this pre-meeting.

Director Berker stated it was interesting to see everyone who was in attendance. The media did publicize the meeting to be by invitation only. One item she did speak up about was the reimbursement information provided which was incorrect.

Director Aguirre gave a big thank you to Dr. Calvin for all the work and dedication to Pioneers and the Imperial Valley. He has done a lot for our community. Director Santillan asked Mr. Sorensen to work with Ms. Ramirez on something to acknowledge Dr. Calvin for all his work. Mr. Sorensen stated he would check with Medical Staff as well to see what they will be doing.

III. PUBLIC COMMENTS – At this time, the Board will hear comments on any agenda item and on any item not on this agenda. If any person wishes to be heard, he or she shall stand; address the chairperson and state the subject, or subjects, upon which he or she desires to comment. Time limit for each speaker is 5 minutes. A total of 15 minutes shall be allocated for each item. *(time: 5:15 pm – 5:30 pm)*

Ms. Bojorquez introduced Mr. Ashraf Malik, new director of Case Management, to the Board. The Board welcomed Mr. Malik to Pioneers.

IV. MEDICAL STAFF REPORT – Ramaiah Indudhara, MD, Chief of Staff, will present for Board consideration, the following matters: (*time: 5:40 pm – 6:00 pm)*

A. Recommendations from the Medical Executive Committee for Medical Staff Membership and/or Clinical Privileges, policies/procedures/forms, or other related recommendations

It was noted that Dr. Indudhara would not be attending the meeting. The privileges and policies went through all the appropriate committees. A motion was made to approve the medical staff report by Director Rubin, seconded by Director Aguirre. **The motion was unanimously carried**.

V. POLICIES/PROCEDURES/REVIEW OF OTHER ITEMS – The Board will consider and may take action on the following: (*time: 6:00 pm – 6:45 pm)*

A. Hospital Policies
   1. Auxiliary Aids and Services for Persons with Disabilities
   2. Health Information Device Acquisition
   3. Paid Time Off (PTO) and Medical Leave Hours
   4. Service Recovery
   5. Without Cause Termination and Severance

B. Approval of Minutes
   1. 10/12/23 Special Meeting
   2. 10/18/23 Supplemental Meeting
   3. 10/24/23 Regular Meeting
   4. 10/30/23 Special Meeting

C. Update Reports
   1. Women’s Auxiliary

Director Rubin advised that the Women’s Auxiliary hosted a bake sale for the employees and Christmas ornaments. The Poinsettia Ball is this Saturday night. They continue to need more volunteers for the gift shop.

   2. LAFCO

Nothing to report.

D. October 2023 Finance Report

Ms. Loper reported that there was a slight decrease in the average daily census; however, it was still higher than last year at this same time. Last year, it was at 34 and this year it was at 46. Revenues went up due to more volumes in the outpatient side. Charity care was higher than normal in October. There were four accounts that were higher than normal that applied to PMHD's charity program. There was a profit of $500,000 to the bottom line for the month of October. Prior year for October, it was a $2.2 million loss. Thus far, for the first four months of this fiscal year, the district has a profit of $1.1 million versus the prior year which had a loss of $7.7 million. This is a really good turnaround in the finances. The SNF is running in the low 80's of ADC, which is almost back up to their average census of 89 before the fire incident. Ms. Loper advised that the cost report was just filed and there is a potential pickup in reimbursement for the SNF. Days cash on hand increased to 37.3 days. This shows that the profit in the financial statement is true. The distressed hospital loan of $28 million was received on November 1st. That will increase days cash on hand to about 105 to 110 days.

E. Human Resources Report

Ms. Dale advised that the report was provided in the board packet and asked if the Board had any questions. Mr. Sorensen requested that she provide the highlights. Ms. Dale noted that the ADP implementation is moving along, and they have started to do validation of the data. Staff are also being trained in the system. She and Senior Leaders have discussed ways to be more competitive to attract more applicants. There has been success in the recruitment of nurses outside of the Imperial Valley. Currently, there are about 68 open positions across the organization which includes the skilled nursing facility. The PAC Committee is in full swing, and they have brought back many of the events that employees liked in the past. There will be a tree lighting event this Friday at the Gala Lawn and everyone is invited to attend. Implicit bias has been assigned to staff and has been completed by the OB nurses that were required to take the training. New employee all day orientation has been reinstituted. A Training and Education Specialist position will be posted to meet the organization's educational needs. Director Berker asked how many terminations there were for the month. Ms. Dale advised that there were 24 terminations; three of those were involuntary. She also clarified that most of the terminations were per diems that had not worked for many months and therefore were terminated. Director Rubin asked how many employees are at the skilled nursing facility. There are 147 employees at the SNF.

F. Authorize Addendum for GE Carescape Upgrade and EMR Cutover with GE HealthCare
Contract Value: $55,814.25; Contract Term: Five (5) year; Budgeted: Partially; Budget Classification: Purchased Services/Repairs & Maintenance

G. Authorize Amendment No. 2 to Supplemental Funding Enhancement Program Agreement with Steve Clark & Associates
Contract Value: $48,000; Contract Term: One (1) year; Budgeted: Yes; Budget Classification: Purchased Services

SECTION

H. Authorize Hospital Service Agreement with MedCare Partners, Inc. dba MedCare Health Plan
Contract Value: 104% fee schedule; Contract Term: One (1) year; Budgeted: No; Budget Classification: Revenue

I. Authorize Renewal of Maintenance Agreement for EMC Storage Area Network with Dell Technologies
Contract Value: $52,380.43; Contract Term: Three (3) years; Budgeted: Yes; Budget Classification: Repairs & Maintenance

J. Authorize Renewal of Service Agreement for RadPro Digital Portable Xray System with Canon Medical Systems USA, Inc.
Contract Value: $77,600; Contract Term: Four (4) years; Budgeted: No; Budget Classification: Repairs & Maintenance

K. Authorize Third Amendment to Administrative Services Agreement with Rady Children's Hospital – San Diego
Contract Value: Reduction of 75%; Contract Term: One (1) year; Budgeted: Yes; Budget Classification: Purchased Services

L. Authorize Renewal of Health Organization Billing Errors and Omissions and Regulatory Coverage with BETA Healthcare Group
Contract Value: $47,288.34; Contract Term: One (1) year; Budgeted: Yes; Budget Classification: Insurance

M. Authorize Professional Service Agreement with Mehboob Ghulam, DO
Contract Value: based on volumes; Contract Term: Three (3) years; Budgeted: Yes; Budget Classification: Professional Fees

N. Authorize Healthcare Staffing Services Agreement with DRWanted.com, LLC
Contract Value: based recruitment efforts; Contract Term: Three (3) years; Budgeted: No; Budget Classification: Purchased Services

O. Authorize Master Services Agreement with WellStack, Inc.
Contract Value: $10,000/mo.; Contract Term: on-going with 30-day notice; Budgeted: No; Budget Classification: Subscription

P. Authorize Agreement for Professional Services with GE Healthcare IITS USA Corp.
Contract Value: $34,596.80; Contract Term: One-time; Budgeted: No; Budget Classification: Purchased Services

Q. Authorize Agreement with GE Medical Systems Information Technologies, Inc.
Contract Value: $39,810; Contract Term: One-time; Budgeted: No; Budget Classification: Purchased Services/Capital

R. Authorize Risk and Quality Management System Agreement with Symplr Care Management, LLC
Contract Value: $45,000; Contract Term: One-time; Budgeted: No; Budget Classification: Purchased Services

S. Authorize Renewal of Agreement for Offsite Records Storage Services with Pioneers Van and Storage
Contract Value: $96,505; Contract Term: One (1) year; Budgeted: Yes; Budget Classification: Purchased Services

T. Authorize Lithotripsy Services Agreement with Imperial Valley Lithotripsy, LLC
Contract Value: based on volumes; Contract Term: Five (5) years; Budgeted: No; Budget Classification: Purchased Services

U. Authorize Purchase of Barracuda Email Security with CDW Government
Contract Value: $67,914.52; Contract Term: One (1) year; Budgeted: No; Budget Classification: License/Repairs & Maintenance

V. Authorize Renewal of IT Backup Solution with Greenman IT Support
Contract Value: $72,000; Contract Term: One (1) year; Budgeted: Yes; Budget Classification: Repairs & Maintenance

SECTION

W. Authorize Implementation to Cerner and Multiview with Global Health Exchange
Contract Value: $44,761.50; Contract Term: One-time; Budgeted: No; Budget Classification: Purchased Services

Ms. Teague gave an overview of the items which are needed for interfacing the Cerner system which is scheduled to go live in April 2024.

ITEM F – This is for the integration of all the bedside medical devices
ITEM O – Is the patient portal which PMHD currently pays for, but that will be replaced once Cerner goes live.
ITEM P – This is for integration between Cerner and the Cath Lab system.
ITEM Q – This is to maintain the current EKG system we have as the one that Cerner uses will be sunsetting.
ITEM R – This is for MIDAS which is used for quality and risk events.
ITEM W – This is for interface with GHX which is required by our GPO to send multiple feeds between our vendors and Cerner.

All these items were not initially budgeted because it was unknown at the beginning of the project what would be needed; however, there was contingency money budgeted to try and have funding available once the implementation got underway.

ITEM M – It was asked if a deadline date can be added to the term in section d. A discussion ensued on what can be added and enforcement options. Recommended language to be added to physician contracts that payment will be held if their charts are not completed.

ITEM T – Director Berker asked how much PMHD is being reimbursed for the lithotripsy procedures. The machine would be stored at Pioneers but can be used for free if prior notification is provided. If no prior notification is given before the procedure, then there will be a charge. There are not a lot of cases done.

A motion was made to approve Items A through W by Director Aguirre, seconded by Director Fonseca. **The motion was unanimously carried.**

VI. MANAGEMENT REPORTS – The Board will receive the following information reports and may take action. *(time: 6:45 pm – 7:30 pm)*

A. Operations Reports – Damon Sorensen, Interim CEO

1. CEO Report (Interim Chief Executive Officer)

Mr. Sorensen noted that it is important that Pioneers improve employee engagement given the union talks. The newsletter will be an important thing to start again and have received a lot of feedback that employees really enjoyed that in the past. He is also pleased with the financial turnaround that PMHD is making. Pioneers will be sharing more information with the community, but we must stick to the facts. We will share our performance and what we have done for the community. Mr. Sorensen advised the Board that there is a new SNF administrator, Damien Rapp. He started about three weeks ago. We are hopeful

that we will finally have some stable leadership at the nursing facility. Director Rubin mentioned that she has not heard good reports regarding the SNF and would be touching base with Mr. Sorensen about the issues she's heard. Director Santillan recommended to Mr. Sorensen that when new directors or physicians start at Pioneers, they should be brought to the Board meetings, so the Board members can meet them. Mr. Sorensen noted that we will work on putting a process in place for that to happen in the future. He reported that he has received an offer for the office space in El Centro and will move forward with the sale.

2. Hospital operations (Chief Nursing Officer)

There was nothing further to report.

3. Clinics operations (Chief of Clinic Operations)

Ms. Zamora advised that there were two resignations in the Clinics. One was a mid-level, and the other was an RN. She noted that they had recruited a physical therapist, but after AB 918 passed, the candidate decided to rescind his acceptance of the job offer. There is another potential candidate being considered. There was one candidate's CV received on Monday for the OB recruitment effort. The documents were shared with Dr. Kuraitis for his review and the Medical Staff is conducting a background check. The search agencies have been contacted to add Primary Care and Rheumatology to their recruitment efforts. Urology and GI are still in progress, but there have been no applicants. No show rate continues to be at 15% for the month of October and year-to-date. Work will continue on improving this measure.

4. Medical staff (Chief Nursing Officer)

Nothing to report.

5. Finance (Chief Financial Officer)

Nothing to report.

6. Information technology (Chief Nursing Officer)

Nothing to report.

7. Marketing (Director of Marketing)

Director Rubin asked Ms. Ramirez to highlight some of the positive comments that have been posted on social media regarding the OB department. She recommended Ms. Ramirez write articles and submit them to the Desert Review and Calexico Chronicle. It may be beneficial for Pioneers to highlight the positive things that are being done. Ms. Rubin also recommended speaking with the Ambulance and EMT staff to find out how the Base Station transition has worked out since they moved to PMHD since July 2023. The Community would be interested in this kind of information. Ms. Ramirez reported that she will be starting the Pioneers Newsletter every month and that kind of information will be

provided in that publication. It will be posted on social media and printed to be placed in several community locations. Director Berker asked if there would be information in the newsletter where the Community can make inquiries. Ms. Ramirez advised that contact information may be placed in the newsletter where the public can reach out if they have any questions. Director Rubin stated that there needs to be a bigger sign outside letting the public know where the outpatient registration is located. It was advised that this information can also be added to the newsletter. Ms. Ramirez mentioned that PMHD developed a holiday greeting commercial and should already be airing. One Board member acknowledged seeing it. Various departments are working on health informational pieces to share with the public. A discussion ensued on various locations to provide info regarding Pioneers accomplishments and services.

8. Facilities, logistics, construction, support

The application for the daVinci is currently with HCAi/OSHPD and it is in its third revision. We are hoping to receive approval sometime in January 2024. The robot will arrive at Pioneers by the middle of December.

9. Quality resources - (Director of Quality Resources)

Nothing to report.

10. Board matters

Nothing to report.

B. Legal Counsel Report – Sally Nguyen

1. All matters to be discussed in Closed Session

VII. CLOSED SESSION – The following matters will be considered by the Board in closed session; the Board will reconvene in open session to announce any action taken on matters considered in closed session. *(time: 7:30 pm – 7:50 pm)*

A. QUALITY ASSURANCE – Safe Harbor: Health & Safety Code 32155 the Board will hear reports of a hospital medical audit committee relating to:

1. Quality Report/Scorecard

B. CONSIDERATION OF MATTERS INVOLVING TRADE SECRETS – Safe Harbor: Health and Safety Code §32106, subparagraph (b)

1. Based on the Board's prior findings regarding Trade Secret classification, as contained in Resolution 2023-01, consideration and discussion of possible initiation of the following:
    a. Updating Certain District Strategic Planning Initiatives

C. PENDING OR THREATENED LITIGATION – Safe Harbor: Subdivision (b) of Government Code §54956.9

1. Conference with Legal Counsel regarding threatened litigation involving possible facts or circumstances not yet known to potential party or parties, disclosure of which could adversely affect the District's position.
    a. Compliance Issues

VIII. RECONVENE TO OPEN SESSION (*time: 7:50 – 8:00 pm)*

A. Take Actions as Required on Closed Session Matters

There were no reportable actions taken in closed session.

IX. ADJOURNMENT *(time: 8:00 pm)*

The meeting was adjourned to the next meeting.

_____
Clerk of the Board

_____
Board Secretary

PIONEERS
MEMORIAL HEALTHCARE DISTRICT

HUMAN RESOURCES REPORT: NOVEMBER 2023

LABOR SUMMARY

November Information

New Hires: 17

Terminations: 26

23 Voluntary, 3 Involuntary

Final Employee Count: 1013

HR UPDATES

PAY SCALES /WAGE ANALYSIS

HR is working with the Nursing Administration to revamp our Nursing classifications and rates.

ANNUAL PREFORMANCE REVIEWS

Annual performance reviews have been assigned within UltiPro. All managers and Directors are currently completing them.
We are at 55 % completion and Directors have until 12/31/2023 to complete reviews for assigned staff.

TRAINING AND EDUCATION:

We are actively interviewing for the education and training specialist role we have posted. We are revamping and reviewing many of our training courses in HealthStream as well as looking at new vendors for training and content for our clinical staff.

Employee Health Summary

We had 25 employee COVID illnesses in November (24 in October; 54 in September). 6 of the positive ee's were reported from our Skilled Nursing Center. No clusters identified in Acute Care. We are still pending TB screening compliance for 112 ee's. Flu vaccine continues to be offered and encouraged for all healthcare workers. 51% of our employees have received flu vaccination; 9% declined flu vaccine; 40% have not participated.

PIONEERS
MEMORIAL HEALTHCARE DISTRICT

HUMAN RESOURCES REPORT: NOVEMBER 2023

Workers' Compensation Summary

10 employee injuries were reported in November. 6 injuries from acute care, 4 injuries from SNF. Two COVID Illness, one sharp injury, one body fluid exposures, one groin pain, one fall walking up the stairs, one toe sprain, one low back contusion, one elbow contusion, one R upper extremity sprain. 8 of the injuries resulted in work comp claims to BETA; one injury received first aid care; one injury required no medical care/reported for tracking purposes. Employees for 3 of the 11 claims have been discharged from care after receiving treatment.

RECRUITMENT

For the month of November, we onboarded 38 Students and 0 Volunteers

Recruitment for open positions:

Nursing: Full time – 24 Part / Per Diem time - 7

Clinical Professional (Allied Health) -2

Patient Services -3

Support Services - 1

Skilled Nursing -14

SERVICE RECOGNITION/ RETENTION

PAC committee's 50/50 Holiday raffle is going fantastic! We hope to have a great holiday win for some lucky PMHD employees which will be drawn 12/15/2023.

December—PAC hosted the annual Christmas Tree lighting on December 1st.

December 8th, we will host our Ugly Christmas Sweater Contest and On December 15th, we will judge the best Department Christmas door contest.

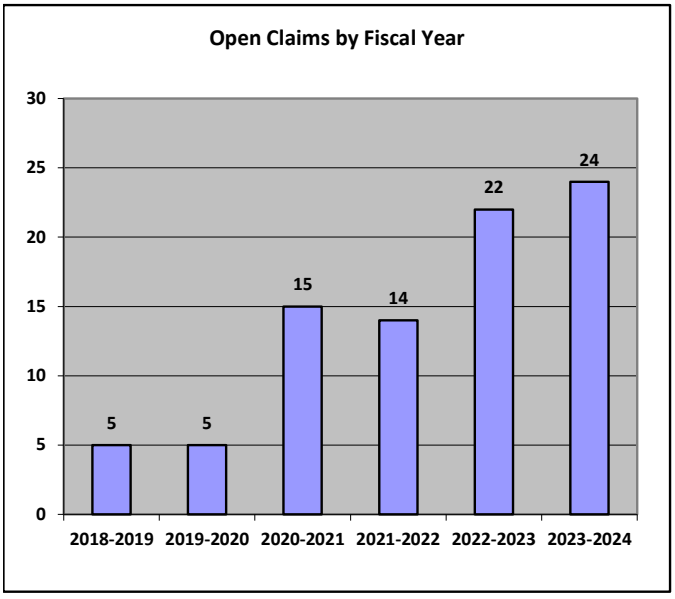
UPCOMING EVENTS:

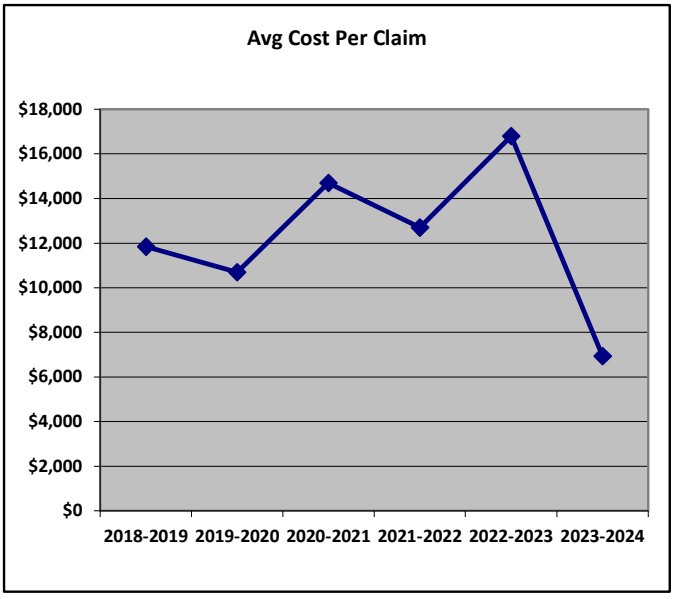
We have begun planning the employee recognition/awards banquet and we plan to have this event in April of 2024.

Workers' Compensation Scorecard

November 2023

Pioneers Memorial Healthcare District



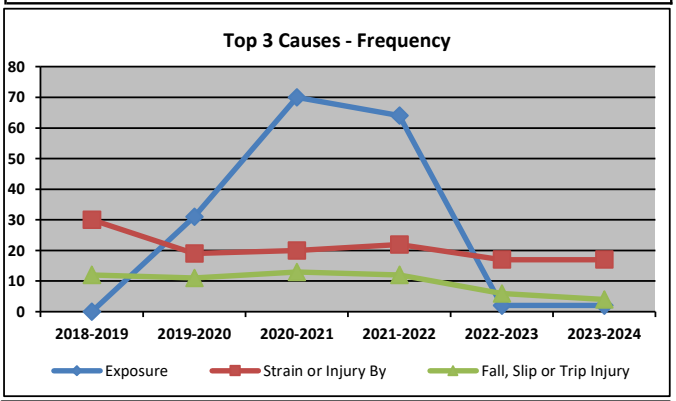


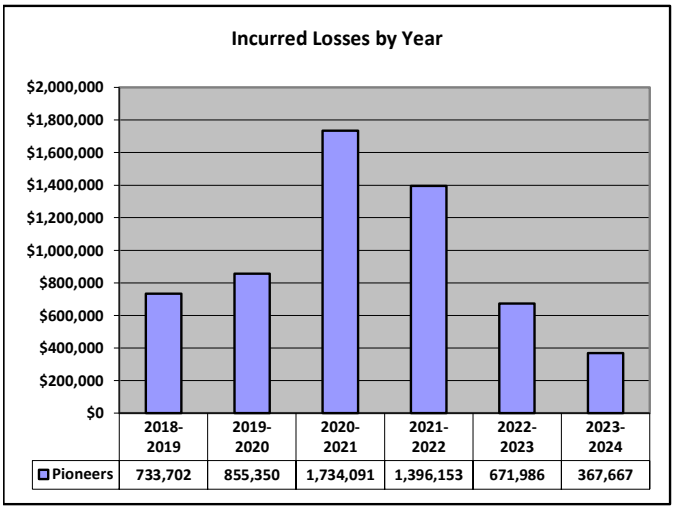
Claim Activity by Month
Current Fiscal Year

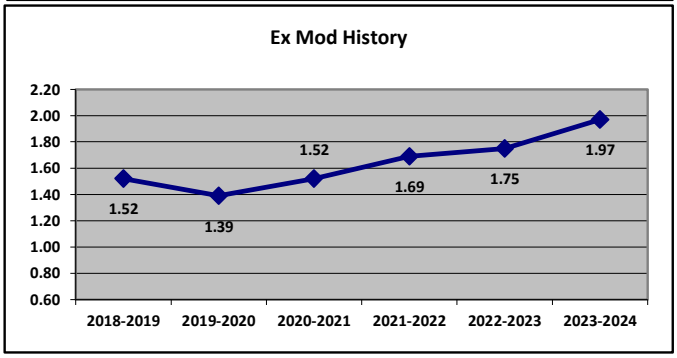
	2023-2024		Last 5 Years
Month	Count	Closed	Closed
Jul	15	8	3
Aug	7	6	6
Sep	12	11	5
Oct	12	4	10
Nov	7	-	11
Dec	-	-	-
Jan	-	-	-
Feb	-	-	-
Mar	-	-	-
Apr	-	-	-
May	-	-	-
Jun	-	-	-
Total 2023-2024	53	29	35

Cause of Injury by Claim Type
Dating Back to Fiscal Year 2018-2019

	Indem	Medical
Strain or Injury By	22.8%	40.2%
Fall, Slip or Trip Injury	8.8%	24.1%
Strain or Injury By	22.8%	40.2%
Struck or Injured By	2.3%	5.4%
Exposure	48.1%	0.0%
All Other	-4.8%	-9.8%

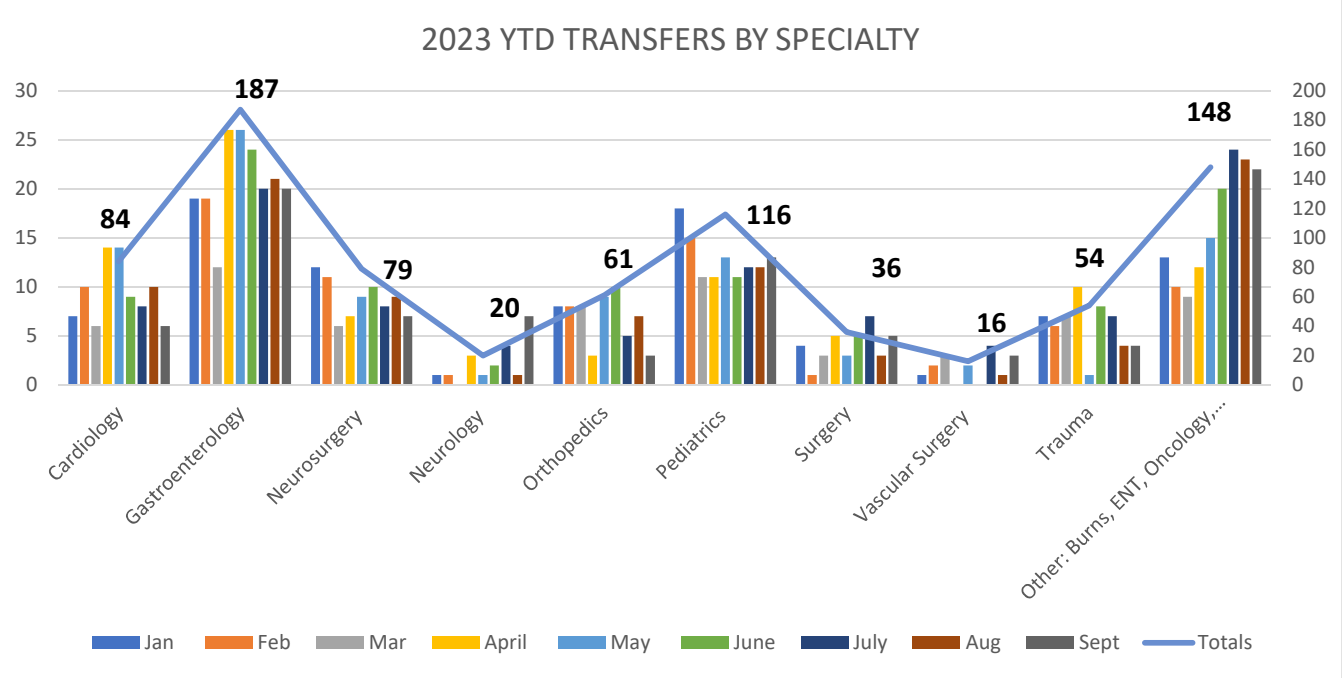






PIONEERS
MEMORIAL HEALTHCARE DISTRICT

September 2023 Transfer Report



2023 TRANSFERS TOTALS										
Specialty	**Jan**	**Feb**	**Mar**	**April**	**May**	**June**	**July**	**Aug**	**Sept**	**Totals**
Cardiology	7	10	6	14	14	9	8	10	6	84
Gastroenterology	19	19	12	26	26	24	20	21	20	187
Neurosurgery	12	11	6	7	9	10	8	9	7	79
Neurology	1	1	0	3	1	2	4	1	7	20
Orthopedics	8	8	8	3	9	10	5	7	3	61
Pediatrics	18	15	11	11	13	11	12	12	13	116
Surgery	4	1	3	5	3	5	7	3	5	36
Vascular Surgery	1	2	3	0	2	0	4	1	3	16
Trauma	7	6	7	10	1	8	7	4	4	54
Other: Burns, ENT, Oncology, Ophthalmology, Podiatry	13	10	9	12	15	20	24	23	22	148
TOTALS Year To Date	**90**	**83**	**65**	**91**	**93**	**99**	**99**	**91**	**90**	**801**

MONTHLY TRANSFERS BY SPECIALTY

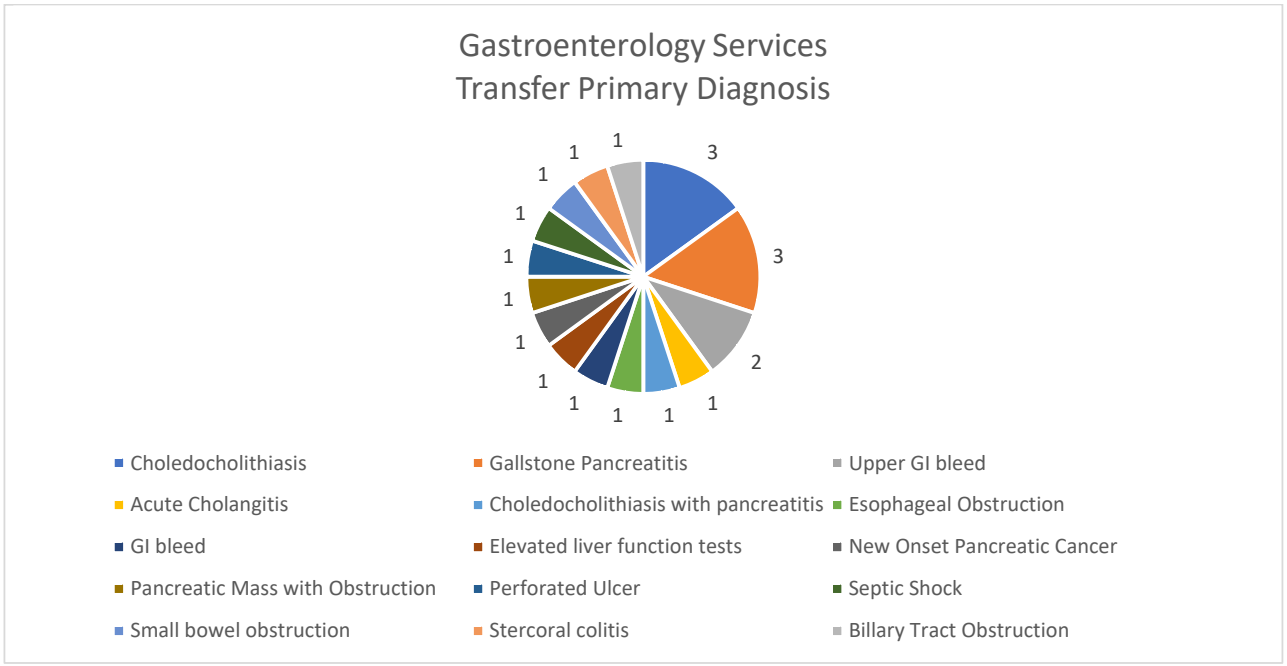
There was a total of There has been a total of 801 transfers from January through September. Top specialty services during this time were Gastroenterology (187), Pediatrics (116), Neurosurgery/Neurology (99), and Cardiology (84).

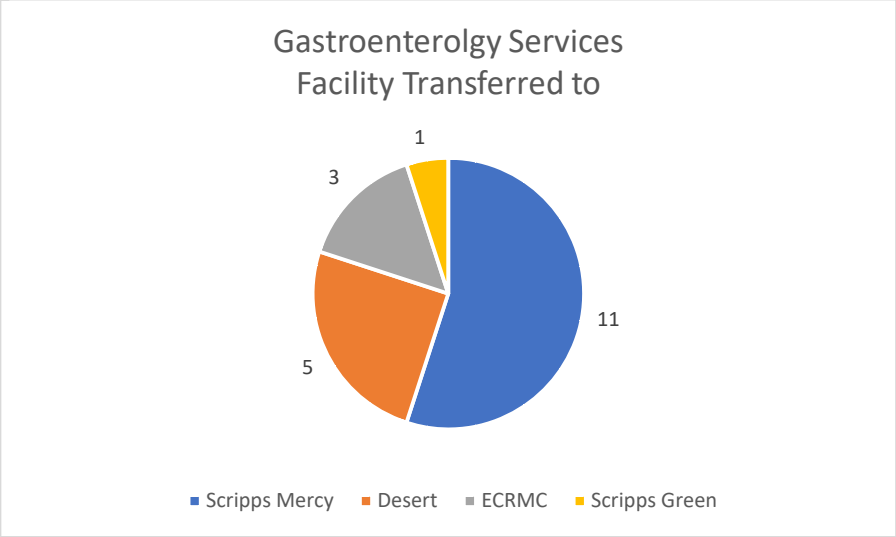
Top specialty services transferred in the month of September were Gastroenterology (20), Pediatrics (13), Neurosurgery/Neurology (14).

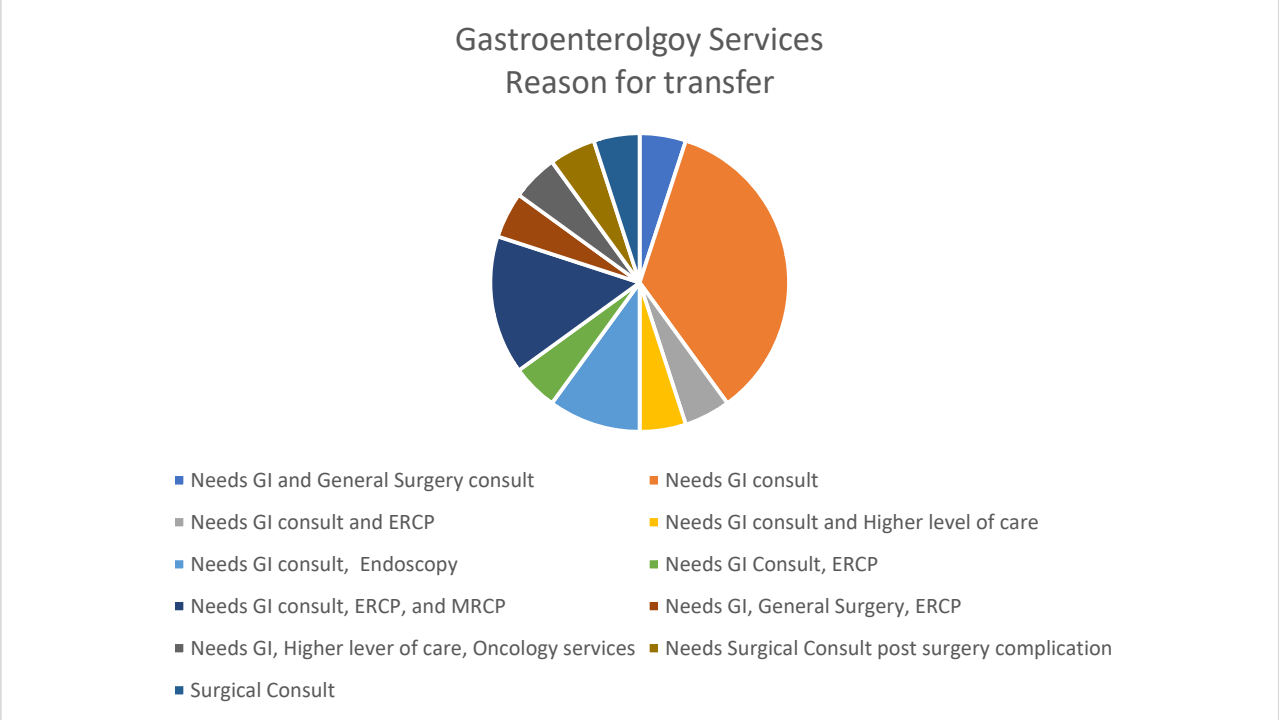
A total of 20 GI cases were transferred. Diagnoses varied for gastroenterology specialty services. 3 of the 20 cases were transferred to ECRMC. 3 more cases were referred to ECRMC however the on-call GI specialist declined to accept in two of the cases, and in one case ECRMC reported they did not have a GI specialist on call. The Need for GI specialty, ERCP and MRCP availability are top reasons for transfer.

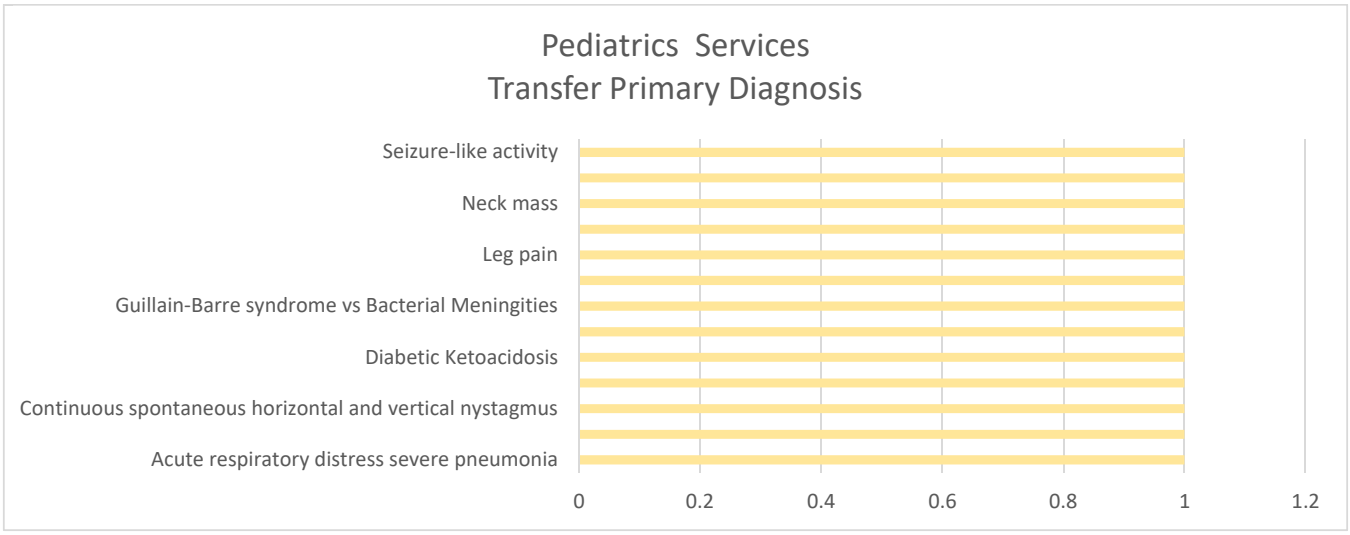
A total of 13 pediatric cases were transferred. Pediatric Specialty Services' primary diagnoses varied. All cases were referred due to specialty care not available at PMHD. All cases were transferred to San Diego Rady Children's Hospital. Neurology, Surgical, orthopedics specialty services are needed.

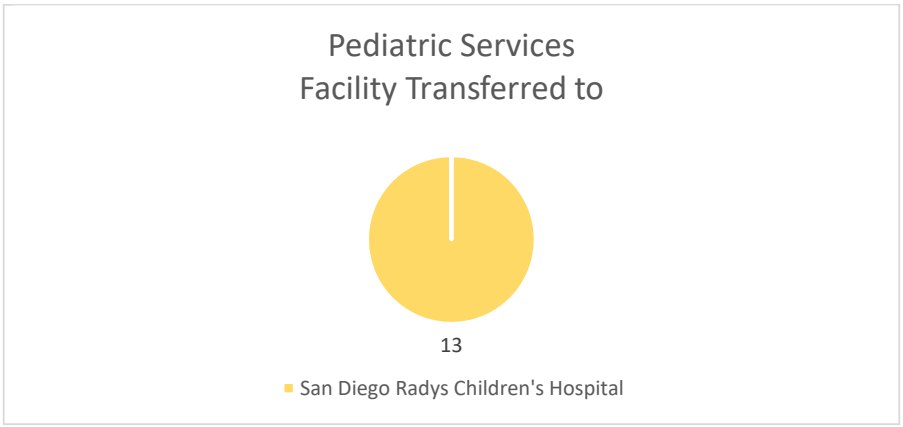
A total of 14 cases were transferred for neurosurgery (7) and/or neurology (7) services. Neurology on call (phone consultation only) was available for all the neurology cases; however, 5 out of the 7 cases required neurology consultation and management and neurosurgical consultation. 2 of the patients needing neurosurgery were 91 years of age, 1 had a DNR/DNI and comfort care order.

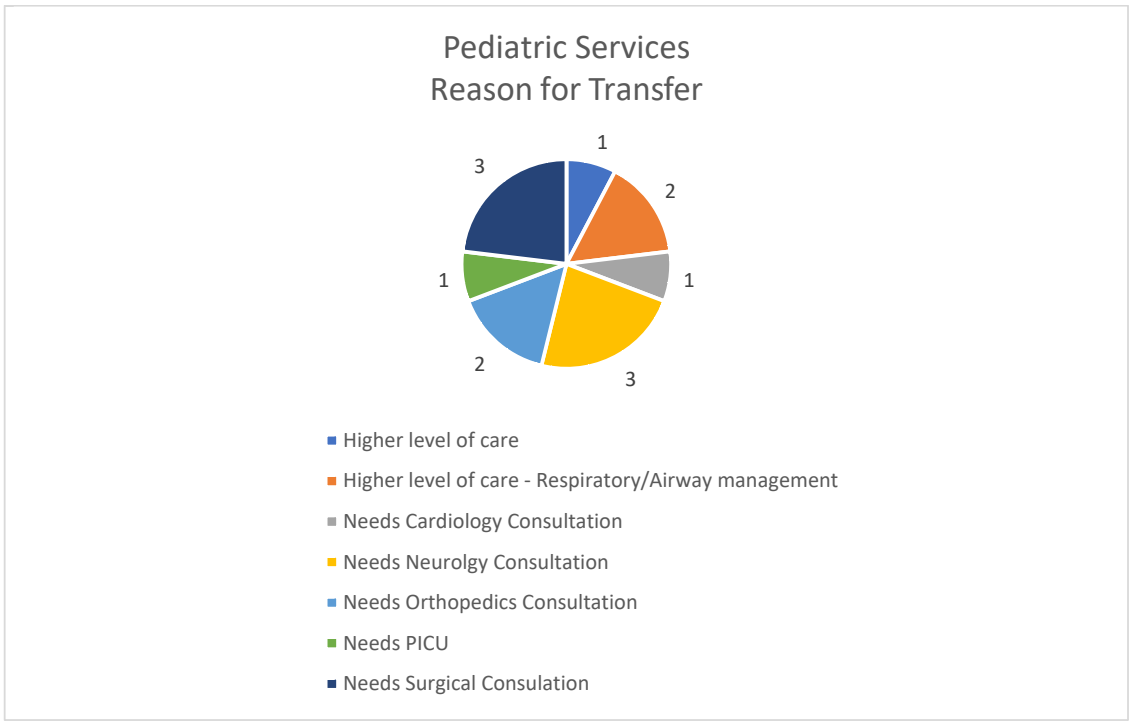


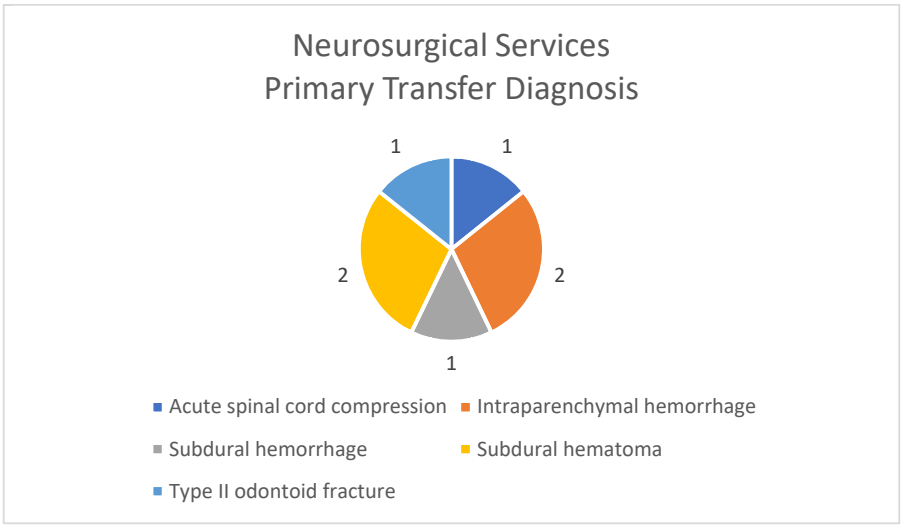

Gastroenterolgy Services
Facility Transferred to
1
3
11
5
Scripps Mercy
Desert
ECRMC
Scripps Green

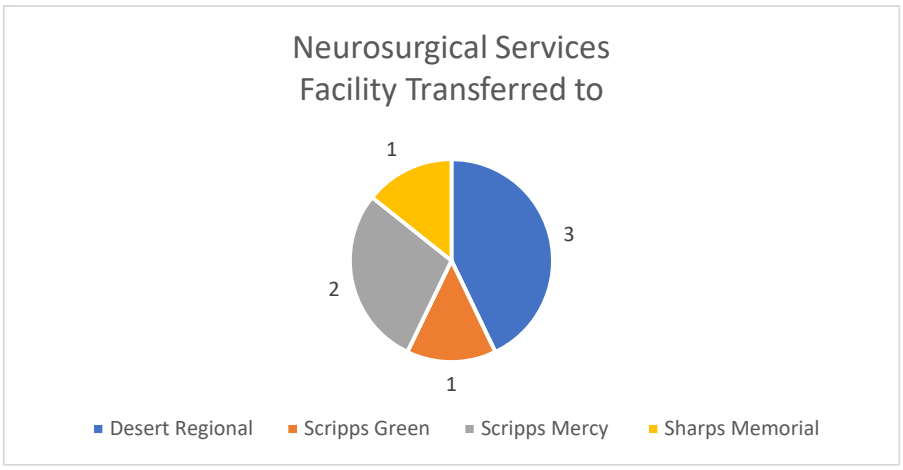

Gastroenterolgoy Services
Reason for transfer
Needs GI and General Surgery consult
Needs GI consult
Needs GI consult and ERCP
Needs GI consult and Higher level of care
Needs GI consult, Endoscopy
Needs GI Consult, ERCP
Needs GI consult, ERCP, and MRCP
Needs GI, General Surgery, ERCP
Needs GI, Higher lever of care, Oncology services
Needs Surgical Consult post surgery complication
Surgical Consult

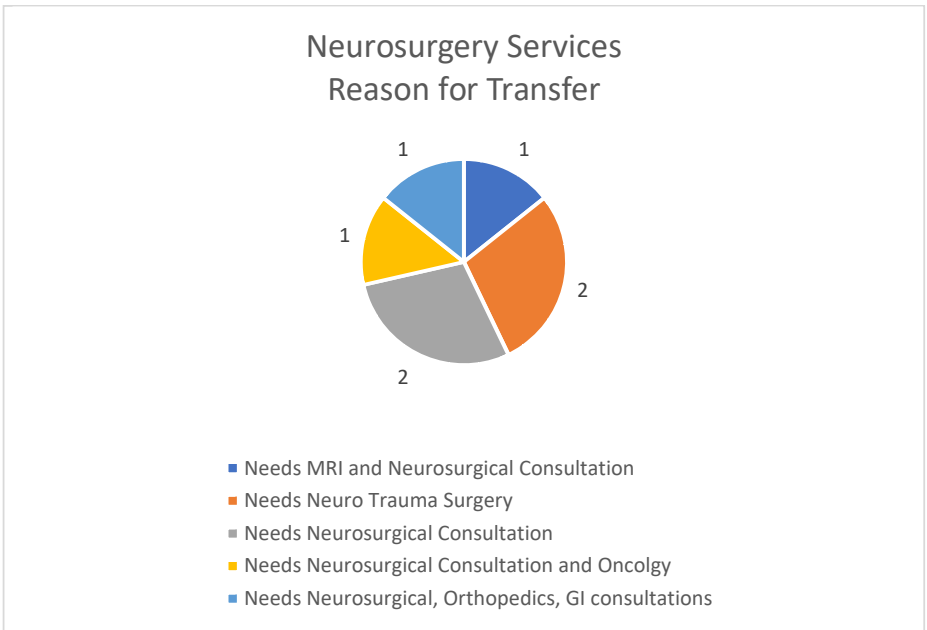

Pediatrics Services
Transfer Primary Diagnosis
Seizure-like activity
Neck mass
Leg pain
Guillain-Barre syndrome vs Bacterial Meningities
Diabetic Ketoacidosis
Continuous spontaneous horizontal and vertical nystagmus
Acute respiratory distress severe pneumonia
0
0.2
0.4
0.6
0.8
1
1.2


Pediatric Services
Facility Transferred to
13
San Diego Radys Children's Hospital


Pediatric Services
Reason for Transfer
1
2
1
3
2
1
3
Higher level of care
Higher level of care - Respiratory/Airway management
Needs Cardiology Consultation
Needs Neurolgy Consultation
Needs Orthopedics Consultation
Needs PICU
Needs Surgical Consulation


Neurosurgical Services
Primary Transfer Diagnosis
1
1
2
2
1
Acute spinal cord compression
Intraparenchymal hemorrhage
Subdural hemorrhage
Subdural hematoma
Type II odontoid fracture


Neurosurgical Services
Facility Transferred to
1
3
2
1
Desert Regional
Scripps Green
Scripps Mercy
Sharps Memorial


Neurosurgery Services
Reason for Transfer
1
1
1
2
2
Needs MRI and Neurosurgical Consultation
Needs Neuro Trauma Surgery
Needs Neurosurgical Consultation
Needs Neurosurgical Consultation and Oncolgy
Needs Neurosurgical, Orthopedics, GI consultations