

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

Tuesday, March 26, 2024
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. 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*)
- IV. MEDICAL STAFF REPORT** – Ramaiah Indudhara, MD, Chief of Staff, will present for Board consideration, the following matters: (*time: 5:30 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
- 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. Antimicrobial Stewardship
 - 2. Hazardous Drug Handling
 - 3. Per Diem Program
 - B. Update Reports
 - 1. Women's Auxiliary
 - 2. LAFCO

SECTION

C. Human Resources Report

D. Authorize Amendment No. 1 Agreement for Radiology Services with Imperial Valley Radiology Medical Group

Contract Value: \$3,225,000/yr.; Contract Term: Three (3) years; Budgeted: No; Budget Classification: Professional Fees

E. Authorize 340B Pharmacy Services Agreement with Rite Aid Hdqtrs. Corp.

Contract Value: estimated \$300,000; Contract Term: Three (3) years; Budgeted: N/A; Budget Classification: Revenue

F. Authorize Locum Tenens Coverage Agreement with Alumni Staffing, LLC

Contract Value: based on recruitment; Contract Term: One (1) year; Budgeted: No; Budget Classification: Purchased Services

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 – Christopher Bjornberg, CEO

1. CEO Report (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/Director of Information Systems)
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

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)*

SECTION**A. 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

B. CONFERENCE WITH LEGAL COUNSEL – ANTICIPATED LITIGATION – Initiation of
litigation pursuant to paragraph (4) of subdivision (d) of section 54956.9

1. Potential Cases: 1

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



DATE: March 19, 2024

TO: Pioneers Memorial Healthcare District Board of Directors

FROM: Ramaiah Indudhara, M.D; Chief of Staff

SUBJ: Medical Staff Recommendations for Approval

ITEMS FOR CONSIDERATION: Recommendations from the Medical Executive Committee for Medical Staff Membership and/or Clinical Privileges, policies/procedures/forms or other related recommendations.

SUMMARY AND BACKGROUND: The Medical Executive Committee, upon the recommendations of the Credentials Committee and the respective clinical services and/or chiefs and based on the completed credential files, policies, and procedures, recommends that medical staff membership and/or clinical privileges be granted as outlined below:

1. Recommendation for **Initial Appointment** to the **Provisional Staff effective April 1, 2024** for the following:

- Arce Gastelum, Alheli, MD Internal Medicine, Endocrinology
- Gomez, Rahul, DO Internal Medicine

2. Recommend **Reappointment** effective **April 1, 2024** for the following:

- Hassan, Sammy, DO Anesthesiology
- Hermann, Matthew, MD Teleradiology
- Maxey, Robert, MD Teleradiology
- Self, Lewis, MD Internal Medicine
- Zadeh, Alidad, DO Internal Medicine
- Flentje, Clinton, CRNA Nurse Anesthetist
- Gerber, Kimberly, CRNA Nurse Anesthetist
- Romo, Jorge, PA Physician Assistant

3. Recommend Request for **Release from Proctoring and Advancement** effective **April 1, 2024:**

- None

4. Recommend acceptance of the following **Resignations from Staff** effective **April 1, 2024:**

- Lin, Victor, DO Failure to reappoint
- Morneau, Leonard, MD Voluntary Resignation
- Rutman, Michael, MD Failure to reappoint
- Favila, Susana, FNP Failure to reappoint
- Marshall, Milena, CRNA, DNP Voluntary resignation
- Ndam, Jean-Marc, CRNA Failure to reappoint

5. Recommend acceptance of the following policies/forms:

- Aerosol Transmission Plan (ATP) – CLN-02378
- Family Medicine Delineation of Privilege Form
- Robotic Assisted Surgery Delineation of Privilege Form

6. Ms. Bojorquez – Implementation of Cerner EMR – Ongoing, those present were reminded of the implementation of the new EMR. Go Live Date April 15, 2024. Ms. Bojorquez gave the transfer report of the patients transferred out for high level of care for Gastroenterology, Cardiac. It was also mentioned cross training staff for departments, staff will be able to cover areas that have sick calls or high census. Lastly, she mentioned the Employee engagement survey, providers are encouraged to participate.

7. Clinical Service and Committee Reports:

- Medicine – No meeting was held. Dr. Tariq reported - working with administration and the University of Riverside for resident program.
- Emergency Medicine – A meeting was held.

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- Surgery/Anesthesia/Pathology – A meeting was held. Discussed and approved Robotic Assist privileges were approved. Dr. Larra informed committee for the last 3 months they have had student CRNA's rotate through the program will be an asset to the team to help with volumes in the OR and OB.
- OB/GYN – A meeting was held. Discussed and approved Robotic Assist privileges.
- Pediatrics – No meeting was held.
- Medical Imaging – No meeting was held.
- Ambulatory Services – Ms. Zamora highlighted good participation of the staff in Cerner reintegration process. Every Friday Cerner orientation classes are held for the staff. Carrie sent out an updated lists on a weekly basis for providers that have not signed up to register, emails were sent out last week.
- Credentials & Bylaws – A meeting was held it was presented at MEC.
- MSQC- Policies were reviewed and approved then forwarded for consideration to the MEC. Chart delinquencies were also discussed.
- Utilization Management – No meeting held.
- Hospitalist – Stephan Papp, MD welcomed as the new Medical Director of the hospitalist group.

RECOMMENDATION: That Pioneers Memorial Healthcare District Board of Directors approves each of the recommendations of the Medical Executive Committee for medical staff membership and clinical privileges as outlined above, policies and procedures as noted and authorizes the chief executive officer to sign any documents to implement the same.

Respectfully submitted,
Ramaiah Indudhara, MD, MBA, FACS
Chief of Staff
RI/arc

POLICIES FOR APPROVAL AT MEC

	Policy	Policy No.	Page #	Revisions (see policy for full description)
1.	Aerosol Transmission Plan (ATP)	CLN-02378	<ul style="list-style-type: none"> 01-30 	<ul style="list-style-type: none"> Removed mandatory source masking from 5.4.1 – Exception-Current COVID-19 pandemic requires the use of a procedure or surgical mask (unless higher protection is indicated) for all staff and patients that are over two years of age and able to safely tolerate as means of source control. Patient who are alone in rooms do not need to wear a mask unless otherwise indicated. Added “Cal-OSHA standards” to 5.14.1 for clarification. Removed attachment E regarding 2010-2011 influenza season. Reorganized/Clarified attachments titles. Updated/removed outdated references.
2.	Robotic Assist Surgery Delineation of Privilege form	N/A	<ul style="list-style-type: none"> 	<ul style="list-style-type: none"> New Privilege Form

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Title: Antimicrobial Stewardship Program		Policy No. CLN-02971
Current Author: Edward Padilla		Page 1 of 10
Latest Review/Revision Date: 01/08/2024		Effective: 3/25/2013
		Manual: Clinical Pharmacy

Collaborating Departments: Infection Control, Microbiology, Information Systems		Keywords: Infection Control; Antibiotics; Selection; Antibigram; Clinical Activities; Infectious Disease		
Approval Route: List all required approval				
MARCC 1/16/2024	PSQC	Other: P & T Subcommittee		
Clinical Service _____		MSQC 2/2024	MEC 2/2024	BOD 2/2024

1.0 Purpose:

- 1.1 To improve antimicrobial use and treatment of infectious diseases by optimizing antimicrobial selection, and providing antimicrobial therapy at the appropriate dose, frequency, and duration according to indication
- 1.2 To achieve optimal clinical outcomes related to antimicrobial use (e.g. reduced morbidity, reduced mortality, and reduced length of hospital stay) while minimizing toxicity, adverse events, and the emergence of antimicrobial-resistant organisms
- 1.3 To reduce antimicrobial days of therapy (DOT) and reduce healthcare costs associated with treatment of infectious diseases without adversely impacting quality of care

2.0 Scope:

- 2.1 Medical Staff
- 2.2 Pharmacy
- 2.3 Microbiology and Laboratory
- 2.4 Infection Control
- 2.5 Information Technology

3.0 Policy:

- 3.1 The implementation of an antimicrobial stewardship program (ASP) can decrease the emergence and transmission of multi-drug resistant pathogens, and can decrease healthcare costs associated with treating infectious diseases without adversely impacting the quality of care.
 - 3.1.1 The ASP initiatives, in conjunction with infection control and prevention, are designed to reduce or prevent the emergence and transmission of infections due to multidrug-resistant organisms (MDROs).
 - 3.1.2 The Antimicrobial Stewardship Program (ASP) initiatives are consistent with evidence-based practices and regulatory requirements as outlined by the Infectious Disease Society of America (IDSA), California Department of Public Health (CDPH), and Centers for Disease Control and Prevention (CDC)
- 3.2 A multidisciplinary Antimicrobial Stewardship Team (AST) oversees the Antimicrobial Stewardship Program (ASP) and works collaboratively with the Infection Control Committee, the Pharmacy and Therapeutics Committee, hospital administration, and medical staff leadership.
- 3.3 Healthcare information technology (i.e., electronic medical records, computerized physician order entry, antibiogram/microbiology lab data and clinical decision support) is used to support and optimize ASP initiatives.

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- 3.4 Metric, process, and outcome measures are used to assess the effectiveness of the Antimicrobial Stewardship Program initiatives and the overall impact on antimicrobial use and resistance patterns.
- 3.5 This policy will establish the Antimicrobial Stewardship Team at PMHD to promote multidisciplinary collaboration for a successful antimicrobial stewardship program, and will provide procedures for implementing strategies using recommended interventions to optimize antimicrobial therapy and improve antimicrobial use at PMHD.

4.0 Definitions:

- 4.1 Antimicrobial stewardship refers to collaborative and coordinated interventions designed to improve and measure the appropriate use of antimicrobial agents by promoting the selection of the optimal antimicrobial regime including dosing, duration of therapy, and route of administration.
 - 4.1.1 When used in conjunction with infection prevention and control, antimicrobial stewardship also prevents the transmission of antimicrobial-resistant pathogens.
- 4.2 Antimicrobial and antibiotic will be used interchangeably in this policy, and will both be pertaining to all anti-infective therapy

5.0 Procedure:

- 5.1 Antimicrobial Stewardship Team (AST)
 - 5.1.1 The AST is responsible for oversight and implementation of the Antimicrobial Stewardship Program initiatives. The AST is also responsible for reporting findings and recommendations to licensed independent practitioners (LIP), the Infection Control Committee, and the Pharmacy and Therapeutics (P&T) Committee.
 - 5.1.2 The core members of the PMHD multidisciplinary AST, at minimum, include an infectious disease physician and clinical pharmacist with antimicrobial stewardship training
 - 5.1.2.1 When an infectious disease physician is not available, a physician with antimicrobial stewardship training may fill the role.
 - 5.1.2.2 Other members of the AST may include other practitioners, a microbiologist or lab representative, an information system specialist, and an infection control professional.
 - 5.1.3 The AST will report to the P&T Committee. The report is then forwarded to the Medical Executive Committee (MEC) for review by medical staff.
 - 5.1.4 Computer Surveillance and Decision Support
 - 5.1.4.1 Information technology (i.e., electronic medical records, computerized physician order entry, antibiogram/microbiology lab data, MedMined™ Surveillance Advisor, and clinical decision support) is utilized and optimized to support the ASP initiatives including, but not limited to:
 - 5.1.4.1.1 Improving access to patient-specific information such as microbiology cultures and susceptibilities, hepatic/renal function, drug interactions, and allergies

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- 5.1.4.1.2 Tracking resistance patterns
- 5.1.4.1.3 Identifying nosocomial infections
- 5.1.4.1.4 Facilitating and tracking interventions
- 5.1.4.1.5 Surveillance of adverse drug events (ADE)
- 5.1.5 Microbiology laboratory: the microbiology laboratory plays a critical role in antimicrobial stewardship by providing:
 - 5.1.5.1 Patient-specific cultures and susceptibility data using suppression cascade reporting
 - 5.1.5.2 Surveillance of resistant organisms
 - 5.1.5.3 Antibigram data development and maintenance.
 - 5.1.5.4 Suppression Cascade Reporting
 - 5.1.5.4.1 Implement cascade reporting of antibiotic susceptibilities for common pathogens (i.e., suppression of unnecessarily broad spectrum agents for bacteria that are susceptible to less broad spectrum agents).
- 5.1.6 Pharmacy
 - 5.1.6.1 The infectious diseases pharmacist is responsible for overseeing the daily operation of the ASP, and daily implementation of the ASP initiatives, strategies, and interventions
 - 5.1.6.2 The infectious diseases pharmacist or clinical pharmacist, as a member of the antimicrobial stewardship team, will utilize the interventions and strategies as appropriate listed in Section 5.2 and Section 5.3, and make recommendations to the LIPs; and as appropriate to the infectious disease physician, AST, and/or P&T committee on a daily basis, with the intention of optimizing antimicrobial therapy for patients receiving broad and/or extended spectrum antibiotics.
 - 5.1.6.3 The infectious disease pharmacists may order (per protocol) per this policy the following laboratory tests required to manage patients receiving antimicrobial therapy:
 - 5.1.6.3.1 Culture Nasal R/O MRSA (S)
 - 5.1.6.3.2 MRSA, PCR (S)
 - 5.1.6.3.3 Culture Respiratory (S)
 - 5.1.6.3.4 Culture Urine (S)
 - 5.1.6.3.5 Urinalysis, Complete (S)
 - 5.1.6.3.6 Procalcitonin (PCT)
 - 5.1.6.3.7 Meningitis/Encephalitis (ME) Panel, PCR (S)
 - 5.1.6.3.8 Respiratory Panel, PCR (S)
 - 5.1.6.3.9 CBC w/AutoDiff (S)
 - 5.1.6.3.10 CDiff (Clostridium difficile Antigen and Toxin (S))
 - 5.1.6.4 The infectious diseases pharmacist or clinical pharmacist will also be responsible for the following:
 - 5.1.6.4.1 Vancomycin and aminoglycoside pharmacokinetic (PK) dosing per PMHD Policy CLN-02967(Pharmacy Vancomycin Management Policy) and PMHD Policy CLN-02868 (Pharmacy Aminoglycoside Management Policy)

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- 5.1.6.4.2 Medication utilization evaluation (MUE) of at least one antimicrobial medication
- 5.1.6.4.3 Drug use criteria (DUC) development and implementation
- 5.1.6.4.4 Antibigram development and maintenance, with monitoring of drug resistant pathogens
- 5.1.6.4.5 Ensuring proper documentation of ASP clinical interventions
- 5.1.7 Infection Control Team: the infection control team plays a critical role in antimicrobial stewardship by providing:
 - 5.1.7.1 Surveillance, tracking, reporting, and prevention of multidrug-resistant organisms (MDRO): initiatives are developed to prevent infections due to MDROs including, but not limited to; methicillin-resistant *Staphylococcus aureus* (MRSA), vancomycin-resistant enterococcus (VRE), vancomycin-resistant *Staphylococcus aureus* (VRSA), extended spectrum β -lactamase (ESBL) producing pathogens, and carbapenem-resistant enterobacteriaceae (CRE), and *Clostridium difficile*
 - 5.1.7.2 Practices consistent with evidence-based standards of practice and regulatory requirements are developed and implemented to reduce the risk of *transmitting* multidrug-resistant organisms.
 - 5.1.7.3 Risk assessments: conducted annually for multidrug-resistant organism acquisition and transmission.
 - 5.1.7.3.1 Based on the risk assessment, a targeted or hospital-wide surveillance initiative is implemented.
 - 5.1.7.3.2 As indicated by the risk assessment, a laboratory-based alert system is implemented to identify new patients and readmitted or transferred patients who are known to be positive for multidrug-resistant organisms.
- 5.2 Strategies
 - 5.2.1 Antimicrobial formulary review
 - 5.2.1.1 Review costs associated with antimicrobials
 - 5.2.1.2 Assess for duplicative and/or unnecessary agents
 - 5.2.1.3 Ensure antimicrobials on formulary are aligned with hospital antibiogram
 - 5.2.2 Formulary Restrictions and Preauthorization Requirements: guidelines for the usage of restricted antimicrobial agents are provided in Attachment C (Restricted Antimicrobial Usage Guidelines). The following formulary restrictions and preauthorization requirements for antimicrobial use will be implemented:
 - 5.2.2.1 *Formulary-Based Restriction (Closed Formulary)*
 - 5.2.2.1.1 The antimicrobial formulary, including any formulary restriction on use, are reviewed and approved through the P&T Committee.
 - 5.2.2.1.2 Formulary changes are communicated to the microbiology lab in order to update susceptibility testing protocols

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5.2.2.2 *Criteria-Based Restriction:* medications with high resistance liability, excess utilization, serious adverse events, or elevated costs may be considered for criteria-based restrictions.

5.2.2.2.1 Criteria-based medications are not dispensed until the criteria are met. These medications include:

- Aztreonam (Azactam®)
- Ceftaroline (Teflaro®)
- Daptomycin (Cubicin®)
- Ertapenem (Invanz®)
- Linezolid (Zyvox®)
- Meropenem (Merrem®)
- Imipenem and Cilastatin (Primaxin®)
- Micafungin (Mycamine®)
- Voriconazole (Vfend®)
- Dalbavancin (Dalvance®)

5.2.2.2.2 Requests to override the restriction based on pre-defined criteria (see Attachment C: Restricted Antimicrobial Usage Guidelines) are treated as a non-formulary medication, and require documentation of the reason for override at the time of order entry in QCPR.

5.2.2.2.2.1 Overrides of criteria-based restricted antimicrobials are reviewed by the AST, and are reported to the P&T Committee for review

5.2.2.3 *Preauthorization-Based Restriction:* Select antibiotics are only prescribed with the preauthorization of an approved practitioner

5.2.2.3.1 The following medications must be approved for use by the infectious disease specialist as soon as possible, but no later than 72 hours. If the infectious disease specialist is not available, approval may be obtained from the critical care specialist:

- Colistin (colistimethate) (Coly-Mycin M®)
- Polymyxin B
- Tigecycline (Tygacil®)
- Fidaxomicin (Difcid®)
- Ceftazidime and Avibactam (Avycaz®)
- Rifabutin (Mycobutin®)

5.2.3 Prospective audits with intervention and feedback

5.2.3.1 Conduct audits and review of antimicrobials at the time of order entry, and provide direct feedback to the prescriber using recommendations in Section 5.3.

5.2.3.1.1 Special consideration to be given to broad and extended-spectrum antibiotics, including antibiotics that provide coverage for hospital-acquired MRSA, ESBL-producing microorganisms, and *Pseudomonas aeruginosa*

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- 5.2.3.2 Review patient charts daily for patients receiving antimicrobial therapy, and evaluate the appropriateness of therapy including dose, frequency, and duration based on indication, and assess for opportunities for streamlining/de-escalation/discontinuation of therapy using recommendations in Section 5.3.1
- 5.2.3.2.1 Special consideration to be given to extended-spectrum antibiotics, including antibiotics that provide coverage for hospital-acquired MRSA and *Pseudomonas aeruginosa*
- 5.2.3.3 Evaluate antimicrobial therapy for patients receiving extended-spectrum antibiotics (carbapenems, β -lactams with *Pseudomonas aeruginosa* coverage, and antibiotics with HA-MRSA coverage) at least every 3 days for possible opportunities to de-escalate or discontinue therapy
- 5.2.4 Antibiotic Time Out
 - 5.2.4.1 A re-evaluation of all patients receiving antimicrobial therapy after 48 hours, but no later than 72 hours after initiation of antimicrobial therapy is recommended. This should be done by a clinical pharmacist, ASP team member, and/or the patient's practitioner
 - 5.2.4.2 This "Time-Out" should evaluate the need for continuation of antimicrobial therapy and will assess the following:
 - Presence of an infection including signs and symptom
 - C&S report results
 - Appropriate antimicrobial dose, frequency, and duration
 - IV to PO conversion criteria
- 5.2.5 Documentation of interventions
 - 5.2.5.1 Interventions and recommendations made by the AST will be documented in MedMined™ Surveillance Advisor or in the electronic medical record.
- 5.2.6 Tracking and reporting: metrics, process and outcome measures are used to assess the effectiveness of the ASP initiatives and the overall impact on antimicrobial use and resistance patterns
 - 5.2.6.1 The following antimicrobial stewardship program metrics, process and outcome measures will be reported to the P&T committee at each meeting:
 - 5.2.6.1.1 Antimicrobial utilization measurement and evaluation: antimicrobial utilization will be estimated and reported in days of therapy (DOT) and/or Days of Therapy (DOT) per 1,000 Patient Days/Days at Risk/Days Present
 - 5.2.6.1.2 At least one MUE related to antibiotics is conducted; goals are established with an accompanying action plan based on results
 - 5.2.6.2 The following antimicrobial stewardship program metrics will be reported to the P&T Committee, Medical Executive Committee (MEC), or the Patient Safety Quality Council (PSQC) at least annually:
 - 5.2.6.2.1 Hospital acquired infections that are required for reporting to the National Healthcare Safety Network (NHSN)
 - 5.2.6.2.2 Infections due to multi-drug resistant organisms (MDRO) based on microbiology results: number and/or frequency of infections due to microorganisms such as *Pseudomonas aeruginosa* (*PsA*), methicillin-

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resistant *Staphylococcus aureus* (MRSA), and extended spectrum β -lactamase (ESBL) producing pathogens

5.2.6.2.3 Resistance: antimicrobial susceptibility and resistance data for the most common pathogens

5.2.6.3 Antibigram: an antibiogram will be updated annually, and will be uploaded to the pharmacy's PMHD intranet site using the following recommendations from the Clinical and Laboratory Standards Institute (CLSI) guideline on antibiogram preparation:

5.2.6.3.1 Susceptibility data will be analyzed for accuracy

5.2.6.3.2 Report data for species with ≥ 30 isolates

5.2.6.3.2.1 If reporting for species < 30 isolates, must indicate reduction of statistical validity of result

5.2.6.3.3 Include only diagnostic cultures

5.2.6.3.4 Include only the first isolate of a species per patient per analysis period, irrespective of site or antibiotic susceptibility profile

5.2.6.3.5 Include unsuppressed results

5.2.6.3.6 Include antibiotics routinely tested on hospital formulary

5.2.6.3.7 For *Streptococcus pneumoniae*, list the susceptibility using both meningitis and non-meningitis breakpoints for cefotaxime, ceftriaxone, and penicillin

5.2.6.3.8 For *Staphylococcus aureus*, list the susceptibility for both methicillin susceptible and methicillin resistant species

5.2.6.3.9 Procedures for developing the antibiogram outside of CLSI recommendations will be noted on the antibiogram

5.2.6.4 Interventions: number and proportion of accepted and/or rejected interventions, including individual prescriber data will be reported to the P&T Committee at least annually

5.2.7 Education: educate and promote ASP strategies and prescribing criteria

5.2.7.1 Pharmacists will receive antibiotic stewardship education annually, with additional infectious disease-related topics as needed

5.2.7.2 The AST will provide education material regarding antibiotic stewardship to prescribers. This may include, but not limited to pocket guides, memos, management guidelines, order sets, and newsletters.

5.2.7.3 Education may be provided to practitioners in conjunction with active intervention and antimicrobial oversight (e.g., prospective audit and feedback).

5.3 Interventions

5.3.1 Documentation of indication

5.3.1.1 The licensed independent practitioner (LIP) will be responsible for entering an indication for all antimicrobial orders at the time of order entry

5.3.2 Documentation of allergies: patient allergies should be identified and properly documented in QCPR

5.3.3 Appropriate empiric antimicrobial selection: appropriate antimicrobial therapy based on indication, hospital-specific susceptibility data, and patient specific parameters

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- 5.3.3.1 PMHD's antimicrobial formulary, order sets, management recommendations, and treatment algorithms provided in this ASP policy, should be used to guide empiric antimicrobial therapy
- 5.3.3.2 Antimicrobial formulary: institutional antimicrobial formulary is provided in Attachment F
- 5.3.3.3 Evidence based order sets: evidence based order sets will be available to prescribers via hard-copy or electronically via QCPR at the time of LIP order entry.
 - 5.3.3.3.1 These order sets will be developed using the most current literature and practice guidelines, and using PMHD's most current antibiogram
- 5.3.3.4 Management recommendations including treatment algorithms and clinical pathways
 - Bronchitis and Pneumonia: see Attachment G
 - Sepsis: see Attachment H
 - *Clostridium difficile* Infection: see Attachment I
 - Asymptomatic Bacteriuria and Urinary Tract Infection: see Attachment J
 - Skin and Soft Tissue Infections and Bone Infections: see Attachment K
- 5.3.4 Appropriate Dose and Frequency
 - 5.3.4.1 All antimicrobial orders will be evaluated for appropriate dose and frequency based on indication by a clinical pharmacist.
 - 5.3.4.2 The clinical pharmacist will evaluate the creatinine clearance for all patients placed on antimicrobial therapy and adjust dose/frequency based on PMHD Policy CLN-02983 (Renal Dosing Pharmacy Protocol)
 - 5.3.4.3 The clinical pharmacist will be responsible for monitoring and adjusting vancomycin and aminoglycoside therapy for all patients per PMHD Policy CLN-02967 (Pharmacy Vancomycin Management Policy) and PMHD Policy CLN-02868 (Pharmacy Aminoglycoside Management Policy)
- 5.3.5 Appropriate length of therapy
 - 5.3.5.1 All administration of antimicrobial therapy should be restricted to the minimum duration required for maximum efficacy to avoid unnecessary prolonged antimicrobial exposure
 - 5.3.5.2 Recommended durations of antimicrobial therapy are provided in Attachment A: Antibiotic Length of Therapy for Select Conditions
- 5.3.6 Appropriate use of combination therapy
 - 5.3.6.1 A clinical pharmacist will evaluate all antimicrobial combination therapy for appropriate use and make necessary recommendations to the prescribing LIP
- 5.3.7 Culture and Susceptibility (C&S) Timing: relevant cultures need to be obtained prior to the initiation of antimicrobial therapy.
- 5.3.8 MRSA surveillance: identifying patients colonized with MRSA may be useful in guiding antibiotic streamlining/de-escalation

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- 5.3.8.1 Patients presenting with signs/symptoms of infection and MRSA risk factors should be screened for MRSA colonization with a MRSA nasal swab.
- 5.3.9 Streamlining or De-escalation
 - 5.3.9.1 Culture and susceptibility (C&S) reports will be evaluated daily for patients receiving broad-spectrum and extended-spectrum antimicrobial therapy
 - 5.3.9.2 A clinical pharmacist or ASP team member/s will assess C&S for opportunities to de-escalate or streamline antimicrobial therapy, and make appropriate recommendations to the LIP based on their findings.

6.0 References:

- 6.1 The Joint Commission Infection Control Standards and NPSG 7.03.01
- 6.2 Centers of Medicare and Medicaid Services (CMS) CoP §482.42
- 6.3 Healthcare Facilities Accreditation Program (HFAP)
- 6.4 DNV National Integrated Accreditation for Healthcare Organizations (NIAHO –DNV) IC.1 Infection Prevention and Control System
- 6.5 California Department of Public Health: The California Antimicrobial Stewardship Program Initiative.
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- 6.6 Butler J, Foltz C, et al. Taking an Antibiotic Time-out: Utilization and Usability of a Self-Stewardship Time-out Program for Renewal of Vancomycin and Piperacillin-Tazobactam. Hosp Pharm. 2015 Nov;50(11):1011-24. doi: 10.1310/hpj5011-1011. Epub 2015 Nov 24.
- 6.7 Davidson LE, Doron S. Antimicrobial Stewardship. Mayo Clin Proc. 2011 Nov;86(11):1113-23. doi: 10.4065/mcp.2011.0358.
- 6.8 Billeter M, Brennan PJ, et al. Infectious Diseases Society of America and the Society for Healthcare Epidemiology of America guidelines for developing an institutional program to enhance antimicrobial stewardship. Clin Infect Dis. 2007 Jan 15;44(2):159-77. Epub 2006 Dec 13.
- 6.9 Masterton RG. Antibiotic De-Escalation. Crit Care Clin. 2011 Jan;27(1):149-62. doi: 10.1016/j.ccc.2010.09.009.
- 6.10 See PMHD related policy Antibigram; CLN-03000
- 6.11 See PMHD related policy IV to PO Conversion; CLN-02801
- 6.12 See PMHD related policy Formulary Management; CLN-02823
- 6.13 See PMHD related policy Vancomycin Management; CLN-02967
- 6.14 See PMHD related policy Pharmacy Aminoglycoside Management; CLN-02868
- 6.15 Garey KW. Improving patient outcomes with effective antimicrobial stewardship programs. University of Houston College of Pharmacy Department of Pharmacy Practice and Translational Research. Houston, TX.
- 6.16 CDC. Core Elements of Hospital Antibiotic Stewardship Programs. Atlanta, GA: US Department of Health and Human Services, CDC; 2014. Available at <http://www.cdc.gov/getsmart/healthcare/implementation/core-elements.html>.
- 6.17 National Quality Partner's antibiotic Stewardship Action Team. National Quality Partners Playbook: Antibiotic Stewardship in Acute Care. Washington, DC: National Quality Forum, NQF; 2016. Available at <http://www.qualityforum.org/Publications/2016/05/National>

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- 6.18 Nebraska Medicine. Antimicrobial Stewardship Program.
<http://www.nebraskamed.com/careers/education-programs/asp>.
- 6.19 UCLA Health. Antimicrobial Stewardship Program. <http://www.asp.mednet.ucla.edu/pages/>
- 6.20 Deresinski S, Holubar M. Antimicrobial Stewardship. In: UpToDate, Hooper DC, UpToDate, Waltham, MA. (Accessed January 2017).
- 6.21 Beaumont JL, Peterson LR, et al. Prediction of Methicillin-Resistant Staphylococcus aureus Involvement in Disease Sites by Concomitant Nasal Sampling. J Clin Microbiol. 2008 Feb; 46(2): 588–592. Published online 2007 Dec 5. doi: 10.1128/JCM.01746-07.
- 6.22 Chung A, Dangerfield B, et al. Predictive Value of Methicillin-Resistant Staphylococcus aureus (MRSA) Nasal Swab PCR Assay for MRSA Pneumonia. Antimicrob Agents Chemother. 2014 Feb; 58(2): 859–864. doi: 10.1128/AAC.01805-13.
- 6.23 American Society of Health-System Pharmacists. A Hospital's Guide to Antimicrobial Stewardship Programs. www.ashpadvantage.com/docs/stewardship-white-paper.pdf. (Accessed January 2017).
- 6.24 Clinical and Laboratory Standards Institute. M100-S23: Performance Standards for Antimicrobial Susceptibility Testing, Twenty-Third Informational Supplement, January 2013. http://reflab.yums.ac.ir/uploads/clsi_m100-s23-2013.pdf (Accessed January 2017).

7.0 Attachment List:

- 7.1 Attachment A: Antibiotic Length of Therapy for Select Conditions
- 7.2 Attachment B: Antimicrobial Prophylaxis in Surgery
- 7.3 Attachment C: Restricted Antimicrobial Usage Guidelines
- 7.4 Attachment D: Criteria-Based Antimicrobial Order Form
- 7.5 Attachment E: Procalcitonin (PCT) Guidance for Sepsis and Lower Respiratory Tract Infections
- 7.6 Attachment F: PMHD Antimicrobial Formulary
- 7.7 Attachment G: PMHD Bronchitis and Pneumonia Management Recommendations
- 7.8 Attachment H: PMHD Sepsis Management Recommendations
- 7.9 Attachment I: PMHD Clostridium difficile Infection Management Recommendations
- 7.10 Attachment J: PMHD Asymptomatic Bacteriuria and Urinary Tract Infections Management Recommendations
- 7.11 Attachment K: PMHD Skin and Soft Tissue Infections and Bone Infections Management Recommendations
- 7.12 Attachment L: PMHD Statement of Leadership Commitment to Antimicrobial Stewardship

8.0 Summary of Revisions:

- 8.1 Revision of Attachments B, C, D, F, G, H, J, and K

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Collaborating Departments: Pharmacy, Safety Officer, Nursing, Human Resources (Employee Health)		Keywords: Hazardous, Carcinogen, Toxic, Genotoxicity, Antineoplastic, Chemotherapy		
Approval Route: List all required approval				
MARCC 11/9/2023	PSQC	Other: Safety & P&T Committee		
Clinical Service _____		MSQC 1/2024	MEC 1/2024	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 procedures that promote patient safety, worker safety, and environmental protection when handling hazardous drugs (HDs) (i.e. receiving, storing, compounding/manipulating, dispensing, administering, and disposing) from the point of entry into the facility to the point of disposal.

2.0 Scope:

- 2.1 Medical Staff
- 2.2 Pharmacy staff
- 2.3 Nursing staff
- 2.4 Clinical and non-clinical staff with potential exposure to hazardous drugs

3.0 Policy:

- 3.1 Hazardous Drug (HD) Handling is in compliance with the standards set forth in USP <800> *Hazardous Drugs – Handling in Healthcare Setting* and; USP <795> *Pharmaceutical Compounding Non-sterile Preparations* and USP <797> *Pharmaceutical Compounding Sterile Preparations* as appropriate.
- 3.2 The hospital identifies in writing its hazardous drugs.
- 3.3 The risks associated with handling hazardous drugs are communicated to all staff involved in accordance with the organization's Hazard Communication Program.
- 3.4 Safety Data Sheets are readily available to personnel handling HDs.
- 3.5 The hospital designates a qualified and trained individual to oversee compliance with USP<800> Hazardous Drug Handling standards and other applicable laws and regulations.

4.0 Definitions:

- 4.1 Hazardous Drug (HD): As defined by the NIOSH Working Group, drugs considered hazardous include those that exhibit one or more of the following six characteristics in humans or animals:
 - 4.1.1 Carcinogenicity
 - 4.1.2 Teratogenicity or other developmental toxicity
 - 4.1.3 Reproductive toxicity in humans
 - 4.1.4 Organ toxicity at low doses in humans or animals
 - 4.1.5 Genotoxicity

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- 4.1.6 Structure and toxicity profiles of new drugs that mimic existing drugs determined hazardous by the above criteria
- 4.2 National Institute for Occupational Safety and Health (NIOSH) defines three groups of drugs:
 - 4.2.1 Group 1: Antineoplastic drugs (AHFS classification 10:00) [ASHP/AHFS DI 2016]
These drugs represent an occupational hazard to health care 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).
 - 4.2.2 Group 2: Non-antineoplastic drugs that meet one or more of the NIOSH criteria for a hazardous drug.
 - 4.2.3 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.

5.0 Procedure:**5.1 Identification of Hazardous Drugs (HD)**

- 5.1.1 Hazardous drugs are identified based on the *NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings*.
- 5.1.2 The facility maintains a list of the hazardous drugs that are handled in the hospital.
Attachment: Hazardous Drug List and Risk Assessment Tool
- 5.1.3 The list of hazardous drugs identifies the HDs based on the three NIOSH groups.
 - 5.1.3.1 Group 1: Antineoplastic drugs
 - 5.1.3.2 Group 2: Non-antineoplastic drugs that meet one or more of the NIOSH criteria for a hazardous drug.
 - 5.1.3.3 Group 3: Drugs that primarily pose a reproductive risk
- 5.1.4 The hazardous drug list is reviewed and updated at least every 12 months and as necessary as new drugs with hazard potential are brought into the facility.
 - 5.1.4.1 New agents or dose forms used in the facility are reviewed for inclusion on the hospital's list.
 - 5.1.4.2 When it is not possible to identify whether a drug is considered hazardous, the drug is added to the hazardous drug list and managed in accordance with the appropriate category until additional information can be obtained.
- 5.1.5 Containment Requirements
 - 5.1.5.1 HD active pharmaceutical ingredient (API) and antineoplastic agents requiring manipulation follow all of the containment requirements defined in USP<800>.
 - 5.1.5.2 Final dose forms that do not require additional manipulation other than counting or repacking do not require additional containment unless specified by the manufacturer, or if there are visual indicators of dust or leakage from packaging.
 - 5.1.5.3 An assessment of risk is performed for other HDs to define alternate containment strategies and work place practices.

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<Note: If an assessment of risk is not performed all of the containment requirements defined in USP<800> are applied to all HDs>

5.1.6 Assessment of Risk

5.1.6.1 The hospital performs a risk assessment for *eligible* hazardous drugs to determine alternate containment strategies, work place practices and required/recommended personal protective equipment (PPE). **Attachment:** Hazardous Drug Risk Assessment Template

5.1.6.2 The risk assessment considers at minimum:

5.1.6.2.1 Type of HD (i.e. antineoplastic, non-antineoplastic, reproductive risk only)

5.1.6.2.2 Dosage form

5.1.6.2.3 Risk of exposure

5.1.6.2.4 Packaging

5.1.6.2.5 Manipulation

5.1.6.3 The alternate containment strategies /work place practices determined by the assessment of risk are documented.

5.1.6.4 The assessment of risk is reviewed at least every 12 months and the review is documented.

5.1.7 HD's Eligible for Risk Assessment

5.1.7.1 Final dose forms of compounded HDs and commercially manufactured HDs that do not require manipulation other than counting or repacking (unless required by the manufacturer)

5.1.8 HDs Not Eligible for Risk Assessment

5.1.8.1 HD active pharmaceutical ingredients (API)

5.1.8.2 HD antineoplastics requiring manipulation

5.2 Hazard Communication Program

5.2.1 Employees who are in contact with any hazardous chemicals or products containing hazardous substances are informed and trained on appropriate handling and safety precautions in accordance with federal and state requirements.

<Note: Certain States administer their own OSHA Approved Safety and Health Programs. These programs meet or exceed Federal guidelines and may have additional rules and regulations that are not part of the Federal guidelines. Hospitals located in a "State Plan" state must contact their state office for all compliance/policy/regulatory issues and violation reports. For a listing of State Plans <http://www.osha.gov/dcsp/osp/index.html>.>

5.2.2 A list of hazardous drug/substances present in the workplace is maintained.

5.2.3 Safety Data Sheets (DS's) for hazardous substances found in the workplace are maintained and readily available.

5.2.4 Documentation of employee's acknowledgement of hazardous drug risks is maintained. **Attachment:** *Hazardous Drug Acknowledgement Form*

5.2.5 See Hazard Communication Program

5.2.6 <See SOPs Hazardous Drugs: Hazard Communication Program>

5.3 Responsibilities of Personnel Handling Hazardous Drugs

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5.3.1 The hospital designated qualified and trained individual understands the rationale for risk prevention policies, risk to himself and others, risk of noncompliance that may compromise safety, and responsibility to report potentially hazardous situations to the management team. The individual is responsible for:

- 5.3.1.1 Developing and implementing appropriate procedures
- 5.3.1.2 Overseeing compliance
- 5.3.1.3 Ensuring competency of personnel
- 5.3.1.4 Ensuring environmental control of the storage and compounding areas
- 5.3.1.5 Overseeing facility monitoring
- 5.3.1.6 Maintenance of testing and sampling reports, including acting on results

5.3.2 All personnel who handle HDs are responsible for understanding the fundamental practices and precautions and for continually evaluating these procedures and the quality of final HDs to prevent harm to patients, minimize exposure to personnel, and minimize contamination of the work and patient-care environment.

5.4 **Personnel Training**

5.4.1 Personnel handling HDs are trained based on their job functions (e.g., receipt, storage, compounding, repackaging, dispensing, administering, and disposing of HDs).

The training includes at least the following:

- 5.4.1.1 Overview of the list of HDs and their risks
- 5.4.1.2 Review of Standard Operating Procedures (SOPs) related to handling of HDs
- 5.4.1.3 Proper use of Personal Protective Equipment (PPE)
- 5.4.1.4 Proper use of equipment and devices (e.g., engineering controls)
- 5.4.1.5 Response to known or suspected HD exposure
- 5.4.1.6 Spill management
- 5.4.1.7 Proper disposal of HDs and trace contaminated materials

5.4.2 Training occurs *before* the employee independently handles HDs, when new HDs are brought into the facility, before new equipment is used, and when SOPs are added or change.

5.4.3 Competency is assessed and documented *before* independently handling HDs and every 12 months

5.5 **HD Handling Areas**

5.5.1 Signs designating the hazard are prominently displayed before the entrance to the HD handling areas.

5.5.2 Access to the HD handling areas is restricted to authorized personnel.

5.5.3 Designated areas are available for:

- 5.5.3.1 Receipt and unpacking
- 5.5.3.2 Storage of HDs
- 5.5.3.3 Non-sterile HD compounding
- 5.5.3.4 Sterile HD compounding

5.6 **Environmental & Engineering Control**

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- 5.6.1 Environmental and engineering controls comply with local, state, and federal regulation and are in compliance with the standards set forth in USP <800> *Hazardous Drugs – Handling in Healthcare Settings*, USP <795> *Pharmaceutical Compounding Non-sterile Preparations*, and USP <797> *Pharmaceutical Compounding Sterile Preparations*.

5.7 Personal Protective Equipment (PPE)

- 5.7.1 PPE is worn when handling HDs as defined in the facility SOPs based on the risk assessment of exposure and activity performed. <See NIOSH Table 5 for general guidance on PPE>
- 5.7.2 PPE is worn as defined by the SOPs during:
- 5.7.2.1 Receiving
 - 5.7.2.1.1 USP <800> Required PPE: Chemotherapy gloves
 - 5.7.2.2 Storage
 - 5.7.2.3 Transport
 - 5.7.2.4 Compounding (sterile and non-sterile)
 - 5.7.2.4.1 USP <800> Required PPE: Gowns, head, hair, two pairs of shoe covers and two pairs of chemotherapy gloves are required for compounding sterile and non-sterile HDs
 - 5.7.2.5 Administration
 - 5.7.2.5.1 USP <800> Required PPE: Two pairs of chemotherapy gloves are required for administering antineoplastic HDs. Gowns shown to resist permeability by HDs are required when administering injectable antineoplastic HDs
 - 5.7.2.6 Deactivation/decontamination, cleaning, and disinfecting
 - 5.7.2.6.1 USP <800> Required PPE: Two pairs of chemotherapy gloves and impermeable disposable gown. Additionally, eye protection and face shields if splashing is likely and if warranted by the activity, respiratory protection
 - 5.7.2.7 Spill control
 - 5.7.2.8 Waste disposal
- 5.7.3 PPE includes; gloves, gowns, head, hair shoe and sleeve covers, eye and face protection and respiratory protection.
- 5.7.4 Disposable PPE is preferred. Disposable PPE must not be re-used.
- 5.7.5 Re-usable PPE, if used, is decontaminated and cleaned between uses.
- 5.7.6 Gloves are American Society for Testing and Materials (ASTM) standard D6978 (or its successor) and are powder free.
- 5.7.7 Gowns are disposable and shown to resist permeability of HDs, close in the back, have long sleeves and closed cuffs.
<See SOPs for Hazardous Drugs: PPE>

5.8 Receiving

- 5.8.1 Antineoplastic HDs and all HD APIs are unpacked (i.e., removal from external shipping containers) in an area that is neutral/normal or negative pressure relative to

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the surrounding areas. HDs are *not* unpacked from their external shipping containers in sterile compounding areas or in positive pressure areas.

- 5.8.2 Hazardous drugs are received in sealed, impervious plastic to segregate them from non-hazardous drugs.
- 5.8.3 Personal protective equipment (PPE), including chemotherapy gloves, is worn when receiving/unpacking hazardous drugs.
- 5.8.4 HDs are delivered to the HD storage area immediately after unpacking.
- 5.8.5 Prior to storing HDs, the outer surface of the product/packaging is wiped down (not sprayed) with a neutralizing solution to remove surface contaminants.
- 5.8.6 A spill kit is kept in the receiving area.
- 5.8.7 During the receiving process, each shipping container containing HDs is inspected for damage or breakage such as visible stains due to leakage or the sound of broken glass.
- 5.8.8 Receiving and Handling Damaged HD Shipping Containers
 - 5.8.8.1 Damaged packages or shipping cartons are considered spills that must be reported to the designated person and managed according defined Standard Operating Procedures (SOPs) (See Spill Management).
 - 5.8.8.2 If damage is suspected, trained personnel wearing appropriate PPE:
 - 5.8.8.2.1 Seal the container without opening and contact the supplier
 - 5.8.8.2.2 If returning to the supplier, enclose the entire container in an impervious container and label as "hazardous".
 - 5.8.8.2.3 If the container must be opened, the container is moved to a Containment Primary Engineering Control (C-PEC) and placed on a plastic backed preparation mat.
 - 5.8.8.2.4 Remove undamaged items and wipe the outside with disposable wipes.
 - 5.8.8.2.5 Place damaged items in an impervious container and label the outside "hazardous".
 - 5.8.8.2.5.1 Dispose of in compliance with HD disposal policies.
 - 5.8.8.2.5.2 The C-PEC is deactivated, decontaminated, and cleaned. The mat and all disposables are discarded as hazardous waste.
 - 5.8.8.3 Segregate HDs waiting to be returned to the supplier in a designated negative pressure area.

5.9 Storage

- 5.9.1 Antineoplastic HDs requiring manipulation (other than counting or repackaging of final dosage forms) and any HD API are stored separately from non-HDs in an externally ventilated, negative-pressure room with at least 12 air changes per hour (ACPH).
- 5.9.2 Non-antineoplastic, reproductive risk only and final dosage forms of antineoplastic HDs may be stored with other inventory as defined by hospital policy.
- 5.9.3 Drug packages, bins, shelves, and storage areas bear distinctive labels identifying those drugs requiring special handling precautions.

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- 5.9.4 HDs are stored in bins with high fronts placed on shelves that have guards to prevent accidental falling.
- 5.9.5 HDs used for non-sterile compounding are *not* stored in sterile compounding areas.
- 5.9.6 Sterile and non-sterile HDs may be stored together, but HDs used for non-sterile compounding should not be stored in areas designated for sterile compounding to minimize traffic into the sterile compounding area.
- 5.9.7 Refrigerated antineoplastic HDs are stored in a dedicated refrigerator in a negative pressure area with at least 12 ACPH [e.g., storage room, buffer room, or containment segregated compounding area (C-SCA)].
- 5.9.8 It is not recommended that hazardous drugs be stored in automated dispensing cabinets. If stored in automated dispensing cabinets, HDs have auxiliary labeling to alert staff of the need to refer to documents outlining proper handling and PPE.

5.10 Preparation/Compounding

- 5.10.1 *Required PPE for HD Compounding*; Gowns: head, hair, two pairs of shoe covers and two pairs of chemotherapy gloves are required for compounding sterile and non-sterile HDs
- 5.10.2 HDs are compounded in compliance with applicable USP standards for compounding including USP <795> and USP <797>.
- 5.10.3 Sterile and non-sterile HD compounding and HD manipulation occurs in a Containment Primary engineering control (C-PEC) inside a Containment Secondary Engineering Control (C-SEC) as defined by USP <795>, USP <797> and USP <800>.
- 5.10.4 The C-SEC used for sterile and non-sterile compounding is:
 - 5.10.4.1 Externally vented
 - 5.10.4.2 Physically separated (i.e., a different room from other preparation areas)
 - 5.10.4.3 Has an appropriate air exchange (e.g., ACPH)
 - 5.10.4.4 Negative pressure between 0.01 and 0.03 inches of water column relative to all adjacent areas
- 5.10.5 A sink is available for hand washing and an eyewash station and/or other emergency or safety precautions that meet applicable laws and regulations are readily available.
- 5.10.6 The C-PEC used for sterile compounding is not routinely used for non-sterile compounding or manipulation.
 - 5.10.6.1 If occasionally used, the C-PEC is deactivated, decontaminated, cleaned, and disinfected prior to sterile compounding.
- 5.10.7 Disposable or clean equipment for compounding (such as mortars and pestles, and spatulas) are dedicated for use with HDs only.
- 5.10.8 Closed system transfer devices (CSTD) are used as a supplemental engineering control during the compounding of antineoplastic agents when the dosage form allows.
- 5.10.9 IV tubing is attached and primed with plain fluids before compounding antineoplastics.
- 5.10.10 CSTD are attached prior to removal from the C-PEC for use during administration of antineoplastic injectables.

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5.10.11 Final preparation is surface decontaminated and the outer glove removed while still in the C-PEC. (In an isolator, the fixed gloves are surface cleaned after outer glove removal.) Labeling and placement in the containment bag for transport occurs prior to removal of the inner gloves.

5.10.12 Transport bags are not inside the C-PEC during the compounding process.

5.10.13 When compounding HD preparations in a C-PEC, a plastic-backed preparation mat is placed on the work surface of the C-PEC. The mat is changed immediately if a spill occurs and regularly during use, and is discarded at the end of the daily compounding activity.

5.10.14 Sharps containers and HD waste containers are sealed and surface decontaminated before removal from the biological safety cabinet or compounding aseptic isolator.

<See SOPs for Hazardous Drug: Compounding>

5.11 **Packaging/Repackaging**

5.11.1 Repackaging and counting final dose forms that do not produce particles, aerosols, and gases do not need to be performed in a C-SEC.

5.11.2 Packaging containers and materials are used that maintain physical integrity, stability, and sterility (if applicable); protect the HD from damage, leakage, contamination, and degradation; and protects healthcare workers.

5.11.3 Equipment used for counting and/or repacking HDs is decontaminated after each drug and is dedicated for HD use only.

5.11.4 Tablet and capsule forms of HDs are not counted or repackaged using automated machines.

5.12 **Labeling**

5.12.1 HDs identified as requiring special HD handling precautions are clearly labeled at all times.

5.12.2 The labeling process for compounded preparations does not introduce contamination into the non-HD handling areas.

5.13 **Transportation**

5.13.1 HDs for transport are labeled, stored and handled in compliance with local, state and federal regulation

5.13.2 Transport personnel receive documented training on safe handling of HDs during transport and action to take in the event of a spill.

5.13.3 Pneumatic tubes systems are not used to transport any liquid HDs or any antineoplastic HDs.

5.13.4 Carts and transport containers with guards are used to protect against falling and breakage.

5.13.5 When transporting HDs outside of the facility, the Transport Information on the Safety Data Sheet is consulted. The labels and accessory labeling for the HDs include storage instructions, disposal instructions, and HD category information in a format that is consistent with the carrier's policies and federal, state and local regulations.

5.14 **Administration**

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- 5.15 USP <800> Required PPE: Two pairs of chemotherapy gloves are required for administering antineoplastic HDs. Gowns shown to resist permeability by HDs are required when administering injectable antineoplastic HDs
- 5.16 Closed system transfer devices (CSTD) are used when administering antineoplastics when the dosage form allows.
- 5.17 Administration is performed safely using protective medical devices and techniques. <See Chemotherapy Safety Policy: Administration>

5.18 Disposal

- 5.18.1 Personnel who perform routine custodial waste removal and cleaning activities in HD handling areas are trained in appropriate procedures to protect themselves and the environment to prevent HD contamination.
- 5.18.2 Disposal of all HD waste, including, but not limited to, unused HDs and trace contaminated PPE and other materials, comply with all applicable federal, state, and local regulations.
- 5.18.3 Refer to Pharmaceutical Waste Management Plan
<See SOPs Hazardous Drugs: Disposal>

5.19 Deactivation, Decontamination, Cleaning and Disinfecting

- 5.19.1 Areas where HDs are handled and reusable equipment and devices are deactivated, decontaminated, and cleaned. Additionally, sterile compounding areas and devices are disinfected. **Attachment:** Hazardous Drug Deactivation, Decontamination and Cleaning Chart and Products List
- 5.19.2 C-PEC with an area under the work tray are deactivated, decontaminated, and cleaned monthly.
- 5.19.3 Personnel who perform deactivation, decontamination, cleaning, and disinfection activities in HD handling areas are trained in appropriate procedures to protect themselves and the environment from contamination.
- 5.19.4 USP <800> Required PPE: Two pairs of chemotherapy gloves and impermeable disposable gown; additionally, eye protection and face shields if splashing is likely and if warranted by the activity, respiratory protection
- 5.19.5 Deactivation
- 5.19.5.1 Deactivation is performed to render compounds inactive or inert
- 5.19.5.2 Products with known deactivation properties (EPA registered oxidizers) are used when appropriate. Note: Avoid use when there is likelihood of adverse effects such as generation of hazardous byproducts, respiratory effects, and/or damage to surfaces.
- 5.19.6 Decontamination
- 5.19.6.1 HD residue is transferred from non-disposable surfaces to absorbent, disposable wipes, pads, or towels. Decontamination occurs:
- 5.19.6.1.1 Between compounding different hazardous drugs
- 5.19.6.1.2 Daily (when used)
- 5.19.6.1.3 When a spill occurs
- 5.19.6.1.4 Before and after certification
- 5.19.6.1.5 When voluntary interruption occurs

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5.19.6.1.6 When (if) the ventilation tool is moved

5.19.7 Cleaning

- 5.19.7.1 Cleaning is performed in accordance with USP <795> and USP <797> requirements.
- 5.19.7.2 Cleaning is not performed while compounding activities are occurring.
- 5.19.7.3 Water, detergent, surfactants, solvents, and/or other chemicals are used to remove contaminants.
- 5.19.7.4 Cleaning products are chosen that do not introduce contaminants.
- 5.19.7.5 All materials used for cleaning are disposed of as hazardous waste.

5.19.8 Disinfection

- 5.19.8.1 Sterile compounding areas are disinfected after cleaning as defined by USP <797>.
<See SOP Hazardous Drugs: Deactivation, Decontamination, Cleaning and Disinfecting>

5.20 Spill Management

- 5.20.1 Personnel authorized to clean up a spill of HDs receive training in spill management and the use of PPE and NIOSH certified respirators.
- 5.20.2 Spills are contained and cleaned immediately by qualified personnel wearing appropriate PPE.
- 5.20.3 Qualified personnel are available at all times while HDs are being handled.
- 5.20.4 Signs are available for restricting access to the spill area.
- 5.20.5 Spill kits containing the materials needed to clean HD spills are readily available in areas where HDs are routinely handled.
 - 5.20.5.1 If HDs are being prepared or administered in a non-routine patient care area, a spill kit and respirator are made available.
- 5.20.6 Spill materials are disposed of as hazardous waste.
<See SOPs Hazardous Drugs: Spill Management>

5.21 Documentation and Standard Operating Procedures (SOPs)

- 5.21.1 SOPs are reviewed at least every 12 months by the designated person and the review is documented.
- 5.21.2 SOPs for handling HDs address:
 - 5.21.2.1 Hazard communication program
 - 5.21.2.2 Occupational safety program
 - 5.21.2.3 Designation of HD areas
 - 5.21.2.4 Receipt
 - 5.21.2.5 Storage
 - 5.21.2.6 Compounding
 - 5.21.2.7 Use and maintenance of proper engineering controls (e.g., C-PECs, C-SECs, and CSTDs)
 - 5.21.2.8 Hand hygiene and use of PPE based on activity (e.g., receipt, transport, compounding, administration, spill, and disposal)
 - 5.21.2.9 Deactivation, decontamination, cleaning, and disinfection
 - 5.21.2.10 Dispensing

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- 5.21.2.11 Transport
- 5.21.2.12 Administering
- 5.21.2.13 Environmental monitoring (e.g., wipe sampling)
- 5.21.2.14 Disposal
- 5.21.2.15 Spill control
- 5.21.2.16 Medical surveillance

5.22 Environmental Quality and Control

- 5.22.1 Environmental wipe sampling for HD surface residue is performed routinely (e.g., initially as a benchmark and at least every 6 months, or more often as needed, to verify containment. Surface wipe sampling includes:
 - 5.22.1.1 Interior of C-PEC and equipment in C-PEC
 - 5.22.1.2 Pass through chambers
 - 5.22.1.3 Surfaces in staging areas
 - 5.22.1.4 Work areas near C-PEC
 - 5.22.1.5 Areas adjacent to C-PEC including floors under the C-PEC, in the staging area and in the dispensing area
 - 5.22.1.6 Areas immediately outside of the HD buffer room or C-SCA
 - 5.22.1.7 Patient administration areas
- 5.22.2 If measurable contamination is identified, the designated individual identifies, documents, and contains the contamination (i.e., evaluate work practices, re-train staff, perform thorough deactivation, decontamination, and cleaning, or improve engineering controls).
 - 5.22.2.1 If deactivation, decontamination and cleaning are performed, the surface wipe sampling is repeated.

5.23 Medical Surveillance

- 5.23.1 Employees who handle hazardous drugs as a regular part of their job assignment are enrolled in a medical surveillance program.
- 5.23.2 The medical surveillance plan is consistent with the facility's Human Resources policies and procedures.
- 5.23.3 The medical surveillance plan includes:
 - 5.23.3.1 Mechanism to recognize employees who may be exposed to HDs under their job duties.
 - 5.23.3.2 Use of the facilities employee health service to confidentially perform health surveillance.
 - 5.23.3.3 Completion of pre-placement health status and medical history including:
 - 5.23.3.3.1 Medical and reproductive history
 - 5.23.3.3.2 Working history assessment of HD exposure. (Exposure can be assessed through a review of records of HDs handled including quantities and dose forms, estimated number of HDs handled per week, estimated hours handling HDs per week or month, completion of a physical assessment and lab studies linked to target organs of commonly used HDs.)
 - 5.23.3.3.3 Physical exam

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5.23.3.3.4 Lab testing

- 5.23.3.4 Medical surveillance records are maintained in accordance with OSHA standards.
- 5.23.3.5 Periodic surveillance is performed in accordance with facility policy and includes updated health and exposure history, physical assessment, and lab measures as appropriate.
- 5.23.3.6 When employment ends, an exit physical exam is completed.
- 5.23.3.7 If any health changes suggesting toxicity are identified, a referral to the appropriate healthcare specialist occurs.
- 5.23.3.8 If acute exposure occurs, including, but not limited to, spills, needle stick, or aerosolized contamination, a post exposure exam occurs.
 - 5.23.3.8.1 The exam focuses on the involved area and the organ(s) commonly affected by the HDs.
- 5.23.3.9 In addition to employee surveillance, routine monitoring of the following factors is completed to protect employees:
 - 5.23.3.9.1 Environmental sampling (when analytical methods are available)
 - 5.23.3.9.2 Engineering controls in proper operating condition
 - 5.23.3.9.3 Employee compliance with policies
 - 5.23.3.9.4 Proper personnel protective equipment is available
 - 5.23.3.9.5 Employee compliance with protective equipment

6.0 References:

- 6.1 National Institute for Occupational Safety and Health (NIOSH) List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings (Accessed October 2016)
http://www.cdc.gov/niosh/topics/antineoplastic/pdf/hazardous-drugs-list_2016-161.pdf
- 6.2 USP General Chapter <800> Hazardous Drugs-Handling in Health Care Settings
- 6.3 The Joint Commission Standards MM.01.01.03 , EC.02.02.01
- 6.4 Health Facilities Accreditation Program (HFAP) 25.00.00, 25.00.05, 25.01.02 and 25.01.22
- 6.5 Centers for Medicare and Medicaid Services (CMS) §482.25(b)
- 6.6 DNV National Integrated Accreditation for Healthcare Organizations (NIAHO –DNV) MM.1, PE.5
- 6.7 ASHP Guidelines on Handling Hazardous Drugs
<http://www.ashp.org/DocLibrary/BestPractices/PrepGdlHazDrugs.aspx> (Accessed April 2016)
- 6.8 OSHA Clinicians Webpage
<https://www.osha.gov/dts/oom/clinicians/index.html#medicalrecords> (Accessed May 2016)
- 6.9 RELATED POLICIES:
 - 6.9.1 PMHD Policy Hazard Communication Program
 - 6.9.2 PMHD Policy Chemotherapy Safety

7.0 Attachment List:

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- 7.1 Attachment A: Hazardous Drug Acknowledgement Form
- 7.2 Attachment B: CPS Hazardous Drug List and Risk Assessment Template
- 7.3 Attachment C: Hazardous Drug Deactivation, Decontamination and Cleaning Chart and Products List
- 7.4 Attachment D: Standard Operating Procedures (SOPs) for Hazardous Drugs
- 7.5 Attachment E: PMHD Hazardous Drug List
- 7.6 Attachment F: PMHD Safe Handling of Hazardous Drugs Chart
- 7.7 Attachment G: NIOSH Table 5 General Guidance on PPE
- 7.8 Attachment H: ID & Classification of Hazardous Drugs – Hazardous Drug Algorithm

8.0 Summary of Revisions:

- 8.1 Changed to “Annual Review”

Hazardous Drug Acknowledgement Form

Name of Employee: _____

I understand working with or near hazardous drugs in healthcare settings may cause skin rashes, infertility, miscarriage, birth defects, and possibly leukemia or other cancers.

I understand that **Pioneers Memorial Healthcare District Pharmacy** maintains detailed policies and procedures on the proper storage, handling, transport and disposal of hazardous drugs. **Pioneers Memorial Healthcare District Pharmacy** has put in place a variety of administrative, engineering and work practice controls to reduce the risk of occupational exposure to hazardous drugs. I understand **Pioneers Memorial Healthcare District Pharmacy's** policies and procedures will be reviewed and/or amended on an annual basis and the policies and procedures seek to reflect information, standards and regulations from relevant local, state and federal regulatory bodies as well as practice standards from professional associations.

I have been provided with didactic training that reflects the policies and procedures on hazardous drugs and have been afforded the opportunity to ask questions. After completion of the training I have been required to take and successfully pass written testing. I have also had my hazardous drug handling techniques observed and documented on **Pioneers Memorial Healthcare District Pharmacy's** Hazardous Drug Competency Form. Review of hazardous drug information and competency evaluation will occur annually. I received and successfully completed this training before performing any activity associated with hazardous drugs. I understand **Pioneers Memorial Healthcare District Pharmacy's** policies and procedures and agree to comply with them at all times. I also agree that I will immediately seek out the Pharmacy Manager or my direct supervisor should a question occur during work activities.

I acknowledge that failure to follow the established policies and procedures may put me at risk of exposure to hazardous substances which can lead to acute effects such as skin rashes; chronic effects, including adverse reproductive events such as infertility, miscarriage, or birth defects; and possibly the development of cancer.

Signature of Employee Name above

Date

Hazardous Drug Assessment of Risk



Hospital Name	Pioneers Memorial Healthcare District
City, State	Brawley, California
Review Date	April 18, 2017
Designated Owner	

ver: January 2017

Hazardous Drug Risk Assessment Template

Introduction

Last Updated: January 2017



INTRODUCTION

The CPS Hazardous Drug Risk Assessment Template provides a step by step process to assist your facility with meeting two requirements of USP Chapter <800> Hazardous Drug Handling in Healthcare Settings.

- 1) **Hazardous Drug List:** Develop a facility specific list of hazardous drugs (HDs) based on the National Institute for Occupational Safety and Health (NIOSH) List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, 2016.
- 2) **Hazardous Drug Risk Assessment:** Complete and document an assessment of risk for eligible hazardous drugs and dosage forms, as defined by USP<800>, to evaluate the risk potential for occupational exposure to these agents in your facility.

The assessment needs to be based on the hazardous drugs and dosage forms found in your facility; the NIOSH groups 1, 2 or 3; the types of activities that are performed; and the potential type(s) of exposure.

The risk assessment tabs in the workbook should be completed by a multidisciplinary team that evaluates the severity, frequency and detectability of HD exposure. Suggested team members should include representatives from pharmacy, nursing, risk management, employee health, etc.

Based on the results of the assessment facilities must define, in standard operating procedures (SOPS), work place practices and containment strategies to minimize the potential for occupational exposure to these agents. Of importance, NIOSH group 1 antineoplastic agents that require any form of manipulation and HD active pharmaceutical ingredients (API) MUST, at minimum, follow ALL of the containment strategies defined in USP <800>. In this assessment template only the oral dosage forms for NIOSH group 1 are eligible for evaluation of exposure risk. All other dosage forms in this group default to the USP <800> requirements. For guidance please see the CPS Template Policy Hazardous Drug Handling.

Per USP<800>:

Containment Requirements

- Drugs on the NIOSH list that must follow the requirements in this chapter include:
 - Any HD API
 - Any antineoplastic requiring HD manipulation
- Drugs on the NIOSH list that do not have to follow all the containment requirements of this chapter if an assessment of risk is performed and implemented include:
 - Final dosage forms of compounded HD preparations and conventionally manufactured HD products, including antineoplastic dosage forms that do not require any further manipulation other than counting or repackaging (unless required by the manufacturer)
- For dosage forms of other HDs on the NIOSH list, the entity may perform an assessment of risk to determine alternative containment strategies and/work practices

"Some dosage forms of drugs defined as hazardous may not pose a significant risk of direct occupational exposure because of their dosage formulation (e.g., tablets or capsules—solid, intact medications that are administered to patients without modifying the formulation). However, dust from tablets and capsules may present a risk of exposure by skin contact and/or inhalation. An assessment of risk may be performed for these dosage forms to determine alternative containment strategies and/or work practices. If an assessment of risk is not performed, all HDs must be handled with all containment strategies defined in this chapter.

The assessment of risk must, at a minimum, consider the following:

- Type of HD (e.g., antineoplastic, non-antineoplastic, reproductive risk only)
- Dosage form
- Risk of exposure
- Packaging
- Manipulation

If an assessment of risk approach is taken, the entity must document what alternative containment strategies and/or work practices are being employed for specific dosage forms to minimize occupational exposure. If used, the assessment of risk must be reviewed at least every 12 months and the review documented.”

Hazardous Drug Risk Assessment Template**Instructions***Last Updated: January 2017***INSTRUCTIONS***Part 1. Build Hazardous Drug (HD) List*

- Step 1.** Switch to tab "NIOSH List 2016"
- Step 2.** Beginning with Table 1, place a "Y" next to each medication currently on the formulary
Note: The dosage forms for each as dose formulations will need to be entered in Step 5.
- Step 3.** Complete for both Table 2 and 3.
Note: At the end of each table is three blank, free text, spaces that may be used to add an investigation HD, etc.

Part 2. Select Dosage Forms

- Step 4.** Switch to the tab listed below titled "Dosage Forms".
- Step 5.** The list entered in the NIOSH List tab will alphabetically contain all HD indicated as on formulary. For each medication, enter an "X" for the current dosage formulations that are on formulary.

Example:

Hazardous Drug List	Dosage formulations									
	API	Oral Solid	Oral Liquid	Topical Drug	Ampoule	SC, IM Injection	IV Solution	Solution for Irrigation	Powder/Solution for Inhalation	Other
raloxifene		x								
carbamazepine		x	x			x				
clonazepam		x								
warfarin		x								

- Step 6.** After all "x"s have been entered, click the "Populate Risk Assessment" button.
Note: Please be sure you have selected all applicable medications and dosage forms from the 2016 NIOSH list before proceeding. After clicking "Yes" on the message box you will be unable to add additional medications and dosage forms to the "RA - Group" tabs.
- Step 7.** The three tabs named RA - Group 1, 2, and 3 will contain the specific medications and dosage forms a risk assessment needs to be conducted for each NIOSH group of hazardous drugs.
Note: USP<800> specifically indicates that a risk assessment cannot be conducted for any HD active pharmaceutical ingredient (API) or HD antineoplastic requiring manipulation. USP<800> requires these specific agents to follow, at minimum, all containment strategies defined in the chapter. The assessment tool identifies agents that are not eligible for an assessment of risk, populates the potential exposure types for each and the Action Plan with, "Per USP<800>" any HD API and any antineoplastic requiring HD manipulation must follow all containment requirements within the chapter. Eye protection and respiratory protection are required for spill management."
- Step 8.** Switch to the individual tabs to complete the risk assessments! Please note all three need to be complete for all medications listed.

Part 3. Complete Risk Assessments

- Step 9.** Under "Risk Assessment Conducted By:" enter the team or individual who conducted the risk assessment. Under "Date Assessment Conducted:" enter the date.

Note: For NIOSH Group 1 antineoplastic dosage forms requiring manipulations and HD API in all NIOSH Groups that are not eligible for an assessment of risk an X will default for each type of exposure.

Example:

Based on the outcome in the risk priority number (RPN) field, processes may need to be developed to mitigate the risk. See scale on the PRA scoring template for additional information.

Example:

Step 13. Complete the risk assessment for all dosage forms listed on the three tabs.

Note: Row adjustment may be necessary to fit lengthy action plans!

COMPREHENSIVE
PHARMACY SERVICES

Part 4. Print Hazardous Drug list

Step 16. Switch to tab "HDList"

Step 17. Print the report to have a streamlined HD list. This tab contains the same information as the "HDRecommendation" tab; but does not include the containment recommendations.

Hazardous Drug Risk Assessment Template**Additional Information**

Last Updated: January 2017

**Potential Types of Exposure per USP <800>**

Activity	Potential Exposure
Receiving	Contact with HD residue on containers, work surfaces or floor
Dispensing	Counting or repacking
Compounding / Manipulating	<ul style="list-style-type: none"> • Crushing or splitting tablets or opening capsules • Pouring liquids from one container to another • Weighing or mixing HD components • Reconstituting powdered or lyophilized HDs • Preparing or diluting injectable HDs • Expelling air from syringes • Contact with HD residue on PPE or other garments • Deactivating, decontaminating, cleaning, and disinfecting HD areas • Maintenance activities for HD equipment and devices
Administering	<ul style="list-style-type: none"> • Generating aerosols during administration • Performing specialized procedures (e.g., intraoperative intraperitoneal injection or bladder instillation) • Priming IV tubing
Patient Care	Handling body fluids (e.g., urine, feces, sweat, or vomit) or body-fluid-contaminated clothing, dressings, linens, and other materials
Spills	Spill generation, management, clean-up and disposal
Transport	Transporting HDs within the facility
Waste	Collection and disposal of hazardous waste and trace contaminated waste

NIOSH 2016

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 chemotherapy gloves	Protective gown	Eye/face protection	Respiratory protection	Ventilated engineering controls
All types of hazardous drugs	Receiving, unpacking, and placing in storage	No (single glove can be used, unless spill occurs)	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
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, intramuscular 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 vial or ampoule	Compounding	Yes [§]	Yes	No	No	Yes, BSC or CACI; use of CSTD recommended
	Administration of prepared solution	Yes	Yes	No	No	N/A; CSTD required per USP 800 if the dosage form allows
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; recommend use of CSTD
	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	N/A
	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

Proactive Risk Assessment (PRA) Scoring Template

IMPACT/SEVERITY		FREQUENCY/OCCURRENCE		PROBABILITY of DETECTION	
1	No injury/loss	1	Would not occur	1	Always detected
2	Minor injury or illness/loss	2	Possible to occur annually	2	Almost always detected – systems in place
3	Moderate injury/illness/loss	3	Probable to occur annually	3	Probable to be detected – systems in place
4	Severe injury/illness/loss	4	Will occur annually	4	Likely to be detected – systems in place
5	Loss of life or significant impact on	5	Possibly to occur quarterly	5	May or may not be detected – systems in place
		6	Probable to occur quarterly	6	May or may not be detected – manual process
		7	Occurs quarterly	7	Likely not to be detected – manual process
		8	Possibly to occur monthly	8	Probable not to be detected – manual process
		9	Probable to occur monthly	9	Almost never detected – manual process
		10	Occurs monthly	10	Never detected
Risk Score:					
1 to 13	Low Risk	Monitor and assess			
13 to 60	Medium Risk	Establish controls to minimize risk			
> 60	High Risk	Immediate risk reduction strategies required			

NIOSH List of Hazardous Drugs 2016**Formulary Status**

Tables updated: January 2017

For explanation of tables and contents see:

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**[Click to view original PDF file](#)**Table 1. Antineoplastic drugs including those with manufacturers' safe handling guidance (MSHG)**

Drug	AHFS classification	MSHG	Reason for listing	Links	Formulary?
abiraterone	10:00 antineoplastic		Pregnancy Category X; pregnant women wear gloves or do not handle	DailyMed DrugBank	
ado-trastuzumab emtansine	10:00 antineoplastic	Yes	Pregnancy Category D	DailyMed DrugBank	
afatinib	10:00 antineoplastic		Pregnancy Category D; special warnings on contraception for females while taking and 2 weeks post-treatment	DailyMed DrugBank	
altretamine	10:00 antineoplastic	Yes	Pregnancy Category D	DailyMed DrugBank	
amsacrine	NA antineoplastic	Yes	Pregnancy Category ; IARC Group 2B; Not FDA	PI DrugBank	
anastrozole	10:00 antineoplastic		Pregnancy Category X	DailyMed DrugBank	Y
arsenic trioxide	10:00 antineoplastic	Yes	Pregnancy Category D; IARC Group 1 carcinogen	PI DrugBank	
axitinib	10:00 antineoplastic		Pregnancy Category D; teratogenic, embryotoxic and fetotoxic in mice at exposures lower than human exposure	DailyMed DrugBank	
azacitidine	10:00 antineoplastic	Yes	Pregnancy Category D; IARC Group 2A carcinogen	DailyMed DrugBank	Y
bacillus calmette guerin	80:12 vaccine	Yes	Pregnancy Category C; special handling requirements	DailyMed	
belinostat	10:00 antineoplastic	Yes	Pregnancy Category D; genotoxic, targeting actively dividing cells and thus may cause teratogenicity and/or embryo-fetal lethality	DailyMed DrugBank	
bendamustine	10:00 antineoplastic	Yes	Pregnancy Category D	DailyMed DrugBank	Y
bexarotene	10:00 antineoplastic		Pregnancy Category X	DailyMed DrugBank	
bicalutamide	10:00 antineoplastic		Pregnancy Category X	DailyMed DrugBank	Y
bleomycin	10:00 antineoplastic	Yes	Pregnancy Category D; IARC Group 2B	DailyMed DrugBank	Y
bortezomib	10:00 antineoplastic	Yes	Pregnancy Category D	DailyMed DrugBank	Y
bosutinib	10:00 antineoplastic		Pregnancy Category D	DailyMed DrugBank	
brentuximab vedotin	10:00 antineoplastic	Yes	Pregnancy Category D	DailyMed DrugBank	
busulfan	10:00 antineoplastic	Yes	Pregnancy Category D; IARC Group 1 carcinogen	DailyMed DrugBank	
cabazitaxel	10:00 microtubule inhibitor	Yes	Pregnancy Category D	DailyMed DrugBank	Y
cabozantinib	10:00 antineoplastic		Pregnancy Category D; embryolethal in rats at exposures below the recommended human dose	DailyMed DrugBank	
capecitabine	10:00 antineoplastic	Yes	Pregnancy Category D; metabolized to 5-FU	DailyMed DrugBank	
carboplatin	10:00 antineoplastic	Yes	Pregnancy Category D	DailyMed DrugBank	Y
carfilzomib	10:00 antineoplastic		Pregnancy Category D; special warnings on contraception while taking and 2 weeks post-treatment	DailyMed DrugBank	Y
carmustine	10:00 antineoplastic	Yes	Pregnancy Category D; IARC Group 2A carcinogen	DailyMed DrugBank	Y
chlorambucil	10:00 antineoplastic	Yes	Pregnancy Category D; IARC Group 1 carcinogen	DailyMed DrugBank	
cisplatin	10:00 antineoplastic	Yes	Pregnancy Category D; IARC Group 2A carcinogen	DailyMed DrugBank	Y
cladribine	10:00 antineoplastic	Yes	Pregnancy Category D	DailyMed DrugBank	
clofarabine	10:00 antineoplastic	Yes	Pregnancy Category D	DailyMed DrugBank	
crizotinib	10:00 antineoplastic		Pregnancy Category D	DailyMed DrugBank	
cyclophosphamide	10:00 antineoplastic	Yes	Pregnancy Category D; IARC Group 1 carcinogen	DailyMed DrugBank	Y
cytarabine	10:00 antineoplastic	Yes	Pregnancy Category D	DailyMed DrugBank	Y
dabrafenib	10:00 antineoplastic		Pregnancy Category D; special warnings on contraception for females while taking and 2 weeks post-treatment	DailyMed DrugBank	
dacarbazine	10:00 antineoplastic	Yes	Pregnancy Category C; IARC Group 2B	DailyMed Drugbank	Y
dactinomycin	10:00 antineoplastic	Yes	Pregnancy Category D	DailyMed DrugBank	
dasatinib	10:00 antineoplastic	Yes	Pregnancy Category D	DailyMed DrugBank	
daunorubicin	10:00 antineoplastic	Yes	Pregnancy Category D; IARC Group 2B AKA daunomycin	DailyMed DrugBank	
decitabine	10:00 antineoplastic	Yes	Pregnancy Category D	DailyMed DrugBank	Y
degarelix	10:00 GnRH receptor antagonist		Pregnancy Category X	DailyMed DrugBank	
docetaxel	10:00 antineoplastic	Yes	Pregnancy Category D	DailyMed DrugBank	Y
doxorubicin	10:00 antineoplastic	Yes	Pregnancy Category D; IARC Group 2A carcinogen	DailyMed DrugBank	Y
enzalutamide	10:00 antineoplastic		Pregnancy Category X; embryo-fetal toxicity in mice at exposures lower than patients receiving recommended dose	DailyMed DrugBank	

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epirubicin	10:00 antineoplastic	Yes	Pregnancy Category D	DailyMed	DrugBank	Y
eribulin	10:00 microtubule inhibitor		Pregnancy Category D	DailyMed	DrugBank	Y
erlotinib	10:00 antineoplastic		Pregnancy Category D	DailyMed	DrugBank	
estramustine	10:00 antineoplastic	Yes	Pregnancy Category X	DailyMed	DrugBank	
etoposide	10:00 antineoplastic	Yes	Pregnancy Category D; IARC Group 1 carcinogen	DailyMed	DrugBank	Y
everolimus	10:00 kinase inhibitor	Yes	Pregnancy Category D	DailyMed	DrugBank	
exemestane	10:00 antineoplastic		Pregnancy Category D	DailyMed	DrugBank	
floxuridine	10:00 antineoplastic	Yes	Pregnancy Category D	DailyMed	DrugBank	
fludarabine	10:00 antineoplastic	Yes	Pregnancy Category D	DailyMed	DrugBank	Y
fluorouracil	10:00 antineoplastic	Yes	Pregnancy Category X	DailyMed	DrugBank	Y
flutamide	10:00 antineoplastic		Pregnancy Category D; indicated only for men	DailyMed	DrugBank	Y
fulvestrant	10:00 antineoplastic		Pregnancy Category D	DailyMed	DrugBank	Y
gemcitabine	10:00 antineoplastic	Yes	Pregnancy Category D	DailyMed	DrugBank	Y
gemtuzumab ozogamicin	10:00 antineoplastic	Yes	Pregnancy Category D; discontinued	PI	DrugBank	
goserelin	10:00 antineoplastic		Pregnancy Category X	DailyMed	DrugBank	Y
histrelin	10:00 GnRH		Pregnancy Category X; can cause fetal harm when administered to a pregnant patient with possibility of spontaneous abortion	DailyMed	DrugBank	
hydroxyurea	10:00 antineoplastic	Yes	Pregnancy Category D; special warning on handling bottles and capsules	DailyMed	DrugBank	Y
idarubicin	10:00 antineoplastic	Yes	Pregnancy Category D	DailyMed	DrugBank	
ifosfamide	10:00 antineoplastic	Yes	Pregnancy Category D	DailyMed	DrugBank	Y
imatinib	10:00 antineoplastic	Yes	Pregnancy Category D	DailyMed	DrugBank	
irinotecan	10:00 antineoplastic	Yes	Pregnancy Category D	DailyMed	DrugBank	Y
ixabepilone	10:00 antineoplastic	Yes	Pregnancy Category D	DailyMed	DrugBank	
ixazomib	10:00 antineoplastic	Yes	Pregnancy Category ; male and female patients of childbearing potential must use effective contraception while taking and 3 months post-treatment	DailyMed	DrugBank	
letrozole	10:00 antineoplastic		Pregnancy Category X	DailyMed	DrugBank	
leuprolide	10:00 antineoplastic	Yes	Pregnancy Category X	DailyMed	DrugBank	Y
lomustine	10:00 antineoplastic	Yes	Pregnancy Category D; IARC Group 2A carcinogen	DailyMed	DrugBank	
mechlorethamine	10:00 antineoplastic	Yes	Pregnancy Category D; MOPP(mechlorethamine, vincristine, procarbazine, prednisone) therapy IARC Group 1 carcinogen	DailyMed	DrugBank	
megestrol	10:00 antineoplastic		Pregnancy Category X; pregnant women do not handle	DailyMed	DrugBank	Y
melphalan	10:00 antineoplastic	Yes	Pregnancy Category D; IARC Group 1 carcinogen	DailyMed	DrugBank	
mercaptopurine	10:00 antineoplastic	Yes	Pregnancy Category D	DailyMed	DrugBank	
methotrexate	10:00 antineoplastic	Yes	Pregnancy Category X	DailyMed	DrugBank	Y
mitomycin	10:00 antineoplastic	Yes	Pregnancy Category D; IARC Group 2B	DailyMed	DrugBank	Y
mitotane	10:00 antineoplastic	Yes	Pregnancy Category C	DailyMed	DrugBank	
mitoxantrone	10:00 antineoplastic	Yes	Pregnancy Category D; IARC Group 2B	DailyMed	DrugBank	Y
nelarabine	10:00 antineoplastic	Yes	Pregnancy Category D	DailyMed	DrugBank	
nilotinib	10:00 kinase inhibitor		Pregnancy Category D	DailyMed	DrugBank	
omacetaxin	10:00 antineoplastic	Yes	Pregnancy Category D	DailyMed	DrugBank	
oxaliplatin	10:00 antineoplastic	Yes	Pregnancy Category D	DailyMed	DrugBank	Y
paclitaxel	10:00 antineoplastic	Yes	Pregnancy Category D	DailyMed	DrugBank	Y
panobinostat	10:00 antineoplastic	Yes	Pregnancy Category ; special warnings on contraception for females while taking and one month post-treatment	DailyMed	DrugBank	
pazopanib	10:00 kinase inhibitor		Pregnancy Category D	DailyMed	DrugBank	
pemetrexed	10:00 antineoplastic	Yes	Pregnancy Category D	DailyMed	DrugBank	Y
pentostatin	10:00 antineoplastic	Yes	Pregnancy Category D	DailyMed	DrugBank	
pertuzumab	10:00 antineoplastic		Pregnancy Category D; black box warning on embryo-fetal death and birth defects	DailyMed	DrugBank	Y
pomalidomide	10:00 antineoplastic	Yes	Pregnancy Category X; females of reproductive potential must use 2 forms of contraception or continuously abstain from heterosexual sex while taking and 4 weeks post-treatment	DailyMed	DrugBank	
ponatinib	10:00 antineoplastic		Pregnancy Category D	DailyMed	DrugBank	
pralatrexate	10:00 antineoplastic	Yes	Pregnancy Category D	DailyMed	DrugBank	
procarbazine	10:00 antineoplastic	Yes	Pregnancy Category D; IARC Group 2A carcinogen	DailyMed	DrugBank	
regorafenib	10:00 antineoplastic		Pregnancy Category D; black box warning on severe and sometimes fatal hepatotoxicity; total loss of pregnancy at doses lower than recommended human dose	DailyMed	DrugBank	
romidepsin	10:00 antineoplastic	Yes	Pregnancy Category D	DailyMed	DrugBank	
sorafenib	10:00 antineoplastic		Pregnancy Category D	DailyMed	DrugBank	
streptozocin	10:00 antineoplastic	Yes	Pregnancy Category D; IARC Group 2B	DailyMed	DrugBank	
sunitinib	10:00 antineoplastic		Pregnancy Category D	DailyMed	DrugBank	
tamoxifen	10:00 antineoplastic		Pregnancy Category D; IARC Group 1 carcinogen	DailyMed	DrugBank	Y

temozolomide	10:00 antineoplastic	Yes	Pregnancy Category D	DailyMed	DrugBank	
temsirolimus	10:00 antineoplastic	Yes	Pregnancy Category D	DailyMed	DrugBank	Y
teniposide	10:00 antineoplastic	Yes	Pregnancy Category D; IARC Group 2A carcinogen	DailyMed	DrugBank	
thioguanine	10:00 antineoplastic	Yes	Pregnancy Category D	DailyMed	DrugBank	
thiotepa	10:00 antineoplastic	Yes	Pregnancy Category D; IARC Group 1 carcinogen	DailyMed	DrugBank	
topotecan	10:00 antineoplastic	Yes	Pregnancy Category D	DailyMed	DrugBank	Y
toremifene	10:00 antineoplastic		Pregnancy Category D	DailyMed	DrugBank	
trametinib	10:00 antineoplastic		Pregnancy Category D; embryotoxic and abortifacient at doses less than recommended human dose	DailyMed	DrugBank	
trifluridine/tipiracil	10:00 antineoplastic	Yes	Pregnancy Category ; embryo-fetal lethality and toxicity at doses lower than or similar to the recommended human dose	DailyMed	DrugBank	
triptorelin	10:00 antineoplastic		Pregnancy Category X	DailyMed	DrugBank	
valrubicin	10:00 antineoplastic	Yes	Pregnancy Category C	DailyMed	DrugBank	
vandetanib	10:00 antineoplastic	Yes	Pregnancy Category D	DailyMed	DrugBank	
vemurafenib	10:00 antineoplastic		Pregnancy Category D	DailyMed	DrugBank	
vinblastine	10:00 antineoplastic	Yes	Pregnancy Category D	DailyMed	DrugBank	Y
vincristine	10:00 antineoplastic	Yes	Pregnancy Category D	DailyMed	DrugBank	Y
vinorelbine	10:00 antineoplastic	Yes	Pregnancy Category D	DailyMed	DrugBank	Y
vismodegib	10:00 antineoplastic		Pregnancy Category D; black box warning on embryo-fetal death or severe birth defects; recommend effective contraception for females while taking and 7 months post-treatment; present in semen; no sperm donation while taking and 3 months post-treatment	DailyMed	DrugBank	
vorinostat	10:00 antineoplastic	Yes	Pregnancy Category D	DailyMed	DrugBank	
ziv-aflibercept	10:00 antineoplastic		Pregnancy Category C; embryotoxic and teratogenic in rabbits at exposure levels lower than the RHD, increased incidences of external, visceral and skeletal malformations; FDA pregnancy Category C	DailyMed	DrugBank	
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Table 2. Non-antineoplastic drugs that meet one or more of the NIOSH criteria for a hazardous drug including those with manufacturers' safe handling guidance (MSHG)

Drug	AHFS classification	MSHG	Reason for listing	Links		Formulary Yes or No
abacavir	8:18:08:20 antiviral		Pregnancy Category C; malignant tumors observed in male and female mice and rats; genotoxic in in vivo micronucleus test	DailyMed	DrugBank	
alefacept	84:92 immunosuppressant		Pregnancy Category B; discontinued; increased frequency of malignancies observed in treated patients	PI	DrugBank	
apomorphine	28:36:20:08 dopamine agonist		Pregnancy Category C; genotoxic in several in vitro assays	DailyMed	DrugBank	
azathioprine	92:44 immunosuppressant	Yes	Pregnancy Category D; IARC Group 1 carcinogen	DailyMed	DrugBank	Y
carbamazepine	28:12:92 anticonvulsant		Pregnancy Category D; black box warning for aplastic anemia; congenital malformations in offspring of mothers who took drug; rapid transplacental passage	DailyMed	DrugBank	Y
chloramphenicol	8:12:08		Pregnancy Category C; IARC Group 2A carcinogen	DailyMed	DrugBank	Y
cidofovir	8:18:32 antiviral	Yes	Pregnancy Category C	DailyMed	DrugBank	
cyclosporin	92:44 immunosuppressant		Pregnancy Category C; IARC Group 1 carcinogen	DailyMed	DrugBank	Y
deferiprone	64:00 Fe chelator		Pregnancy Category D; genotoxic in vitro and in vivo	DailyMed	DrugBank	
dexrazoxane	92:56 chelator	Yes	Pregnancy Category D; 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	Y

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diethylstilbestrol	NA		Pregnancy Category X; discontinued; IARC Group 1 carcinogen	DrugBank	
divalproex	28:12:92 anti-convulsant		Pregnancy Category D; black box warning for teratogenicity; tumors seen in laboratory studies at doses below MRHD	DailyMed DrugBank	Y
entecavir	8:18:32 antiviral	Yes	Pregnancy Category C	DailyMed DrugBank	
estradiol	68:16:04 estrogen		Pregnancy Category X; 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, testes, and liver; present in breast milk	DailyMed DrugBank	Y
estrogen-progestin combinations	68:12 contraceptive		Pregnancy Category X; IARC Group 1 carcinogen	DailyMed	
estrogens, conjugated	68:16:04 estrogen		Pregnancy Category X; Black Box warning for endometrial cancer and cardiovascular risks; long-term use in women and laboratory studies increases frequency of several cancers; NTP**;	DailyMed DrugBank	Y
estrogens, esterified	68:16:04 estrogen		Pregnancy Category X; Black Box warning for endometrial cancer and cardiovascular risks; NTP**;	DailyMed DrugBank	
estropipate	68:16:04 estrogen		Pregnancy Category X; black box warning for endometrial carcinoma in post menopausal women and use during pregnancy	DailyMed DrugBank	
fingolimod	92:20 sphingosine-1 phosphate recpt. modulator		Pregnancy Category C; in laboratory studies, increased malformations and embryo-fetal deaths at less than the RHD; malignant lymphomas observed in male and female mice	DailyMed DrugBank	
fluoxymesterone	68:08 androgen		Pregnancy Category X; tumors in mice and rats and possibly humans	DailyMed DrugBank	
fosphenytoin	28:12:12 anticonvulsant		Pregnancy Category D; metabolized to phenytoin	DailyMed DrugBank	
ganciclovir	8:18:32 antiviral	Yes	Pregnancy Category C	DailyMed DrugBank	Y
leflunomide	92:36 antineoplastic		Pregnancy Category X; teratogenic in laboratory studies at 1/10 HD; marked postnatalsurvival at 1/100 HD; severe liver injury reported in patients; carcinogenicity observed at dose below HD	DailyMed DrugBank	Y
lenalidomide	92:20 antiangiogenesis	Yes	Pregnancy Category X	DailyMed DrugBank	
liraglutide	68:20:06 antidiabetic		Pregnancy Category C; black box warning for thyroid C-cel tumors, with supporting evidence in laboratory studies; teratogenic at or below the MRHD	DailyMed DrugBank	
medroxyprogesterone	68:32		Pregnancy Category X; IARC Group 2B	DailyMed DrugBank	Y
methimazole	68:36:08 thyroid inhibitor		Pregnancy Category D; present in breast milk	DailyMed DrugBank	Y
mipomersen	24:06:92 lipid regulator		Pregnancy Category B; black box warning for hepatotoxicity	DailyMed DrugBank	
mycophenolate mofetil	92:44 immunosuppressant		Pregnancy Category D; black box warning for embryo-fetal toxicity, malignancies and serious infections; increased risk of first trimester pregnancy loss and increased risk of congenital malformations; special warnig: 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 immediately; rinse eyes with plain water	DailyMed DrugBank	Y
mycophenolic acid	92:44 immunosuppressant		Pregnancy Category D; black box warning for first trimester pregnancy loss and an increased risk of congenital malformations; also black box warning for lymphomas and other malignancies; genotoxic in vitro and in vivo	DailyMed DrugBank	
nevirapine	8:18:08:16 antiviral		Pregnancy Category C; in laboratory studies, hepatocellular adenomas and carcinomas at doses lower than HD	DailyMed DrugBank	
ospemifene	68:16:12 estrogen agonist		Pregnancy Category X; black box warning for increased risk of endometrial cancer in certain populations; risk of adverse outcomes during pregnancy and labor	DailyMed DrugBank	
oxcarbazepine	28:12:92 anticonvulsant		Pregnancy Category C; tumors observed in laboratory studies at 1/10 MRHD	DailyMed DrugBank	Y
palifermin	84:16 keratinocyte growth factor		Pregnancy Category C; potential for stimulation of tumor growth	DailyMed DrugBank	

paliperidone	28:16:08:04 antipsychotic		Pregnancy Category C; metabolite of risperidone; present in breast milk	DailyMed	DrugBank	
phenoxybenzamine	12:16:04:04 alpha blocker		Pregnancy Category C; IARC Group 2B	DailyMed	DrugBank	
phenytoin	28:12:12 anticonvulsant		Pregnancy Category D; IARC Group 2B	DailyMed	DrugBank	Y
pipobroman	NA		Pregnancy Category D; discontinued		DrugBank	
progesterone	68:32 contraceptive		Pregnancy Category B; IARC Group 2B	DailyMed	DrugBank	
propylthiouracil	68:36:08 antithyroid		Pregnancy Category D; IARC Group 2B	DailyMed	DrugBank	Y
raloxifene	68:16:12 estrogen antagonist		Pregnancy Category X; abortion and developmental abnormalities seen at low doses in laboratory studies; evidence of tumors at low doses in laboratory studies	DailyMed	DrugBank	Y
rasagiline	28:36 MAO inhibitor		Pregnancy Category C	DailyMed	DrugBank	
risperidone	28:16:08:04 psychotropic		Pregnancy Category C; evidence of tumors at low doses in laboratory studies	DailyMed	DrugBank	Y
sirolimus	92:44 immunosuppressant		Pregnancy Category C; AKA rapamycin; increased risk of lymphomas and other malignancies; embryotoxic and fetotoxic at 0.2x HD	DailyMed	DrugBank	Y
spironolactone	24:32:20 tablets		Pregnancy Category C; black box warning for tumorigenicity in laboratory studies	DailyMed	DrugBank	Y
tacrolimus	92:44 immunosuppressant		Pregnancy Category C; increased risk of lymphomas and other malignancies; reproductive effects seen in laboratory studies below the MRHD; excreted in breast milk	DailyMed	DrugBank	Y
thalidomide	92:20 immunomodulator	Yes	Pregnancy Category X	DailyMed	DrugBank	
tofacitinib	92:36 immunosuppressant		Pregnancy Category C; black box warning for lymphoma and other malignancies	DailyMed	DrugBank	
uracil mustard	NA antineoplastic	Yes	Pregnancy Category D; IARC Group 2B; discontinued IARC Group 2B	PI	DrugBank	
valganciclovir	8:18:32 antiviral	Yes	Pregnancy Category C	DailyMed	DrugBank	
zidovudine	8:18:08 antiretroviral		Pregnancy Category C; IARC Group 2B	DailyMed	DrugBank	Y
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Table 3. Non-antineoplastic drugs that primarily have adverse reproductive effects

Drug	AHFS classification	Reason for listing	Links	Formulary Yes or No
acitretin	88:04 retinoid	Pregnancy Category X; black box warning on adverse reproductive effects	DailyMed DrugBank	
alitretinoin	84:92 retinoid	Pregnancy Category D	DailyMed DrugBank	
ambrisentan	24:12:92 endothelin receptor antagonist	Pregnancy Category X; black box warning on adverse reproductive effects; reduced sperm counts in patients	DailyMed DrugBank	
bosentan	24:12:92 endothelin antagonist	Pregnancy Category X; black box warning on adverse reproductive effects	DailyMed DrugBank	
cabergoline	28:36:20:04 dopamine reuptake agonist	Pregnancy Category B; inhibition of conception and embryo-fetal effects at doses below the RHD	DailyMed DrugBank	
cetrorelix	92:40 GnRH antagonist	Pregnancy Category X	DailyMed DrugBank	
choriogonadotropin	68:18 gonadatropin	Pregnancy Category X; defects of forelimbs and central nervous system and alterations in sex ratio have been reported in laboratory studies	DailyMed DrugBank	
clomiphene	68:16:12 ovulation stimulator	Pregnancy Category X	DailyMed DrugBank	
clonazepam	28:12:08 anticonvulsant	Pregnancy Category D; increased risk of congenital abnormalities when taken in the first trimester	DailyMed DrugBank	Y
colchicine	92:16 mitotic inhibitor	Pregnancy Category D; published animal reproduction and developmental studies indicate it causes embryo-fetal toxicity, teratogenicity, and altered postnatal development at exposures within the clinical therapeutic range	DailyMed DrugBank	Y
dinoprostone	76:00 oxytocic	Pregnancy Category C; hazardous only for women in late pregnancy	DailyMed DrugBank	Y
dronedarone	24:04:04 antiarrhythmic	Pregnancy Category X; teratogenic in laboratory studies at 1/2 MRHD	DailyMed DrugBank	Y
dutasteride	92:08 5-alpha reductase inhibitor	Pregnancy Category X; women warned not to handle	DailyMed DrugBank	Y

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ergonovine/methylegonovine	76:00 oxytocic	Pregnancy Category C; use is contraindicated during pregnancy because of its uterotonic effects	DailyMed	DrugBank	Y
eslicarbazepine	28:12:92 antiepileptic	Pregnancy Category C; fetal malformations, fetal growth retardation, embryolethality and reduced body weights observed in animal studies; present in breast milk	DailyMed	DrugBank	
finasteride	92:08 5-alpha reductase inhibitor	Pregnancy Category X; women should not handle crushed or broken tablets when pregnant or potentially pregnant due to risk to a male fetus	DailyMed	DrugBank	Y
fluconazole	8:18:08 antifungal	Pregnancy Category C; case reports describe congenital abnormalities in infants exposed in utero to maternal fluconazole (400-800mg/day)during most or all of the first trimester, similar to those seen in animal studies	DailyMed	DrugBank	Y
ganirelix	92:40 GnRH antagonist	Pregnancy Category X	DailyMed	DrugBank	
gonadotropin, chorionic	68:18 gonadotropins	Pregnancy Category C; 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 bradykinin B2 recpt antagonist	Pregnancy Category C; in laboratory studies, premature birth and abortion rates increased at dose less than 1/40 MRHD; delayed parturition and fetal death occurred at 0.5 and 2x MRHD,	DailyMed	DrugBank	
lomitapide	24:06:92 antilipid	Pregnancy Category X	DailyMed	DrugBank	
macitentan	48:48 pulmonary hypertension	Pregnancy Category X; black box warning for embryo-fetal toxicity; special warnings on contraception for females while taking and one month post-treatment	DailyMed	DrugBank	
menotropins	68:18 gonadotropin	Pregnancy Category X	DailyMed	DrugBank	
methyltestosterone	68:08 androgen	Pregnancy Category X	DailyMed	DrugBank	
mifepristone	76:00 oxytocic	Pregnancy Category X; when given to pregnant women, results in termination of pregnancy	DailyMed	DrugBank	
misoprostal	56:28:28 anti gastric ulcer	Pregnancy Category X	DailyMed	DrugBank	Y
nafarelin	68:18 gonadotropin	Pregnancy Category X	DailyMed	DrugBank	
oxytocin	76:00 oxytocic	Pregnancy Category C; hazardous only for women in 3rd trimester	DailyMed	DrugBank	Y
pamidronate	92:00:00 bone resorption inhibitor	Pregnancy Category D; embryo-fetal toxicity at doses below the recommended human dose	DailyMed	DrugBank	Y
paroxetine	28:16:04:20 SSRI	Pregnancy Category D; increased risk of congenital abnormalities in first trimester; complications in pregnancy in 3rd trimester	DailyMed	DrugBank	Y
pasireotide	68:29:04 somostatin analog	Pregnancy Category C; increased implantation loss and decreased viable fetuses, corpora lutea, and implantation sites at doses below the human recommended dose	DailyMed	DrugBank	
peginesatide	20:16 erythrocyte stimulator	Pregnancy Category C; discontinued; adverse embryo-fetal effects including reduced fetal weight, increased resorption, embryo-fetal lethality, and cleft palate observed at doses below the recommended human dose	PI	DrugBank	
pentetate calcium trisodium	NA chelator	Pregnancy Category C; severe teratogenic effects in laboratory studies in dogs	DailyMed		
plerixafor	20:16 stem cell mobilization	Pregnancy Category D; teratogenic in laboratory studies	DailyMed	DrugBank	
ribavirin	8:18:32 antiviral	Pregnancy Category X; teratogenic and embryotoxic effects in several laboratory studies; contraindicated in women who are pregnant and in male partners of women who are pregnant	DailyMed	DrugBank	
riociguat	48:48 pulmonary hypertension	Pregnancy Category X; exclude pregnancy before treatment, monthly during treatment and one month post-treatment	DailyMed	DrugBank	
telavancin	8:12:28 antibacterial	Pregnancy Category C; black box warning for potential risk to fetus and adverse reproductive outcomes; reduced fetal weights and increased rates of digit and limb malformations in 3 species at clinical doses	DailyMed	DrugBank	Y
temazepam	28:24:08 antiinsomnia	Pregnancy Category X; increased risk of congenital malformations associated with treatment during the first trimester of pregnancy	DailyMed	DrugBank	Y
teriflunomide	92:20 immunosuppressant	Pregnancy Category X; black box warning for severe hepatotoxicity and teratogenicity, including major birth defects	DailyMed	DrugBank	
testosterone	68:08 androgen	Pregnancy Category X; children should avoid unwashed or unclothed application sites on skin	DailyMed	DrugBank	
topiramate	28:12:92 anticonvulsant	Pregnancy Category D	DailyMed	DrugBank	Y

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tretinoin	84:16 retinoid	Pregnancy Category D; black box warning for severe birth defects; special FDA distribution system	DailyMed	DrugBank	
ulipristal	68:12 progesterone agonist/antagonist	Pregnancy Category X	DailyMed	DrugBank	
valproate	28:12:92 anticonvulsant	Pregnancy Category D; black box warning for teratogenicity; congenital malformations including neural tube defects and others; teratogenic in multiple species	DailyMed	DrugBank	Y
valproic acid	28:12:92 anticonvulsant	Pregnancy Category D; black box warning for teratogenicity; congenital malformations including neural tube defects and others; teratogenic in multiple species	DailyMed	DrugBank	Y
vigabatrin	28:12:92 antiepileptic	Pregnancy Category C; malformations seen in laboratory studies below the MRHD	DailyMed	DrugBank	
voriconazole	8:14:08 antifungal	Pregnancy Category D	DailyMed	DrugBank	Y
warfarin	20:12:04:08 anticoagulant	Pregnancy Category X	DailyMed	DrugBank	Y
ziprasidone	28:16:08:04 psychotropic	Pregnancy Category C; developmental toxicity, including 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	DailyMed	DrugBank	Y
zoledronic acid	92:24 bone resorption inhibitor	Pregnancy Category D; number of stillbirths increased a survival of neonates decreased in laboratory studies at low doses	DailyMed	DrugBank	Y
zonisamide	28:12:92 anticonvulsants	Pregnancy Category C; teratogenic in multiple species	DailyMed	DrugBank	
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Table 4. 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.

Hazardous Drug Assessment of Risk

Medications and their specific dosage forms in use at Pioneers Memorial Healthcare District



The table below is utilized to determine the specific dosage formulations are on formulary and to create the initial risk assessment documents. Please follow the steps listed below to begin the process:

- Step 1.** The list below is populated from entries on the NIOSH 2016 List tab
Step 2. Place an "x" in each box for the dosage forms on formulary
Step 3. After all "x"s are entered, click the "Populate Risk Assessment" button below
Step 4. The three tabs named RA - Group 1, 2, 3 will contain the specific medications a risk assessment needs to be conducted for each NIOSH group of hazardous drugs
Step 5. Switch to the tabs to complete risk assessments!

Click when complete:

Hazardous Drug List	Dosage formulations									
	API	Oral Solid	Oral Liquid	Topical Drug	Ampoule	SC, IM Injection	IV Solution	Solution for Irrigation	Powder/Solution for Inhalation	Other
anastrozole		x								
azacitidine						x	x			
azathioprine		x					x			
bendamustine							x			
bicalutamide		x								
bleomycin							x			
bortezomib						x	x			
cabazitaxel							x			
carbamazepine		x	x							
carboplatin							x			
carfilzomib							x			
carmustine							x			
chloramphenicol							x			
cisplatin							x			
clonazepam		x								
colchicine		x								
cyclophosphamide							x			
cyclosporin		x								
cytarabine							x			
dacarbazine							x			
decitabine							x			
dexrazoxane							x			
dinoprostone										x
divalproex		x								
docetaxel							x			

doxorubicin						x				
dronedarone		x								
dutasteride		x								
epirubicin						x				
ergonovine/methylergonovine		x				x				
eribulin						x				
estradiol		x		x						
estrogens, conjugated		x		x		x	x			
etoposide						x				
finasteride		x								
fluconazole		x	x			x				
fludarabine						x				
fluorouracil						x				
flutamide		x								
fulvestrant						x				
ganciclovir						x				
gemcitabine						x				
goserelin						x				
hydroxyurea		x								
ifosfamide						x				
irinotecan						x	x			
leflunomide		x								
leuprolide						x				
medroxyprogesterone		x				x				
megestrol		x	x							
methimazole		x								
methotrexate		x				x	x			
misoprostal		x								
mitomycin						x	x	x		
mitoxantrone						x				
mycophenolate mofetil		x								
oxaliplatin						x				
oxcarbazepine		x								
oxytocin						x	x			
paclitaxel						x				
pamidronate						x				
paroxetine		x								
pemetrexed						x				
pertuzumab						x				
phenytoin		x	x			x				
propylthiouracil		x								
raloxifene		x								
risperidone		x								
sirolimus			x							

spironolactone		x								
tacrolimus		x								
tamoxifen		x								
telavancin							x			
temazepam		x								
temsirolimus							x			
topiramate		x								
topotecan							x			
valproate							x			
valproic acid		x	x							
vinblastine							x			
vincristine							x			
vinorelbine							x			
voriconazole		x					x			
warfarin		x								
zidovudine		x					x			
ziprasidone		x				x				
zoledronic acid							x			

REGULAR MEETING OF THE BOARD OF DIRECTORS - V. POLICIES/PROCEDURES/REVIEW OF OTHER ITEMS

Hazardous Drug Assessment of Risk

Hospital Name:	Pioneers Memorial Healthcare Dis	Risk Assessment Conducted By:	John P. Teague
City/State:	Brawley, California	Date Assessment Conducted:	4/18/2017



NIOSH Group 1: Antineoplastic drugs that meet one or more of the NIOSH criteria for a hazardous drug (HD)

NOTE: NIOSH Group 1 hazardous drugs (HD) that require manipulation must follow ALL containment requirements as defined in USP<800>. The risk assessment template below takes into account the HDs that are not eligible for an assessment of risk. The only exception is final dosage forms of antineoplastic drugs that do not require any further manipulation other than counting or repackaging (unless required by the manufacturer).

Types of Exposure: R-Receiving, D-Dispensing, C/M-Compounding/Manipulation, A-Administration, PC-Patient Care, S-Spills, T-Transport, W-Waste Disposal

Legend: API (Active Pharmaceutical Ingredient); ADC (Automated Dispensing Cabinet); C-PEC (Containment- Primary Engineering Control); CSTD (Closed System Transfer Device); PPE (Personal Protective Equipment)

Risk of Exposure: Severity (SEV) x Frequency of Occurrence (OCC) x Probability to Detect (DET) = Risk Priority Number (RPN)

*If final RPN is: 1-13 Monitor and assess | 14-60 Establish controls to minimize risk | 61+ Immediate risk reduction strategies required

Initial Risk Assessment										Action Plan/Results															Action Plan (Document in Standard Operating Procedures)
NIOSH Group 1: Antineoplastic Drugs	Dosage Forms	Potential Type(s) of Exposure							Rating				Storage				Engineering Controls to Minimize Exposure			Personal Protective Equipment (PPE) by Type of Exposure					
		R	D	C/M	A	PC	S	T	W	SEV	OCC	DET	RPN	Neg. Pressure Ventilated Room	Segregated Area With Other Inventory	ADC	C-PEC	CSTD	Other	Gloves	Gown	Eye Protection	Respiratory Protection		
anastrozole	Oral Solid		X	X	X					3	1	6	18			X				X					Decrease risk of contact by wearing gloves when handling anastrozole tablets or bottles containing anastrozole. Compounding must follow all of the containment requirements in USP <800>.
azacitidine	IV Solution	X	X	X	X	X	X	X	X					X	X		X	X		X	X	X	X		Per USP<800> any HD API and any antineoplastic requiring HD manipulation must follow all containment requirements within the chapter. Eye protection and respiratory protection are required for spill management.
azacitidine	SC, IM Injection	X	X	X	X	X	X	X	X					X	X		X	X		X	X	X	X		Per USP<800> any HD API and any antineoplastic requiring HD manipulation must follow all containment requirements within the chapter. Eye protection and respiratory protection are required for spill management.
bendamustine	IV Solution	X	X	X	X	X	X	X	X					X	X		X	X		X	X	X	X		Per USP<800> any HD API and any antineoplastic requiring HD manipulation must follow all containment requirements within the chapter. Eye protection and respiratory protection are required for spill management.
bicalutamide	Oral Solid		X	X	X					3	1	6	18			X				X					Decrease risk of contact by wearing gloves when handling bicalutamide tablets or bottles containing bicalutamide. Compounding must follow all of the containment requirements in USP <800>.
bleomycin	IV Solution	X	X	X	X	X	X	X	X					X	X		X	X		X	X	X	X		Per USP<800> any HD API and any antineoplastic requiring HD manipulation must follow all containment requirements within the chapter. Eye protection and respiratory protection are required for spill management.
bortezomib	IV Solution	X	X	X	X	X	X	X	X					X	X		X	X		X	X	X	X		Per USP<800> any HD API and any antineoplastic requiring HD manipulation must follow all containment requirements within the chapter. Eye protection and respiratory protection are required for spill management.
bortezomib	SC, IM Injection	X	X	X	X	X	X	X	X					X	X		X	X		X	X	X	X		Per USP<800> any HD API and any antineoplastic requiring HD manipulation must follow all containment requirements within the chapter. Eye protection and respiratory protection are required for spill management.
cabazitaxel	IV Solution	X	X	X	X	X	X	X	X					X	X		X	X		X	X	X	X		Per USP<800> any HD API and any antineoplastic requiring HD manipulation must follow all containment requirements within the chapter. Eye protection and respiratory protection are required for spill management.
carboplatin _f	IV Solution	X	X	X	X	X	X	X	X					X	X		X	X		X	X	X	X		Per USP<800> any HD API and any antineoplastic requiring HD manipulation must follow all containment requirements within the chapter. Eye protection and respiratory protection are required for spill management.
carfilzomib _f	IV Solution	X	X	X	X	X	X	X	X					X	X		X	X		X	X	X	X		Per USP<800> any HD API and any antineoplastic requiring HD manipulation must follow all containment requirements within the chapter. Eye protection and respiratory protection are required for spill management.
carmustine _f	IV Solution	X	X	X	X	X	X	X	X					X	X		X	X		X	X	X	X		Per USP<800> any HD API and any antineoplastic requiring HD manipulation must follow all containment requirements within the chapter. Eye protection and respiratory protection are required for spill management.
cisplatin _f	IV Solution	X	X	X	X	X	X	X	X					X	X		X	X		X	X	X	X		Per USP<800> any HD API and any antineoplastic requiring HD manipulation must follow all containment requirements within the chapter. Eye protection and respiratory protection are required for spill management.
cyclophosphamide _f	IV Solution	X	X	X	X	X	X	X	X					X	X		X	X		X	X	X	X		Per USP<800> any HD API and any antineoplastic requiring HD manipulation must follow all containment requirements within the chapter. Eye protection and respiratory protection are required for spill management.
cytarabine _f	IV Solution	X	X	X	X	X	X	X	X					X	X		X	X		X	X	X	X		Per USP<800> any HD API and any antineoplastic requiring HD manipulation must follow all containment requirements within the chapter. Eye protection and respiratory protection are required for spill management.
dacarbazine _f	IV Solution	X	X	X	X	X	X	X	X					X	X		X	X		X	X	X	X		Per USP<800> any HD API and any antineoplastic requiring HD manipulation must follow all containment requirements within the chapter. Eye protection and respiratory protection are required for spill management.
decitabine _f	IV Solution	X	X	X	X	X	X	X	X					X	X		X	X		X	X	X	X		Per USP<800> any HD API and any antineoplastic requiring HD manipulation must follow all containment requirements within the chapter. Eye protection and respiratory protection are required for spill management.
docetaxel _f	IV Solution	X	X	X	X	X	X	X	X					X	X		X	X		X	X	X	X		Per USP<800> any HD API and any antineoplastic requiring HD manipulation must follow all containment requirements within the chapter. Eye protection and respiratory protection are required for spill management.
doxorubicin _f	IV Solution	X	X	X	X	X	X	X	X					X	X		X	X		X	X	X	X		Per USP<800> any HD API and any antineoplastic requiring HD manipulation must follow all containment requirements within the chapter. Eye protection and respiratory protection are required for spill management.
epirubicin _f	IV Solution	X	X	X	X	X	X	X	X					X	X		X	X		X	X	X	X		Per USP<800> any HD API and any antineoplastic requiring HD manipulation must follow all containment requirements within the chapter. Eye protection and respiratory protection are required for spill management.
eribulin _f	IV Solution	X	X	X	X	X	X	X	X					X	X		X	X		X	X	X	X		Per USP<800> any HD API and any antineoplastic requiring HD manipulation must follow all containment requirements within the chapter. Eye protection and respiratory protection are required for spill management.
etoposide _f	IV Solution	X	X	X	X	X	X	X	X					X	X		X	X		X	X	X	X		Per USP<800> any HD API and any antineoplastic requiring HD manipulation must follow all containment requirements within the chapter. Eye protection and respiratory protection are required for spill management.
fludarabine _f	IV Solution	X	X	X	X	X	X	X	X					X	X		X	X		X	X	X	X		Per USP<800> any HD API and any antineoplastic requiring HD manipulation must follow all containment requirements within the chapter. Eye protection and respiratory protection are required for spill management.

[illegible]

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Hazardous Drug Assessment of Risk			
Hospital Name:	Pioneers Memorial Healthcare Dis	Risk Assessment Conducted By:	John P. Teague
City/State:	Brawley, California	Date Assessment Conducted:	4/18/2017



NIOSH Group 2:	Non-antineoplastic drugs that meet one or more of the NIOSH criteria for a hazardous drug (HD)
NOTE:	Regardless of NIOSH group, all HD active pharmaceutical ingredients (API) must follow all containment requirements listed in USP<800>. This requirement is taken into account in the below risk assessment.
Types of Exposure:	R-Receiving, D-Dispensing, C/M-Compounding/Manipulation, A-Administration, PC-Patient Care, S-Spills, T-Transport, W-Waste Disposal
Legend:	API (Active Pharmaceutical Ingredient); ADC (Automated Dispensing Cabinet); C-PEC (Containment- Primary Engineering Control); CSTD (Closed System Transfer Device); PPE (Personal Protective Equipment)
Risk of Exposure:	Severity (SEV) x Frequency of Occurrence (OCC) x Probability to Detect (DET) = Risk Priority Number (RPN) *If final RPN is: 1-13 Monitor and assess 14-60 Establish controls to minimize risk 61+ Immediate risk reduction strategies required

Initial Risk Assessment													Action Plan/Results												
NIOSH Group 2: Non-antineoplastic Drugs	Dosage Forms	Potential Type(s) of Exposure								Rating				Storage				Engineering Controls to Minimize Exposure			Personal Protective Equipment (PPE) by Type of Exposure				Action Plan (Document in Standard Operating Procedures)
		R	D	C/M	A	PC	S	T	W	SEV	OCC	DET	RPN	Neg. Pressure Ventilated Room	Segregated Area	With Other Inventory	ADC	C-PEC	CSTD	Other	Gloves	Gown	Eye Protection	Respiratory Protection	
azathioprine	IV Solution	X	X	X	X	X	X	X	X	3	2	3	18	X				X	X		X	X	X	X	Follow all containment requirements within the chapter per USP <800>. Eye protection and respiratory protection are required for spill management.
azathioprine	Oral Solid		X	X	X					3	1	3	9			X					X				No additional precautions required, wear gloves while handling. Purchase Unit Dose packaged.
carbamazepine	Oral Liquid		X	X	X		X			2	2	3	12			X					X				No additional precautions required, wear gloves while handling. Purchase Unit Dose packaged.
carbamazepine	Oral Solid		X	X	X					2	3	2	12			X					X				No additional precautions required, wear gloves while handling. Purchase Unit Dose packaged.
chloramphenicol	IV Solution	X	X	X	X	X	X	X	X	3	2	3	18	X				X	X		X	X	X	X	Follow all containment requirements within the chapter per USP <800>. Eye protection and respiratory protection are required for spill management.
cyclosporin	Oral Solid		X	X	X					3	5	3	45			X									No additional precautions required, wear gloves while handling. Purchase Unit Dose packaged.
dexrazoxane	IV Solution	X	X	X	X	X	X	X	X	3	1	4	12	X				X	X		X	X	X	X	Follow all containment requirements within the chapter per USP <800>. Eye protection and respiratory protection are required for spill management.
divalproex	Oral Solid		X	X	X					2	2	3	12			X	X				X				No additional precautions required, wear gloves while handling. Purchase Unit Dose packaged.
estradiol	Oral Solid		X	X	X					2	2	3	12			X					X				No additional precautions required, wear gloves while handling. Purchase Unit Dose packaged.
estradiol _r	Topical Drug				X	X				2	2	5	20			X					X				Wear gloves while administering estradiol topical to patient.
estrogens, conjugated _r	IV Solution	X	X	X	X	X	X	X	X	2	2	6	24			X					X				No additional precautions required following normal sterile compounding procedures.
estrogens, conjugated _r	Oral Solid		X	X	X					2	2	2	8			X	X				X				No additional precautions required, wear gloves while handling.
estrogens, conjugated _r	SC, IM Injection	X		X	X		X			2	2	2	8			X					X				No additional precautions required following normal sterile compounding procedures.
estrogens, conjugated _r	Topical Drug				X	X				2	2	6	24			X					X				Wear gloves while administering conjugated estrogen cream to patient.
ganciclovir _r	IV Solution	X	X	X	X	X	X	X	X	3	3	1	9	X				X	X		X	X	X	X	Follow all containment requirements within the chapter per USP <800>. Eye protection and respiratory protection are required for spill management.
leflunomide _r	Oral Solid		X	X	X					3	2	2	12			X					X				Wear gloves while repackaging into unit-dose containers.
medroxyprogesterone _r	Oral Solid		X	X	X					3	3	3	27			X					X				No additional precautions required, wear gloves while handling. Purchase Unit Dose packaged.
medroxyprogesterone _r	SC, IM Injection	X		X	X		X			3	2	3	18			X					X				No additional precautions required following normal sterile compounding procedures.
methimazole _r	Oral Solid		X	X	X					2	2	3	12			X					X				No additional precautions required, wear gloves while handling. Purchase Unit Dose packaged.
mycophenolate mofetil _r	Oral Solid		X	X	X					2	2	3	12			X					X				No additional precautions required, wear gloves while handling. Purchase Unit Dose packaged. Special Warning: Tablets should not be crushed and capsules should not be opened or crushed.
oxcarbazepine _r	Oral Solid		X	X	X					2	2	3	12			X					X				No additional precautions required, wear gloves while handling. Purchase Unit Dose packaged.
phenytoin _r	IV Solution	X	X	X	X	X	X	X	X	2	2	4	16			X	X				X				No additional precautions required following normal sterile compounding procedures.
phenytoin _r	Oral Liquid		X	X	X		X			2	4	6	48			X	X				X				Wear gloves while repackaging phenytoin suspension into unit-dose syringes.
phenytoin _r	Oral Solid		X	X	X					2	3	4	24			X	X				X				No additional precautions required, wear gloves while handling. Purchase Unit Dose packaged.

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propylthiouracil _r	Oral Solid		X	X	X					2	2	4	16			X					X				No additional precautions required, wear gloves while handling. Purchase Unit Dose packaged.
raloxifene _r	Oral Solid		X	X	X					2	2	4	16			X					X				No additional precautions required, wear gloves while handling. Purchase Unit Dose packaged.
risperidone _r	Oral Solid		X	X	X					2	2	4	16			X	X				X				No additional precautions required, wear gloves while handling. Purchase Unit Dose packaged.
sirolimus _r	Oral Liquid		X	X	X		X			2	2	4	16			X					X				No additional precautions required, wear gloves while handling.
spironolactone _r	Oral Solid		X	X	X					2	3	4	24			X	X				X				No additional precautions required, wear gloves while handling. Purchase Unit Dose packaged.
tacrolimus _r	Oral Solid		X	X	X					2	2	4	16			X					X				No additional precautions required, wear gloves while handling. Purchase Unit Dose packaged.
zidovudine _r	IV Solution	X	X	X	X	X	X	X	X	2	2	3	12			X					X				No additional precautions required following normal sterile compounding procedures.
zidovudine _r	Oral Solid		X	X	X					2	2	4	16			X	X				X				No additional precautions required, wear gloves while handling. Purchase Unit Dose packaged.

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Hazardous Drug Assessment of Risk			
Hospital Name:	Pioneers Memorial Healthcare Dis	Risk Assessment Conducted By:	John P. Teague
City/State:	Brawley, California	Date Assessment Conducted:	4/18/2017



NIOSH Group 3: Non-antineoplastic drugs that primarily have reproductive adverse effects
NOTE: Regardless of NIOSH group, all hazardous drugs (HD) active pharmaceutical ingredients (API) must follow all containment requirements listed in USP<800>. This requirement is taken into account in the below risk assessment.
Types of Exposure: R-Receiving, D-Dispensing, C/M-Compounding/Manipulation, A-Administration, PC-Patient Care, S-Spills, T-Transport, W-Waste Disposal
Legend: API (Active Pharmaceutical Ingredient); ADC (Automated Dispensing Cabinet); C-PEC (Containment- Primary Engineering Control); CSTD (Closed System Transfer Device); PPE (Personal Protective Equipment)
Risk of Exposure: Severity (SEV) x Frequency of Occurrence (OCC) x Probability to Detect (DET) = Risk Priority Number (RPN) *If final RPN is: 1-13 Monitor and assess 14-60 Establish controls to minimize risk 61+ Immediate risk reduction strategies required

Initial Risk Assessment														Action Plan/Results													
NIOSH Group 3: Reproductive Risk Only Drugs on the Hospital's List of Hazardous Drugs	Dosage Forms	Potential Type(s) of Exposure								Rating				Storage				Engineering Controls to Minimize Exposure			Personal Protective Equipment (PPE) by Type of Exposure				Action Plan (Document in Standard Operating Procedures)		
		R	D	C/M	A	PC	S	T	W	SEV	OCC	DET	RPN	Neg. Pressure Ventilated Room	Segregated Area With Other Inventory	ADC	C-PEC	CSTD	Other	Gloves	Gown	Eye Protection	Respiratory Protection				
clonazepam	Oral Solid		X	X	X					2	2	4	16			X	X				X				No additional precautions required, wear gloves while handling. Purchase Unit Dose packaged.		
colchicine	Oral Solid		X	X	X					2	2	4	16			X	X				X				No additional precautions required, wear gloves while handling.		
dinoprostone	Other		X	X	X					2	2	4	16			X	X				X				No additional precautions required, wear gloves while handling.		
dronedarone	Oral Solid		X	X	X					2	2	4	16			X					X				No additional precautions required, wear gloves while handling. Purchase Unit Dose packaged.		
dutasteride	Oral Solid		X	X	X											X	X				X				No additional precautions required, wear gloves while handling. Purchase Unit Dose packaged.		
ergonovine/methylegonovine	Oral Solid		X	X	X					2	3	4	24			X	X				X				No additional precautions required, wear gloves while handling.		
ergonovine/methylegonovine	SC, IM Injection	X		X	X		X			2	3	4	24			X	X				X				No additional precautions required, wear gloves while handling.		
finasteride	Oral Solid		X	X	X					2	3	4	24			X	X				X				No additional precautions required, wear gloves while handling. Purchase Unit Dose packaged.		
fluconazole	IV Solution	X	X	X	X	X	X	X	X	2	2	2	8			X	X				X				No additional precautions required following normal sterile compounding requirements.		
fluconazole _r	Oral Liquid		X	X	X		X			2	2	2	8			X					X				No additional precautions required, wear gloves while handling.		
fluconazole _r	Oral Solid		X	X	X					2	2	2	8			X	X				X				No additional precautions required, wear gloves while handling. Purchase Unit Dose packaged.		
misoprostal _r	Oral Solid		X	X	X					2	8	1	16			X	X	X			X	X	X	X	Follow all containment requirements of USP <800>. If unable to utilize C-PEC in Ventilated Engineering Control, manipulation such as cutting to unit dose performed in designated area with full PPE avoid exposure during pregnancy. Dermal exposure is minimal risk. Repeat exposure should be avoided during pregnancy.		
oxytocin _r	IV Solution	X	X	X	X	X	X	X	X	2	8	4	64			X	X				X				Dermal exposure is minimal risk. Repeat exposure should be avoided during pregnancy.		
oxytocin _r	SC, IM Injection	X		X	X		X			2	2	4	16			X	X				X				Dermal exposure is minimal risk. Repeat exposure should be avoided during pregnancy. Wear gloves while handling.		
pamidronate _r	IV Solution	X	X	X	X	X	X	X	X	2	2	2	8			X					X				No additional precautions required following normal sterile compounding procedures.		
paroxetine _r	Oral Solid		X	X	X					2	2	3	12			X	X				X				No additional precautions required, wear gloves while handling.		
telavancin _r	IV Solution	X	X	X	X	X	X	X	X	2	2	2	8			X					X				No additional precautions required following normal sterile compounding procedures.		
temazepam _r	Oral Solid		X	X	X					2	2	3	12			X					X				No additional precautions required, wear gloves while handling. Purchase Unit Dose packaged.		
topiramate _r	Oral Solid		X	X	X					2	2	3	12			X					X				No additional precautions required, wear gloves while handling. Purchase Unit Dose packaged.		
valproate _r	IV Solution	X	X	X	X	X	X	X	X	2	3	3	18			X	X				X				No additional precautions required following normal sterile compounding procedures.		
valproic acid _r	Oral Liquid		X	X	X		X			2	3	3	18			X	X				X				No additional precautions required, wear gloves while handling. Purchase Unit Dose packaged.		
valproic acid _r	Oral Solid		X	X	X					2	2	3	12			X	X				X				No additional precautions required, wear gloves while handling. Purchase Unit Dose packaged.		
voriconazole _r	IV Solution	X	X	X	X	X	X	X	X	2	2	2	8			X					X				No additional precautions required following normal sterile compounding procedures.		

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voriconazole _r	Oral Solid		X	X	X					2	2	3	12			X	X			X			No additional precautions required, wear gloves while handling. Purchase Unit Dose packaged.
warfarin _r	Oral Solid		X	X	X					2	2	3	12			X	X			X			No additional precautions required, wear gloves while handling. Purchase Unit Dose packaged.
ziprasidone _r	Oral Solid		X	X	X					2	2	3	12			X	X			X			No additional precautions required, wear gloves while handling. Purchase Unit Dose packaged.
ziprasidone _r	SC, IM Injection									2	2	2	8			X	X			X			No additional precautions required following normal sterile compounding procedures.
zoledronic acid _r	IV Solution	X	X	X	X	X	X	X	X	2	2	2	8			X				X			No additional precautions required following normal sterile compounding procedures.

Hazardous Drug List Exposure Avoidance Recommendations**Hospital Name:** *Pioneers Memorial Healthcare District***City/State:** *Brawley, California***Last Reviewed:** *4/18/2017*

This list is reviewed and updated annually and contains all medications classified as hazardous by NIOSH in use at Pioneers Memorial Healthcare District at the time of the last review date. Included below are the recommendations to mitigate the risk of exposure to hazardous drugs based on results from the annual risk assessment.

Hazardous drugs separated by NIOSH Group

Hazardous Drugs	Dosage Forms	Storage				Engineering Controls to Minimize Exposure			Personal Protective Equipment (PPE) by Type of Exposure				Containment Strategies / Work Practice Recommendations to Minimize Risk of Exposure
		Neg. Pressure Ventilated Room	Segregated Area	With Other Inventory	ADC	C-PEC	CSTD	Other	Gloves	Gown	Eye Protection	Respiratory Protection	
NIOSH Group 1: Antineoplastics													
anastrozole	Oral Solid			X					X				Decrease risk of contact by wearing gloves when handling anastrozole tablets or bottles containing anastrozole. Compounding must follow all of the containment requirements in USP <800> and hospital policy
azacitidine	IV Solution	X	X			X	X		X	X	X	X	Follow the containment requirements in USP<800> and hospital policy
azacitidine	SC, IM Injection	X	X			X	X		X	X	X	X	Follow the containment requirements in USP<800> and hospital policy
bendamustine	IV Solution	X	X			X	X		X	X	X	X	Follow the containment requirements in USP<800> and hospital policy

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bicalutamide	Oral Solid			X			X			Decrease risk of contact by wearing gloves when handling bicalutamide tablets or bottles containing bicalutamide. Compounding must follow all of the containment requirements in USP <800> Follow the containment requirements in USP<800> and hospital policy
bleomycin	IV Solution	X	X		X	X	X	X	X	
bortezomib	IV Solution	X	X		X	X	X	X	X	Follow the containment requirements in USP<800> and hospital policy
bortezomib	SC, IM Injection	X	X		X	X	X	X	X	Follow the containment requirements in USP<800> and hospital policy
cabazitaxel	IV Solution	X	X		X	X	X	X	X	Follow the containment requirements in USP<800> and hospital policy
carboplatin Γ	IV Solution	X	X		X	X	X	X	X	Follow the containment requirements in USP<800> and hospital policy
carfilzomib Γ	IV Solution	X	X		X	X	X	X	X	Follow the containment requirements in USP<800> and hospital policy
carmustine Γ	IV Solution	X	X		X	X	X	X	X	Follow the containment requirements in USP<800> and hospital policy
cisplatin Γ	IV Solution	X	X		X	X	X	X	X	Follow the containment requirements in USP<800> and hospital policy

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cyclophosphamide Γ	IV Solution	X	X	X	X	X	X	X	X	Follow the containment requirements in USP<800> and hospital policy
cytarabine Γ	IV Solution	X	X	X	X	X	X	X	X	Follow the containment requirements in USP<800> and hospital policy
dacarbazine Γ	IV Solution	X	X	X	X	X	X	X	X	Follow the containment requirements in USP<800> and hospital policy
decitabine Γ	IV Solution	X	X	X	X	X	X	X	X	Follow the containment requirements in USP<800> and hospital policy
docetaxel Γ	IV Solution	X	X	X	X	X	X	X	X	Follow the containment requirements in USP<800> and hospital policy
doxorubicin Γ	IV Solution	X	X	X	X	X	X	X	X	Follow the containment requirements in USP<800> and hospital policy
epirubicin Γ	IV Solution	X	X	X	X	X	X	X	X	Follow the containment requirements in USP<800> and hospital policy
eribulin Γ	IV Solution	X	X	X	X	X	X	X	X	Follow the containment requirements in USP<800> and hospital policy
etoposide Γ	IV Solution	X	X	X	X	X	X	X	X	Follow the containment requirements in USP<800> and hospital policy

REGULAR MEETING OF THE BOARD OF DIRECTORS - V. POLICIES/PROCEDURES/REVIEW OF OTHER ITEMS

fludarabine Γ	IV Solution	X	X	X	X	X	X	X	X	Follow the containment requirements in USP<800> and hospital policy
fluorouracil Γ	IV Solution	X	X	X	X	X	X	X	X	Follow the containment requirements in USP<800> and hospital policy
flutamide Γ	Oral Solid			X		X				Decrease risk of contact by wearing gloves when handling flutamide caps or bottles containing flutamide. Compounding must follow all of the containment requirements in USP<800> and hospital policy
fulvestrant Γ	SC, IM Injection	X	X	X	X	X	X	X	X	Follow the containment requirements in USP<800> and hospital policy
gemcitabine Γ	IV Solution	X	X	X	X	X	X	X	X	Follow the containment requirements in USP<800> and hospital policy
goserelin Γ	SC, IM Injection	X	X	X	X	X	X	X	X	Follow the containment requirements in USP<800> and hospital policy
hydroxyurea Γ	Oral Solid			X		X				Decrease risk of contact by wearing gloves when handling hydroxyurea tablets or bottles containing hydroxyurea. Compounding must follow all of the containment requirements in USP<800> and hospital policy
ifosfamide Γ	IV Solution	X	X	X	X	X	X	X	X	Follow the containment requirements in USP<800> and hospital policy
irinotecan Γ	IV Solution	X	X	X	X	X	X	X	X	Follow the containment requirements in USP<800> and hospital policy

REGULAR MEETING OF THE BOARD OF DIRECTORS - V. POLICIES/PROCEDURES/REVIEW OF OTHER ITEMS

irinotecan Γ	SC, IM Injection	X	X		X	X		X	X	X	X	Follow the containment requirements in USP<800> and hospital policy
leuprolide Γ	SC, IM Injection		X		X	X		X	X	X	X	Follow the containment requirements in USP<800> and hospital policy
megestrol Γ	Oral Liquid	X	X		X	X		X	X	X	X	Follow the containment requirements in USP<800> and hospital policy
megestrol Γ	Oral Solid			X				X				Decrease risk of contact by wearing gloves when handling megestrol tablets or bottles containing megestrol. Compounding must follow all of the containment requirements in USP<800>
methotrexate Γ	IV Solution	X	X		X	X		X	X	X	X	Follow the containment requirements in USP<800> and hospital policy
methotrexate Γ	Oral Solid			X				X				Decrease risk of contact by wearing gloves when handling methotrexate tablets or bottles containing methotrexate. Compounding must follow all of the containment requirements in USP<800>
methotrexate Γ	SC, IM Injection	X	X		X	X		X	X	X	X	Follow the containment requirements in USP<800> and hospital policy
mitomycin Γ	IV Solution	X	X		X	X		X	X	X	X	Follow the containment requirements in USP<800> and hospital policy
mitomycin Γ	SC, IM Injection	X	X		X	X		X	X	X	X	Follow the containment requirements in USP<800> and hospital policy

REGULAR MEETING OF THE BOARD OF DIRECTORS - V. POLICIES/PROCEDURES/REVIEW OF OTHER ITEMS

mitomycin 1	Solution for Irrigation	X	X		X	X		X	X	X	X	Follow the containment requirements in USP<800> and hospital policy
mitoxantrone 1	IV Solution	X	X		X	X		X	X	X	X	Follow the containment requirements in USP<800> and hospital policy
oxaliplatin 1	IV Solution	X	X		X	X		X	X	X	X	Follow the containment requirements in USP<800> and hospital policy
paclitaxel 1	IV Solution	X	X		X	X		X	X	X	X	Follow the containment requirements in USP<800> and hospital policy
pemetrexed 1	IV Solution	X	X		X	X		X	X	X	X	Follow the containment requirements in USP<800> and hospital policy
pertuzumab 1	IV Solution	X	X		X	X		X	X	X	X	Follow the containment requirements in USP<800> and hospital policy
tamoxifen 1	Oral Solid			X				X				No additional precautions required if delivered in unit-dose packaging to the point of administration.
temsirolimus 1	IV Solution	X	X		X	X		X	X	X	X	Follow the containment requirements in USP<800> and hospital policy
topotecan 1	IV Solution	X	X		X	X		X	X	X	X	Follow the containment requirements in USP<800> and hospital policy

REGULAR MEETING OF THE BOARD OF DIRECTORS - V. POLICIES/PROCEDURES/REVIEW OF OTHER ITEMS

vinblastine	IV Solution	X	X	X	X	X	X	X	X	Follow the containment requirements in USP<800> and hospital policy
vincristine	IV Solution	X	X	X	X	X	X	X	X	Follow the containment requirements in USP<800> and hospital policy
vinorelbine	IV Solution	X	X	X	X	X	X	X	X	Follow the containment requirements in USP<800> and hospital policy
<div> <div>NIOSH Group 2: Non-Antineoplastics</div> </div>										
azathioprine	IV Solution	X		X	X	X	X	X	X	Follow all containment requirements within the chapter per USP <800>. Eye protection and respiratory protection are required for spill management.
azathioprine	Oral Solid		X			X				No additional precautions required, wear gloves while handling. Purchase Unit Dose packaged.
carbamazepine	Oral Liquid		X			X				No additional precautions required, wear gloves while handling. Purchase Unit Dose packaged.
carbamazepine	Oral Solid		X			X				No additional precautions required, wear gloves while handling. Purchase Unit Dose packaged.
chloramphenicol	IV Solution	X		X	X	X	X	X	X	Follow all containment requirements within the chapter per USP <800>. Eye protection and respiratory protection are required for spill management.

REGULAR MEETING OF THE BOARD OF DIRECTORS - V. POLICIES/PROCEDURES/REVIEW OF OTHER ITEMS

cyclosporin	Oral Solid		X							No additional precautions required, wear gloves while handling. Purchase Unit Dose packaged.
dexrazoxane	IV Solution	X			X	X	X	X	X	Follow all containment requirements within the chapter per USP <800>. Eye protection and respiratory protection are required for spill management.
divalproex	Oral Solid		X	X			X			No additional precautions required, wear gloves while handling. Purchase Unit Dose packaged.
estradiol	Oral Solid		X				X			No additional precautions required, wear gloves while handling. Purchase Unit Dose packaged.
estradiol Γ	Topical Drug		X				X			Wear gloves while administering estradiol topical to patient.
estrogens, conjugated Γ	IV Solution		X				X			No additional precautions required following normal sterile compounding procedures.
estrogens, conjugated Γ	Oral Solid		X	X			X			No additional precautions required, wear gloves while handling.
estrogens, conjugated Γ	SC, IM Injection		X				X			No additional precautions required following normal sterile compounding procedures.
estrogens, conjugated Γ	Topical Drug		X				X			Wear gloves while administering conjugated estrogen cream to patient.

REGULAR MEETING OF THE BOARD OF DIRECTORS - V. POLICIES/PROCEDURES/REVIEW OF OTHER ITEMS

ganciclovir Γ	IV Solution	X		X	X	X	X	X	X	Follow all containment requirements within the chapter per USP <800>. Eye protection and respiratory protection are required for spill management.
leflunomide Γ	Oral Solid		X			X				Wear gloves while repackaging into unit-dose containers.
medroxyprogesterone Γ	Oral Solid		X			X				No additional precautions required, wear gloves while handling. Purchase Unit Dose packaged.
medroxyprogesterone Γ	SC, IM Injection		X			X				No additional precautions required following normal sterile compounding procedures.
methimazole Γ	Oral Solid		X			X				No additional precautions required, wear gloves while handling. Purchase Unit Dose packaged.
mycophenolate mofetil Γ	Oral Solid		X			X				No additional precautions required, wear gloves while handling. Purchase Unit Dose packaged. Special Warning: Tablets should not be crushed and capsules should not be opened or crushed.
oxcarbazepine Γ	Oral Solid		X			X				No additional precautions required, wear gloves while handling. Purchase Unit Dose packaged.
phenytoin Γ	IV Solution		X	X		X				No additional precautions required following normal sterile compounding procedures.
phenytoin Γ	Oral Liquid		X	X		X				Wear gloves while repackaging phenytoin suspension into unit-dose syringes.

REGULAR MEETING OF THE BOARD OF DIRECTORS - V. POLICIES/PROCEDURES/REVIEW OF OTHER ITEMS

phenytoin Γ	Oral Solid	X	X	X	No additional precautions required, wear gloves while handling. Purchase Unit Dose packaged.
propylthiouracil Γ	Oral Solid	X		X	No additional precautions required, wear gloves while handling. Purchase Unit Dose packaged.
raloxifene Γ	Oral Solid	X		X	No additional precautions required, wear gloves while handling. Purchase Unit Dose packaged.
risperidone Γ	Oral Solid	X	X	X	No additional precautions required, wear gloves while handling. Purchase Unit Dose packaged.
sirolimus Γ	Oral Liquid	X		X	No additional precautions required, wear gloves while handling.
spironolactone Γ	Oral Solid	X	X	X	No additional precautions required, wear gloves while handling. Purchase Unit Dose packaged.
tacrolimus Γ	Oral Solid	X		X	No additional precautions required, wear gloves while handling. Purchase Unit Dose packaged.
zidovudine Γ	IV Solution	X		X	No additional precautions required following normal sterile compounding procedures.
zidovudine Γ	Oral Solid	X	X	X	No additional precautions required, wear gloves while handling. Purchase Unit Dose packaged.

NIOSH Group 3:
Reproductive Risk Only

clonazepam	Oral Solid	X	X	X	No additional precautions required, wear gloves while handling. Purchase Unit Dose packaged.
colchicine	Oral Solid	X	X	X	No additional precautions required, wear gloves while handling.
dinoprostone	Other	X	X	X	No additional precautions required, wear gloves while handling.
dronedarone	Oral Solid	X		X	No additional precautions required, wear gloves while handling. Purchase Unit Dose packaged.
dutasteride	Oral Solid	X	X	X	No additional precautions required, wear gloves while handling. Purchase Unit Dose packaged.
ergonovine/methylergono vine	Oral Solid	X	X	X	No additional precautions required, wear gloves while handling.
ergonovine/methylergono vine	SC, IM Injection	X	X	X	No additional precautions required, wear gloves while handling.
finasteride	Oral Solid	X	X	X	No additional precautions required, wear gloves while handling. Purchase Unit Dose packaged.

REGULAR MEETING OF THE BOARD OF DIRECTORS - V. POLICIES/PROCEDURES/REVIEW OF OTHER ITEMS

fluconazole	IV Solution	X	X		X				No additional precautions required following normal sterile compounding requirements.
fluconazole _Γ	Oral Liquid	X			X				No additional precautions required, wear gloves while handling.
fluconazole _Γ	Oral Solid	X	X		X				No additional precautions required, wear gloves while handling. Purchase Unit Dose packaged.
misoprostal _Γ	Oral Solid	X	X	X	X	X	X	X	Follow all containment requirements of USP <800>. If unable to utilize C-PEC in Ventilated Engineering Control, manipulation such as cutting to unit dose performed in designated area with full BDF. Dermal exposure is minimal risk. Repeat exposure should be avoided during pregnancy.
oxytocin _Γ	IV Solution	X	X		X				Dermal exposure is minimal risk. Repeat exposure should be avoided during pregnancy. Wear gloves while handling.
oxytocin _Γ	SC, IM Injection	X	X		X				No additional precautions required following normal sterile compounding procedures.
pamidronate _Γ	IV Solution	X			X				No additional precautions required, wear gloves while handling.
paroxetine _Γ	Oral Solid	X	X		X				No additional precautions required following normal sterile compounding procedures.
telavancin _Γ	IV Solution	X			X				No additional precautions required following normal sterile compounding procedures.

REGULAR MEETING OF THE BOARD OF DIRECTORS - V. POLICIES/PROCEDURES/REVIEW OF OTHER ITEMS

temazepam Γ	Oral Solid	X		X	No additional precautions required, wear gloves while handling. Purchase Unit Dose packaged.
topiramate Γ	Oral Solid	X		X	No additional precautions required, wear gloves while handling. Purchase Unit Dose packaged.
valproate Γ	IV Solution	X	X	X	No additional precautions required following normal sterile compounding procedures.
valproic acid Γ	Oral Liquid	X	X	X	No additional precautions required, wear gloves while handling. Purchase Unit Dose packaged.
valproic acid Γ	Oral Solid	X	X	X	No additional precautions required, wear gloves while handling. Purchase Unit Dose packaged.
voriconazole Γ	IV Solution	X		X	No additional precautions required following normal sterile compounding procedures.
voriconazole Γ	Oral Solid	X	X	X	No additional precautions required, wear gloves while handling. Purchase Unit Dose packaged.
warfarin Γ	Oral Solid	X	X	X	No additional precautions required, wear gloves while handling. Purchase Unit Dose packaged.
ziprasidone Γ	Oral Solid	X	X	X	No additional precautions required, wear gloves while handling. Purchase Unit Dose packaged.

REGULAR MEETING OF THE BOARD OF DIRECTORS - V. POLICIES/PROCEDURES/REVIEW OF OTHER ITEMS

ziprasidone Γ	SC, IM Injection	X	X	X	No additional precautions required following normal sterile compounding procedures.
zoledronic acid Γ	IV Solution	X		X	No additional precautions required following normal sterile compounding procedures.

Hazardous Drug List

Hospital Name:	<i>Pioneers Memorial Healthcare District</i>
City/State:	<i>Brawley, California</i>
Last Reviewed:	<i>4/18/2017</i>

**Hazardous drugs and dosage formulations by NIOSH Group**

NIOSH Group 1: Antineoplastics	Dosage Formulation
anastrozole	Oral Solid
azacitidine	IV Solution
azacitidine	SC, IM Injection
bendamustine	IV Solution
bicalutamide	Oral Solid
bleomycin	IV Solution
bortezomib	IV Solution
bortezomib	SC, IM Injection
cabazitaxel	IV Solution
carboplatin Γ	IV Solution
carfilzomib Γ	IV Solution
carmustine Γ	IV Solution
cisplatin Γ	IV Solution
cyclophosphamide Γ	IV Solution
cytarabine Γ	IV Solution
dacarbazine Γ	IV Solution
decitabine Γ	IV Solution
docetaxel Γ	IV Solution
doxorubicin Γ	IV Solution
epirubicin Γ	IV Solution
eribulin Γ	IV Solution
etoposide Γ	IV Solution
fludarabine Γ	IV Solution
fluorouracil Γ	IV Solution
flutamide Γ	Oral Solid
fulvestrant Γ	SC, IM Injection
gemcitabine Γ	IV Solution
goserelin Γ	SC, IM Injection
hydroxyurea Γ	Oral Solid
ifosfamide Γ	IV Solution
irinotecan Γ	IV Solution
irinotecan Γ	SC, IM Injection
leuprolide Γ	SC, IM Injection
megestrol Γ	Oral Liquid
megestrol Γ	Oral Solid
methotrexate Γ	IV Solution
methotrexate Γ	Oral Solid
methotrexate Γ	SC, IM Injection
mitomycin Γ	IV Solution
mitomycin Γ	SC, IM Injection
mitomycin Γ	Solution for Irrigation
mitoxantrone Γ	IV Solution
oxaliplatin Γ	IV Solution

paclitaxel ƒ	IV Solution
pemetrexed ƒ	IV Solution
pertuzumab ƒ	IV Solution
tamoxifen ƒ	Oral Solid
temsirolimus ƒ	IV Solution
topotecan ƒ	IV Solution
vinblastine ƒ	IV Solution
vincristine ƒ	IV Solution
vinorelbine ƒ	IV Solution

NIOSH Group 2: Non-Antineoplastics	Dosage Formulation
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azathioprine	IV Solution
azathioprine	Oral Solid
carbamazepine	Oral Liquid
carbamazepine	Oral Solid
chloramphenicol	IV Solution
cyclosporin	Oral Solid
dexrazoxane	IV Solution
divalproex	Oral Solid
estradiol	Oral Solid
estradiol ƒ	Topical Drug
estrogens, conjugated ƒ	IV Solution
estrogens, conjugated ƒ	Oral Solid
estrogens, conjugated ƒ	SC, IM Injection
estrogens, conjugated ƒ	Topical Drug
ganciclovir ƒ	IV Solution
leflunomide ƒ	Oral Solid
medroxyprogesterone ƒ	Oral Solid
medroxyprogesterone ƒ	SC, IM Injection
methimazole ƒ	Oral Solid
mycophenolate mofetil ƒ	Oral Solid
oxcarbazepine ƒ	Oral Solid
phenytoin ƒ	IV Solution
phenytoin ƒ	Oral Liquid
phenytoin ƒ	Oral Solid
propylthiouracil ƒ	Oral Solid
raloxifene ƒ	Oral Solid
risperidone ƒ	Oral Solid
sirolimus ƒ	Oral Liquid
spironolactone ƒ	Oral Solid
tacrolimus ƒ	Oral Solid
zidovudine ƒ	IV Solution
zidovudine ƒ	Oral Solid

NIOSH Group 3: Reproductive Risk Only	Dosage Formulation
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clonazepam	Oral Solid
colchicine	Oral Solid
dinoprostone	Other
dronedarone	Oral Solid
dutasteride	Oral Solid
ergonovine/methylegonovine	Oral Solid
ergonovine/methylegonovine	SC, IM Injection
finasteride	Oral Solid

fluconazole	IV Solution
fluconazole ƒ	Oral Liquid
fluconazole ƒ	Oral Solid
misoprostal ƒ	Oral Solid
oxytocin ƒ	IV Solution
oxytocin ƒ	SC, IM Injection
pamidronate ƒ	IV Solution
paroxetine ƒ	Oral Solid
telavancin ƒ	IV Solution
temazepam ƒ	Oral Solid
topiramate ƒ	Oral Solid
valproate ƒ	IV Solution
valproic acid ƒ	Oral Liquid
valproic acid ƒ	Oral Solid
voriconazole ƒ	IV Solution
voriconazole ƒ	Oral Solid
warfarin ƒ	Oral Solid
ziprasidone ƒ	Oral Solid
ziprasidone ƒ	SC, IM Injection
zoledronic acid ƒ	IV Solution

Sterile Compounding: Cleaning, Disinfecting & Decontamination/Deactivation

Process	Purpose	Example Agents
Cleaning	Remove organic and inorganic material	<ul style="list-style-type: none"> • Quaternary Ammonium Compound • Peracetic Acid & Hydrogen Peroxide • Phenolic compounds
Disinfection	Destroy microorganisms	<ul style="list-style-type: none"> • Sterile Isopropyl Alcohol 70% • Sodium Hypochlorite above 0.5% (sterile)
Decontamination/ Deactivation	Remove Hazardous Drug (HD) residue/ render compound inert or inactive	<ul style="list-style-type: none"> • Sodium Hypochlorite solutions 0.5-2% • 80% 10mM Sodium Lauryl Sulfate (SLS) and 20% Isopropyl Alcohol • Peracetic Acid & Hydrogen Peroxide, • Hydrogen peroxide (various concentrations)

Specific Formulations (not intended to be a comprehensive list)

<i>Accel TB</i>	One-step surface cleaner & disinfectant	No sporicidal effect	http://www.contechealthcare.com/products/accel-tb/
<i>Peridox</i>	One-step surface cleaner & disinfectant	Sporicidal	http://www.contechealthcare.com/products/pharmacy/cleanroom/peridoxrtu-sporicidal-disinfectant-and-cleaner/
<i>TX6466 Bru-Clean TbC</i>	Requires rinsing with sterile water	No sporicidal effect	https://www.texwipe.com/products/disinfectants/bru-clean.aspx
<i>TX650 TexQ disinfectant and TX651 TexQ disinfectant</i>	One-step surface cleaner & disinfectant	No sporicidal effect	http://www.texwipe.com/store/?gclid=CJOh2cux4cwCFQQpaQodNysHJQ
<i>Pharma-Surface Guard</i>	Two-step process	No sporicidal effect	http://www.healthmark.ca/DATA/DOCUMENT/Pharma_Surface_Guard_Spec_Sheet[3].pdf
<i>Surface Safe (Safetec)</i>	Two-step process	No sporicidal effect	http://www.medtronic.com/content/dam/covidien/library/us/en/product/hazardous-drug-protection/H8228%20Surface%20Safe%20%20Step%20Applicator%20F.pdf

Standard Operating Procedure (SOPs) for Hazardous Drugs

HAZARD COMMUNICATION PROGRAM

<Refer to PMHD Hazard Communication Program>

- PMHD Hazardous Drug List (Attachment E) and PMHD Safe Handling of Hazardous Drugs Chart (Attachment F) to determine the status and requirements for individual drugs.
- All hazardous drugs will be labeled to reflect the nature of these agents:
 - Cytotoxic hazardous drugs will be identified with a special label which states:

**HAZARDOUS – DISPOSE OF PROPERLY
CYTOTOXIC**

- Non-cytotoxic hazardous drugs will be identified with a special label which states:

**HAZARDOUS – DISPOSE OF PROPERLY
NON-CYTOTOXIC**

OCCUPATIONAL SAFETY PROGRAM

- The consequences of occupational exposure to hazardous drugs are difficult to determine. There are no known values regarding the limits of safe exposure to these drugs and no single test or biological marker has been found to be a good indicator of exposure or a good predictor of adverse health effects. The risk of such exposure is most effectively reduced by strict adherence to PPE and best practice procedures.
- Staff who are concerned about the potential impact of any exposure to hazardous drugs on their personal health status should discuss their concerns with their family physician and appropriate Occupational Health, Safety and Wellness staff. All employees are encouraged to consult with and/or arrange regular medical examinations with their family physician as part of their general health and wellness plan.
- While there are no direct measurements to indicate total exposure to cytotoxic drugs, individual staff members may opt to follow selected surveillance components by their own means, which may include:
 - Reproductive and general health questionnaires by the individual's family physician completed at the time of hire and annually
 - Blood work, including complete blood count, liver function tests and urinalysis completed by the individual's family physician at the time of hire and annually
 - Physical examination by the individual's family physician at the time of hire and then annually as needed
 - Follow up by the individual's family physician for those workers who have shown health changes and/or have been exposed to hazardous drugs (e.g., through spills or during routine handling).
- In the event of a known or suspected pregnancy, or if staff are breast feeding or actively trying to conceive, then those who routinely prepare or administer hazardous drugs may wish to consult with their department manager and/or Occupational Health, Safety and Wellness staff to discuss work expectations and/or possible reassignment. Staff who

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continue these work rotations should not participate in higher risk tasks such as spill management.

DESIGNATION OF HD AREAS

- Signs designating the hazard are prominently displayed before the entrance to the HD handling areas.
- Access to the HD handling areas is restricted to authorized personnel.
- Designated areas are available for:
 - Receipt and unpacking
 - Storage of HDs
 - Non-sterile HD compounding
 - Sterile HD compounding

RECEIPT

- All hazardous drugs will be received in the Pharmacy Department.
- When received, cytotoxic drugs should have a hazard warning label or be clearly identified as CYTOTOXIC from the manufacturer and/or distributor and should be packaged in outer zip lock or sealed bags.
- Hazardous drugs requiring refrigeration should be refrigerated immediately upon receipt.
- Packages with visual signs of damage should be quarantined immediately. Notify supervisor or manager and institute spill management procedures if needed.

STORAGE

- Access to areas where hazardous drugs are stored is restricted to authorized staff.
- Cytotoxic drugs will be stored at or below eye level in leak- and break-proof bins intended to contain accidental leakage and reduce the chance of drugs falling on the floor.
- In pharmacy, parenteral dosage forms of cytotoxic drugs will be stored separately from other inventory in a negative pressure room to help prevent drug contamination and exposure to personnel. Refrigerated drugs shall be stored in a dedicated refrigerator in this area.
- On patient care areas, doses of cytotoxic drugs will be stored in dedicated chemotherapy preparation room, if available, or in secure medication preparation room. All doses will be stored at room temperature or in the fridge in a covered container with appropriate cautionary label.
- Non-cytotoxic drugs may be stored with other inventory and will contain auxiliary labeling. Oral tablets and capsules will be in unit dose packages.

COMPOUNDING HDS

- Follow established Medication Management and Pharmacy policies for preparation of all hazardous drugs.
- Consult the PMHD Hazardous Drug List (Attachment E) and PMHD Safe Handling of Hazardous Drugs Chart (Attachment F) to determine the status and requirements for individual drugs.

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- Sterile disposable equipment will be used in the preparation of injectable products to ensure product sterility and optimal protection for staff. If available, closed system transfer devices will be used.
- A sink and eyewash station will be available in areas where cytotoxic drugs are prepared.
- Whenever possible, staff with upper respiratory infections, conjunctivitis, cold sores or cutaneous infections should be excluded from preparing hazardous drugs.
- The pharmacy department will prepare all cytotoxic drugs in a Containment Aseptic Compounding Isolator (CACI) in a cleanroom which incorporates features and operational parameters designed to contain any potential hazard.
 - Doses prepared in IV infusion bags will have primary or secondary tubing sets attached and will be placed in a labeled and sealed outer amber bag prior to delivery. Primary infusion sets are primed with compatible IV fluid.
 - Syringe doses for IV and IM administration have a luer-lock cap attached. Syringe doses for subcutaneous administration will be dispensed with a safety glide needle attached. All syringes are packaged, in a labeled and sealed outer amber bag.
 - Intrathecal doses are placed in a self-seal and labeled pouch.
- Oral solid dosage forms of hazardous drugs (tablets, partial tablets and capsules) are manually repackaged in unit dose packaging, and not placed in automated packaging machines.
- Nursing should not split cytotoxic tablets or open capsules. Any manipulation of an oral hazardous drug which is likely to result in particle generation (opening capsules, splitting or crushing tablets, etc) will be performed by pharmacy in an appropriate location using dedicated equipment. Where possible, dosages should be adjusted to the nearest strength of intact dosage forms.
- Oral liquid formulations of cytotoxic drugs will be compounded or reconstituted in a CACI.
- If the patient is unable to swallow a solid dosage form consult the clinical pharmacist.
- Non-cytotoxic hazardous drugs may be prepared by nursing or pharmacy (see Attachment F).
- All hazardous drugs will be labeled to reflect the nature of these agents:
 - Cytotoxic hazardous drugs will be identified with a special label which states:

**HAZARDOUS – DISPOSE OF PROPERLY
CYTOTOXIC**

- Non-cytotoxic hazardous drugs will be identified with a special label which states:

**HAZARDOUS – DISPOSE OF PROPERLY
NON-CYTOTOXIC**

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USE AND MAINTENANCE OF PROPER ENGINEERING CONTROLS (E.G., C-PECS, C-SECS, AND CSTDS)

<See CSP Policy Attachment C: Standard Operating Procedure for Sterile Compounding>

- Chemotherapy/biotherapy compounding is performed in a vertical laminar airflow Biological Safety Cabinet (BSC), class II or III, or a Compounding Aseptic Containment Isolator (CACI) that provides an ISO Class 5 work environment and is intended for aseptic preparation and containment.
- Chemotherapy/biotherapy may not be prepared in a horizontal flow laminar airflow hood even if the blower is turned off.
- When closed-system vial transfer devices (CSTD) are used, they are used within the ISO Class 5 environment of a BSC or CACI.

BSC or CACI Operation

- The cabinet or isolator is operated with the blower turned on continuously, 24 hours a day, 7 days a week.
- If it is necessary to turn off the device, before turning it off the entire device is thoroughly cleaned with a detergent that will remove surface contamination and then rinsed. Once the device is clean, the blower may be turned off. The work access opening of the BSC and the high-efficiency particulate air (HEPA) exhaust area is covered with impermeable plastic and sealed with tape to prevent any residual contamination from escaping. The BSC must be sealed with plastic whenever it is moved or left inoperative for any period of time.
- Individuals certifying the BSC or CACI are informed of the hazardous nature of the drugs being prepared in the cabinet and should wear appropriate protective apparel.

Routine Cleaning

- BSCs and CACI are cleaned and disinfected regularly in accordance with the manufacturer's recommendations.
- The BSC or CACI is disinfected with sterile 70% alcohol before any aseptic operation begins.
- For routine cleanups of surfaces between decontamination, water (for injection or irrigation) is used with or without a small amount of cleaner.
- If the contamination is soluble only in alcohol, then sterile 70% isopropyl or ethyl alcohol is used in addition to the cleaner.

Decontamination

- BSCs and CACIs are decontaminated in accordance with the manufacturer's recommendations.
- The BSCs and CACIs are decontaminated weekly, whenever there is a spill or the device is moved or serviced, including for certification.
- Decontamination is performed only by properly trained personnel wearing personal protective equipment, including gown, chemo-safe gloves covered by disposable utility gloves, safety glasses or goggles, a hair covering, and a disposable respirator.

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- The blower is kept 'on' during the decontamination procedure, but the glass shield may be raised when necessary to reach all surfaces.
- Decontamination is performed from the top of the cabinet to the bottom, working from an area of least contamination to the area of highest contamination, by applying the cleaner, scrubbing, and rinsing with water for irrigation. Currently, no single reagent will deactivate all known hazardous drugs; therefore, decontamination is limited to removal of contamination from a non-disposable surface (cabinet) to a disposable surface (e.g., gauze or towels) by use of a good cleaning agent that removes chemicals from stainless steel.
- Only heavy non-shedding toweling or gauze is used. Spray cleaners should not be used.
- The HEPA filter must not become wet during cleaning.
- The cover over the HEPA filter is removed and cleaned within the cabinet.
- The work tray is lifted and leaned against the back wall of the device to allow cleaning of the undersurface side.
- The drain spillage trough area collects room dust and all spills, so it is the most heavily contaminated area and must be thoroughly cleaned.
- All contaminated equipment is contained in a plastic sealable cytotoxic waste disposal bag before removal from the hood or isolator and then transferred to the larger contaminate waste container outside the hood.
- After removing and disposing of all protective wear equipment, the outside of the device is wiped down with cleaner.
- The work area surfaces are disinfected with 70% sterile alcohol before performing aseptic operation.
- Hands are washed thoroughly after cleaning the hood.

Compounding

- Personal Protective Equipment (PPE) (i.e., protective chemo-safe gloves, hair covers, face masks, shoe covers, and gowns) is worn when compounding in a BSC or CACI and when using CSTD devices; and during all preparation activities such as opening drug packaging, handling vials, labeling containers, handling finished preparations, and disposing of waste.
- Prior to entering the buffer zone, products are decontaminated by wetting a non-shedding wipe with a neutralizing solution and wiping (not spritzing) the container to remove any surface contaminants. The container is then disinfected with sterile alcohol before entering the buffer zone.
- Chemotherapy infusions are spiked with the appropriate infusion set and primed in an ISO Class 5 environment prior to adding the medication to the bag.
- Negative pressure technique or chemo dispensing pins are used for chemotherapy agents manufactured in a vial.
- Prior to adding any component to the final container/base solution, a second authorized licensed healthcare practitioner (pharmacist) verifies and documents as an independent double check; the base solution and all additives including the drug, volume drawn into each syringe, diluents and actual drug containers. ***The syringe pullback method of verification is NOT used.***

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- Surface decontamination of the final product (and tubing) is performed before labeling and placing the product into the pass through or removing from the cabinet.
- Preparation labels are standardized to minimize the potential for adverse events and clearly include all of the required elements of a medication label including special instructions and warnings regarding handling and administration; order of sequence dependent regimens; adjustment of infusion times, rates or duration.
- The final preparation is placed in a plastic bag or other sealable container for transport before removal from the BSC or CACI.
- Waste containers are sealed and wiped before be removing from the BSC or CACI.

Spills in a BSC or Isolator

- Spills occurring in the BSC or isolator are cleaned up immediately.
- The spill kit is obtained if the volume of the spill exceeds 150 mL or the contents of one drug vial or ampule.
- Utility gloves are worn to remove broken glass in a Class II BSC. In an isolator, utility gloves are used over the fixed glove assembly. In a negative pressure isolator, utility gloves are fastened to the fixed glove with tape. Care must be taken not to damage the fixed glove assembly when handling broken glass.
- Thoroughly clean and decontaminate all surfaces of the BSC or isolator. Clean and decontaminate the drain spillage trough located under the Class II BSC or isolator, if so equipped.
- If the spill results in liquid being introduced onto the HEPA filter, or powdered aerosol contaminating the “clean side” of the HEPA filter, use of the BSC or isolator should be suspended until the equipment has been decontaminated and the HEPA filter replaced.
- If the HEPA filter is contaminated, the unit should be labeled and contained. BSCs are sealed in plastic until the filter can be changed and disposed of properly by trained personnel wearing appropriate protective equipment.

HAND HYGIENE AND USE OF PPE BASED ON ACTIVITY (E.G., RECEIPT, TRANSPORT, COMPOUNDING, ADMINISTRATION, SPILL, AND DISPOSAL)

- It is important to recognize that exposure requires contact with the hazardous drug or contaminated material. Most of the protective measures provided by PPE involve maintaining some form of barrier between the worker and the hazardous drug or contaminated material.
- PPE use is based on drug classification and task being performed (PMHD Safe Handling of Hazardous Drugs Chart [Attachment F]) and PMHD Hazardous Drugs List (Attachment E).
- Staff are required to wear PPE in accordance with the written policies.
- New employees will be required to demonstrate competence in the use of relevant PPE. Training must include fit testing for N95 masks if appropriate.
- PPE should be disposable wherever possible. Understand the proper use and limitations of any selected PPE to ensure that it functions properly.

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- Ensure that all PPE fits correctly and is constructed of materials that are appropriate for the specific task and risk of hazardous drug exposure. Use care when putting on and removing all items to prevent damage to PPE and to reduce the spread of contamination.
- PPE must be used when preparing or administering cytotoxic drugs, handling waste, or cleaning up spills.
- PPE must not be worn outside the areas where hazardous drugs are stored, prepared or administered.
- PPE should be single use and disposed of according to hazardous drug and contaminated waste procedures

Personal Protective Equipment (PPE)

Gloves

- Chemotherapy gloves meet the American Society for Testing and Materials (ASTM) standard D6978.
- Chemotherapy gloves are powder free.
- Gloves are inspected for holes or defects prior to use.
- When used for sterile compounding, the outer glove is sterile.
- Gloves are changed every 30 minutes (unless otherwise specified in writing by the manufacturer), and when torn, punctured, or contaminated.
- Hands are washed with soap and water after glove removal.
- **Gloves are worn when handling HDs including those that are not antineoplastic and those with reproductive risk only.**
- Double gloves are worn:
 - When handling shipping containers/cartons and drug vials, and final preparations
 - During compounding
 - During administration
 - While handling hazardous waste
 - While handling patient bodily fluids when the patient has been treated with a HD
 - During transport of HDs
 - During cleaning procedures, including spill clean up
- Inner gloves are placed under the cuff of the gown, outer gloves donned to cover the cuff of the gown.
- After compounding, outer gloves are removed and placed in the containment bag inside the C-PEC.
- Inside a compounding aseptic isolator, the gauntlet and glove are deactivated, decontaminated, cleaned and sterilized after compounding.
- The clean inner glove should be used to surface decontaminate the final product, label, and place the final product into the pass through.

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Gowns

- Gowns are disposable and resistant to permeability of HDs. Selection is based on the types of HDs used.
- Gowns close in the back; have long sleeves, and elastic or knit cuffs.
- Gowns do not have seams or closures that increase the permeability of HDs.
- Gowns are changed per the manufacturer's written specifications, or in the absence of such, every 2 to 3 hours or after a spill or splash.
- Gowns are worn only in HD handling areas.
- Gowns are worn during compounding, HD administration, when handling waste from a recently HD treated patient, and during cleaning procedures (including spill cleanup).
- Hands are washed after removal and disposal of a used gown.

Head, Hair, Sleeve and Shoe Covers

- Covers are only worn in areas where HDs are handled.
- When compounding HDs, a second set of shoe covers is donned before entering the C-SEC and doffed when exiting.
- Disposable sleeve covers are optional. If worn, better protection is provided by those made of coated materials.

Eye and Face Protection

- An elastomeric mask with a multi-gas cartridge and P-100 filter **should be** worn while unpacking HDs that are not sealed in plastic until the integrity of the packaging has been assessed and determined to be intact.
- A fit-tested NIOSH-certified N95 or more protective respirator is sufficient to protect against airborne particles. N95 respirators offer no protection against gases and vapors and little protection against direct liquid splashes (see the Centers for Disease Control and Prevention's (CDC's) Respirator Trusted-Source Information).
- A full face-piece chemical cartridge type respirator or powered air-purifying respirator (PAPR) **should be** worn when:
 - There is a risk of respiratory exposure including HD spills that cannot be contained with a spill kit.
 - When deactivating, decontaminating, and cleaning under the work surface of a C-PEC.
 - When there is known or suspected exposure to powders or vapors.

Disposal of Used PPE

- PPE worn when handling HDs is considered contaminated with, at minimum, trace quantities of HDs.
- PPE is placed in an appropriate waste container and further disposed of per local, state, and federal regulations.
- PPE worn during compounding is disposed of in the proper waste container *before* leaving the C-SEC.

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- Chemotherapy gloves and sleeve covers (if used) worn during compounding are carefully removed and *discarded immediately* into a waste container approved for trace contaminated waste *inside* the C-PEC or contained in a sealable bag for discarding outside the C-PEC.

DEACTIVATION, DECONTAMINATION, CLEANING, AND DISINFECTION

<See Policy Compounding Sterile Preparations for site specific SOPs for specific cleaning procedures to include agents used, dilutions, frequency, and documentation requirements>

Cleaning Step	Purpose	Agents	Documentation Frequency
Deactivation	Render compound inert/inactive	EPA-registered oxidizers (peroxide formulations, sodium hypochlorite) **PeridoxRTU**	<ul style="list-style-type: none"> ✓ <u>Daily</u> ✓ Between compounding different HD's ✓ Anytime a spill occurs ✓ Before & After certification ✓ Anytime voluntary interruption occurs ✓ If Ventilation tool is moved
Decontamination	Remove HD residue	Sterile alcohol, sterile water, peroxide, sodium hypochlorite **PeridoxRTU**	<ul style="list-style-type: none"> ✓ <u>Daily</u> ✓ Between compounding different HD's ✓ Anytime a spill occurs ✓ Before & After certification ✓ Anytime voluntary interruption occurs ✓ If Ventilation tool is moved
Cleaning	Remove organic & inorganic material	Germicidal detergent & sterile water **PeridoxRTU** (sporicidal effect after 3-min contact time)	<ul style="list-style-type: none"> ✓ <u>Daily</u> work surfaces & floors ✓ <u>Weekly</u> exterior surfaces,

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			walls, floors, ceilings & shelves
Disinfection	Destroy Microorganisms	Sterile alcohol or other EPA-registered disinfectant **Sterile IPA**	✓ Daily work surfaces/ante areas & floors ✓ Beginning & End of Shift ✓ Before any aseptic operation begins

Activity	
Daily HD BA	CACI: DA → GD → sIPA
	Empty Trash
	Horizontal Surfaces
	Floor
Weekly HD BA (+ daily)	Ceiling
	Walls/Doors/Handles
	All surfaces furniture, trash bins, outside PECs
	Storage bins

GD: germicidal detergent sIPA: sterile 70% isopropyl alcohol DA: decontamination agent
HD: hazardous drug BA: buffer area

DISPENSING

- HDs that do not require any further manipulation, other than counting or repackaging of final dosage forms, may be prepared for dispensing without any further requirements for containment unless required by the manufacturer or if visual indicators of HD exposure hazards are present (e.g., HD dust or leakage).
- Counting or repackaging of HDs must be done carefully. Clean equipment should be dedicated for use with HDs and should be decontaminated after every use. Tablet and capsule forms of antineoplastic HDs must not be placed in automated counting or packaging machines, which subject them to stress and may create powdered contaminants.

TRANSPORT

- Parenteral and liquid dosage forms of cytotoxic drugs will be transported by pharmacy staff using a container, cart or other device with raised sides and/or other features to ensure safe transport and to minimize exposure, contain leakage and spills. Containers must be clearly labelled as containing hazardous drugs.
- Cytotoxic drugs will be delivered to patient care area by pharmacy staff, or may be picked up by care area staff who are knowledgeable about safe transport procedures.

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- Parenteral or liquid dosage forms of cytotoxic drugs will not be transported in pneumatic tubes.
- All staff involved in the transportation of hazardous drugs should have quick and reasonable access to a spill kit and be trained in methods to handle hazardous drug spills.
- Transportation outside the entity, hazardous drugs must be packaged appropriately to ensure proper containment and maintenance of temperature requirements, and must meet all requirements as outlined by the Transportation policy.

<See Policy Transportation of Pharmaceutical Agents Off-Campus; CLN-02991>

ADMINISTERING

<Refer to PMHD Chemotherapy Safety Policy>

- HDs must be administered safely using protective medical devices and techniques (See Attachment F). Examples of protective medical devices include needleless and closed systems. Examples of protective techniques include spiking or priming of IV tubing with a non-HD solution in a C-PEC and crushing tablets in a plastic pouch.
- Appropriate PPE must be worn when administering HDs. After use, PPE must be removed and disposed of in a waste container approved for trace-contaminated HD waste at the site of drug administration. Equipment (such as tubing and needles) and packaging materials must be disposed of properly, such as in HD waste containers, after administration.
- CSTDs must be used for administration of antineoplastic HDs when the dosage form allows. Techniques and ancillary devices that minimize the risk posed by open systems must be used when administering HDs through certain routes. Administration into certain organs or body cavities (e.g., the bladder, eye, peritoneal cavity, or chest cavity) often requires equipment for which locking connections may not be readily available or possible.
- Healthcare personnel should avoid manipulating HDs such as crushing tablets or opening capsules if possible. Liquid formulations are preferred if solid oral dosage forms are not appropriate for the patient. If HD dosage forms do require manipulation such as crushing tablet(s) or opening capsule(s) for a single dose, personnel must don appropriate PPE and use a plastic pouch to contain any dust or particles generated.

ENVIRONMENTAL MONITORING (E.G., WIPE SAMPLING)

- Environmental sampling to detect uncontained hazardous drugs is performed routinely; initially as a benchmark and at least every 6 months or more often as needed to verify containment. Surface wipe sampling includes:
 - Working area of the BSCs and CACIs
 - Areas adjacent to the BSCs and CACIs, including the floor directly under the work area
 - Counter tops where finished products are placed
 - Patient administration areas

DISPOSAL

Trace Chemotherapy Waste

Gloves, gowns, wipes and other paraphernalia associated with routine handling, preparation, and administering of chemotherapy are considered trace waste unless they are notably

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contaminated. These items can be placed into a nationally recognized “yellow” chemotherapy waste container.

Hazardous Chemotherapy Waste

P-listed U-listed are all managed as hazardous RCRA waste and are not discarded in the “yellow” chemotherapy bucket containers.

Combination hazardous chemotherapy waste and medical wastes (IV therapy with bag and tubing still intact) need to be handled as a hazardous waste and not medical waste.

Spills and decontamination materials are considered hazardous waste.

Overt contamination and the cleaning of biological safety cabinet or isolator is considered hazardous and not discarded in the “yellow” containers.

Bulk Chemotherapy Waste

Bulk chemotherapy waste is managed as RCRA regulated hazardous waste and is discarded in an RCRA containment container.

SPILL CONTROL

<See Policy Chemotherapy Safety; CLN-02987>

Spill Kit LOCATION

- **#2 Kits located in Pharmacy’s Hazardous Drug Compounding Room**
- **#1 Kit located in:**
 - **The Cancer Institute at Pioneers**
 - **Emergency Department**
 - **Radiology Department for Interventional Radiology procedures**
 - **Medical Surgical Department**

Spill Kit

- Kits contain enough supplies to manage a spill up to 1000mL.
- PPE contained in the kit consists of two pair of gloves, one pair being a heavy utility glove to wear as the outer glove, disposable, non-permeable coveralls or gown, shoe covers, and a face shield or respirator.
- The kit also contains:
 - Absorbent, plastic back sheets or spill pads
 - Disposable toweling
 - A minimum of 2 sealable, thick plastic hazardous waste disposal bags pre-labeled with a warning label
 - A disposable scoop for glass collection
 - A puncture resistant container for glass fragments

Spill Clean up

- Assess the size and scope and call for trained help if necessary

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- Spills larger than 2 kits (2000 mL) may require external help
- Signs are posted to limit access to the spill area
- Gather the spill kit and respirator and don PPE
- After donning PPE, remove broken glass fragments
- Absorb liquid spills with spill pads. Absorb powder spills with damp disposable pads or toweling.
- Clean the spill from the lesser to greater area of contamination
- Rinse the area with water, then detergent, sodium hypochlorite, and neutralizer
- Rinse the area several times and place all materials into waste containers.
- Prior to removal of inner gloves, place all PPE in HD waste container and seal
- Remove inner gloves and contain in a small sealable bag for disposal as hazardous waste
- Wash with soap and water
- Once complete, contact housekeeping to perform a final cleaning
- If the spill occurs inside a BSC or isolator and is introduced into the clean side of the HEPA filter, use of the BSC or isolator should be suspended until the equipment is decontaminated and the HEPA filter is replaced.
- All spill materials are disposed of as hazardous waste.
- An event report is filed and includes:
 - Circumstances of the spill
 - Management of the spill
- Personnel potentially exposed during the spill or spill cleanup are immediately evaluated.
- Non-employees who may have been exposed may require referral to emergency services for initial evaluation.

Cleanup of Large Spills (Larger than 5 mL)

- When a large spill occurs, the area is isolated and aerosol generation avoided. For spills larger than 5 mL, liquid spread is limited by gently covering with absorbent sheets or spill-control pads or pillows. If a powder is involved, damp cloths or towels are used. Specific individuals are trained to clean up large spills.
- Protective apparel, including respirators, are used as with small spills when there is any suspicion of airborne powder or that an aerosol has been or will be generated. The volatility of the drug is assessed in selecting the type of respiratory protection.
- Chemical inactivation is avoided in this setting. All contaminated surfaces are thoroughly cleaned three times with detergent and water. All contaminated absorbent sheets and other materials are placed in the hazardous waste disposal bag.

MEDICAL SURVEILLANCE

- Baseline and after HD exposure
- Assess

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- Labs
- Medical history
- Work history (previous hazardous drug exposure)
- Estimated amount of HD handling
- Symptoms that arise post handling of HDs

Pioneers Memorial Healthcare District Hazardous Drug List

Cytotoxic			Non-Cytotoxic
High Risk: injectable		Medium Risk: tablets, capsules, oral liquids, topical preparations	Low Risk
azaCITIDine azathioprine bendamustine bleomycin bortezomib cabazitaxel CARBOplatin carfilzomib carmustine chloramphenicol CISplatin cyclophosphamide cytarabine dacarbazine decitabine dexrazoxane DOCEtaxel DOXOrubicin epirubicin eribulin etoposide	fludarabine fluorouracil fulvestrant ganciclovir gemcitabine goserelin Ifosfamide irinotecan leuprolide methotrexate mitoMYcin mitoXANtrone oxaliplatin PACLitaxel PEMEtrexed pertuzumab temsirolimus topotecan vinBLASTine vinCRISTine vinorelbine	azathioprine hydroxyurea methotrexate	anastrozole bicalutamide carbamazepine clonazepam colchicine cycloSPORIN dinoprostone divalproex dronedarone dutasteride ergonovine/methylergonovine estradiol estrogens, conjugated finasteride fluconazole flutamide isotretinoin leflunomide leuprolide medroxyprogesterone megestrol methimazole misoprostol mycophenolate oxcarbazepine oxytocin pamidronate paroxetine

			phenytoin propylthiouracil raloxifene risperidone sirolimus spironolactone tacrolimus tamoxifen telavancin temazepam topiramate valproate valproic acid voriconazole warfarin zidovudine ziprasidone zoledronic acid
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1. The following groups of products are not listed on the PMHD Cytotoxic and Non-Cytotoxic Hazardous Drug list, but require handling precautions:
 - Salts, pegylated and liposomal medications: only the parent compound is listed. All derivatives of a hazardous medication must be handled the same as the parent compound.
 - Combination products containing one or more hazardous medications shall be handled as hazardous medications (e.g. Arthrotec® which contains misoprostol and diclofenac).
 - Radioactive pharmaceuticals: nuclear medicine has policies and procedure for safe handling of radioactive pharmaceuticals. These products are generally not handled by pharmacy.
 - Chemicals / raw powders; see the Material Safety Data Sheet (MSDS) for safe handling precautions.

Acknowledgement: This list is adapted from the National Institute for Occupational Safety and Health (NIOSH) List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings 2016.

Pioneers Memorial Healthcare District Safe Handling of Hazardous Drugs Chart

Precautions	CYTOTOXIC: High Risk		CYTOTOXIC: Medium Risk	Non-CYTOTOXIC: Low Risk		
	Injectable	Compromised ^a Medium Risk oral dosage form	Intact oral dosage form	Injectable	Intact oral dosage form	Compromised ^a dosage form
DOSE PREPARATION:						
Prepared by	Pharmacy	Pharmacy	Pharmacy	Nursing	Pharmacy	Pharmacy
Preparation area	BSC or CACI	BSC or CACI	Designated packaging area	Med room using aseptic technique	Designated packaging area	BSC or CACI
PPE for staff preparing the dose	Double Chemo gloves (outer must be sterile), Gowns, Head/Hair Covers & Double Shoe covers	Double Chemo gloves, Gowns, Head/Hair Covers & Double Shoe covers	Single Chemo gloves	Single Chemo Gloves, mask (if aerosolization possible)	Single Chemo Gloves	Pharmacy: Double Chemo gloves, Gowns, Head/Hair Cover (if not done in control device), face shield (if not done in control device), N-95 mask (if not done in control device) Nursing: Double Chemo Gloves ^c
Label and eMAR comment	Hazardous Drug: Cytotoxic	Hazardous Drug: Cytotoxic	Hazardous Drug: Cytotoxic	Hazardous Drug: Non-Cytotoxic	Hazardous Drug: Non-Cytotoxic Do not open or crush	Hazardous Drug: Non-Cytotoxic (± Do not open or crush)
DELIVERY AND STORAGE:						
Packaging requirements	Labeled dose in a sealed bag or intrathecal pouch	Solid: labeled sealed package	Single tablet or capsule in labeled sealed package	Single dose vial or ampoule	Single tablet or capsule in labeled sealed package	Partial tablet in labeled sealed package
		Liquid: labeled single dose syringe or multidose Rx bottle in sealed outer bag				Labeled Rx bottle (liquid) [multidose]
Transport	Delivered by pharmacy.	Solid: no special precautions Liquid: Do not use pneumatic tube	No special precautions	No special precautions	No special precautions	Solid: no special precautions Liquid: do not use pneumatic tube
Storage on patient care area	Labeled cytotoxic container in designated ‘chemo’ prep room or med room	Designated ‘chemo’ prep room (if available) or labeled cytotoxic container in med room	Designated ‘chemo’ prep room (if available) or in med room	In Pyxis machine or patient’s unit dose bin in med room	In Pyxis machine or patient’s unit dose bin in med room	In Pyxis machine, patient unit dose bin or fridge in med room
ADMINISTRATION:						
Administration precautions	Double Chemo gloves, gown & face shield	Double Chemo gloves (gown, face shield if splash likely)	Single Chemo gloves	Single Chemo Gloves	Single Chemo Gloves ^c	Single Chemo Gloves ^c (gown, face shield if splash likely)
DISPOSAL:						
Contaminated material (infusion bag, syringes, tubing, drape cloths, etc)	Double Chemo gloves, gown & face shield	Double Chemo gloves (gown, face shield if splash likely)	Single Chemo gloves	Single Chemo Gloves	Single Chemo Gloves ^c	Single Chemo Gloves ^c
	Puncture resistant containers identified with Cytotoxic hazard symbol			Approved pharmaceutical waste container		
Patient excreta	Chemo gloves (gown, face shield if splash likely)			As per Routine Precautions		
	Toilet (urine, feces, emesis), puncture resistant container with Cytotoxic hazard symbol (disposable items), or non-permeable laundry bag (non-disposable items)			Toilet (urine, feces, emesis) or approved pharmaceutical waste container.		
SPILL MANAGEMENT:						
High Risk drug spill (MINOR) – USE SPILL KIT	Double Chemo gloves ^b , gown,N-95 mask, face shield	Double Chemo gloves ^b , gown, N-95 mask	Double Chemo gloves ^b (±gown, N-95 mask)	NA	NA	NA
High Risk (injectable) drug spill (MAJOR)	Initiate CODE ORANGE			NA	NA	NA

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REGULAR MEETING OF THE BOARD OF DIRECTORS - V. POLICIES/PROCEDURES/REVIEW OF OTHER ITEMS

Low Risk drug spill(± Spill Kit)		Single Chemo Gloves (± gown, N-95 mask)	Single Chemo Gloves	Single Chemo Gloves (± gown, N-95 mask)
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a. Compromised dosage form: any solid dosage form (tablet, capsule) that is changed in any way such as splitting or crushing a tablet, opening a capsule, making a suspension. All liquids, topical & inhalation preparations (including commercially prepared products) are considered a 'compromised' dosage form.

b. Outer gloves must be nitrile or other chemotherapy resistant gloves.

c. Caregivers should avoid contact with skin and mucous membranes. Gloves should be worn if contact is anticipated.

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 controls
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 otherwise 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 spit up‡	No	N/A
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 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, Intramuscular 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	Non	No	Yes, BSC or CACI; recommend CSTD
	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
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

Formulation	Activity	Double chemotherapy gloves	Protective gown	Eye/face protection	Respiratory protection	Ventilated engineering controls
Powder/solution for Inhalation/aerosol treatment	Compounding	Yes	Yes	Yes, if not done in control device	Yes, if not done in control device	Yes, BSC or CACI

Formulation	Activity	Double chemo-therapy gloves	Protective gown	Eye/face protection	Respiratory protection	Ventilated engineering controls
	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

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].

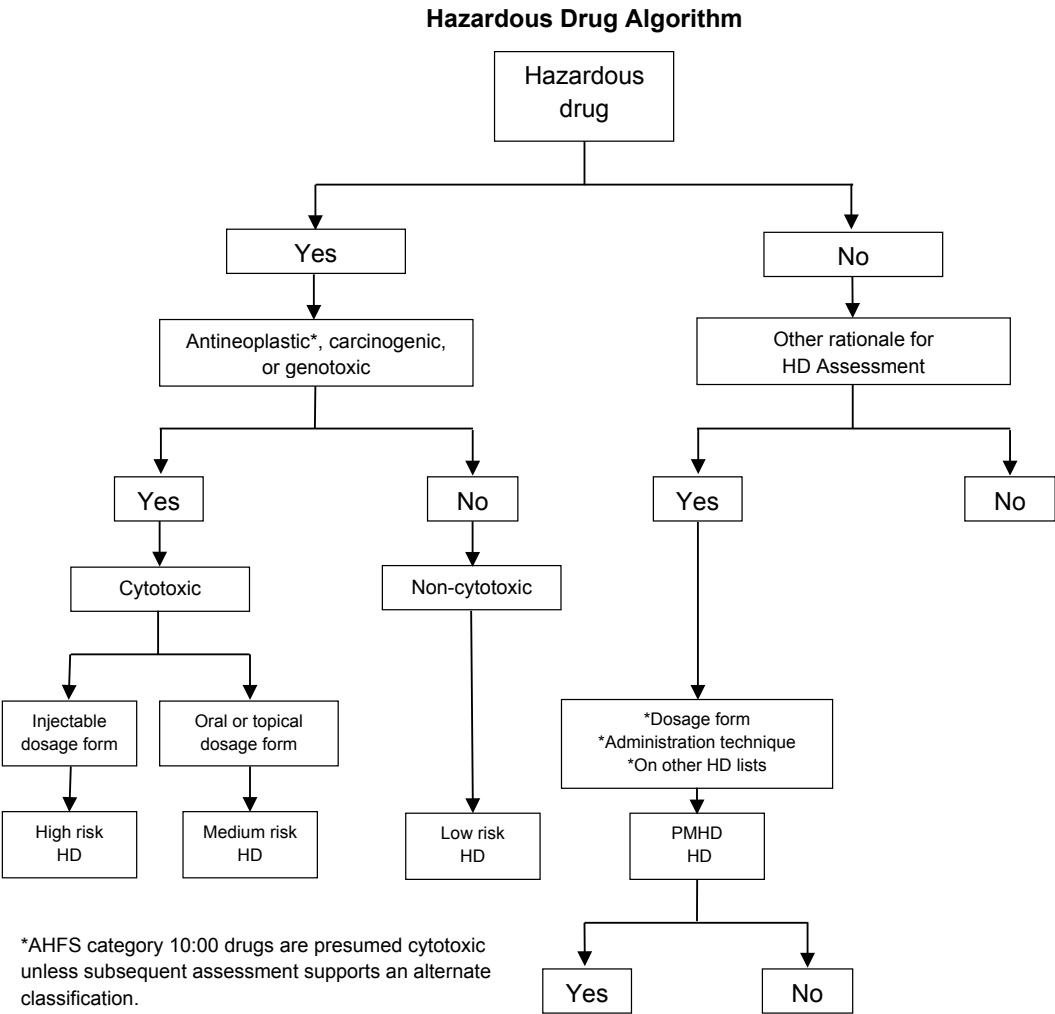
†For nonsterile preparations, a ventilated engineering control such as a fume hood or Class I BSC or a HEPA-filtered enclosure (such as a powder hood) is sufficient if the control device exhaust is HEPA filtered or appropriately exhausted to the outside of the building. It is recommended that these activities 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.

Identification & Classification of Hazardous Drugs – Hazardous Drug Algorithm



Pioneers Memorial Healthcare District

Title: Per Diem Program		Policy No. HRD-00040
		Page 1 of 2
Current Author: Charity Dale		Effective: 7/1/2007
Latest Review/Revision Date: 11/2/2023		Manual: HR / Compensation

Collaborating Departments: Nursing Admin; Administration		Keywords: per diem		
Approval Route: List all required approval				
MARCC 1/16/2024	PSQC	Other:		
Clinical Service _____	MSQC	MEC	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 The Per Diem Program is defined for new and/or existing staff (if approved by department director and based on departments needs) to provide qualified intermittent staff for various positions, and to allow staff to take part in a flexible work schedule.
- 1.2 Per-diem employees fall within a special classification of employees who are paid higher hourly wages than would otherwise be available. These employees receive higher wages in lieu of employer-sponsored benefits that can be waived under state and federal laws.

2.0 Scope: District-Wide**3.0 Definitions:**

- 3.1 BLS – Basic Life Support
- 3.2 ACLS – Advanced Cardiac Life Support
- 3.3 PALS – Pediatric Advanced Life Support
- 3.4 NALS – Neonatal Advanced Life Support
- 3.5 NRP – Neonatal Resuscitation Program

4.0 Policy:

- 4.1 The Per Diem Program is a program by which staff are called upon on an as-needed basis to supplement staffing
- 4.2 Orientation
 - 4.2.1 General orientation must occur prior to beginning Clinical (Unit) Orientation
 - 4.2.2 If an effort to accommodate the various needs of Per Diem staff and recognize the operational needs of the District, 2 Per Diem classes have been developed. The various options are based upon a clinical and non-clinical employee and have different requirements and pay options associated with the class.
- 4.3 Required Experience/Licensure/Certification for Per Diem Nursing Staff
 - 4.3.1 Current California licensure
 - 4.3.2 Current BLS, ACLS, PALS, NALS, NRP, if required by unit
 - 4.3.3 Unit certification or education requirements met, if applicable.
- 4.4 Per Diem One Non-Clinical / Clinical Non-Nursing– 5% Differential added to base rate.
 - 4.4.1 Work a minimum of 2 shifts per pay period.

Pioneers Memorial Healthcare District

Title: Per Diem Program		Policy No. HRD-00040
		Page 2 of 2
Current Author: Charity Dale		Effective: 7/1/2007
Latest Review/Revision Date: 11/2/2023		Manual: HR / Compensation

4.4.2 Work 2 weekend shifts in 2 pay periods.

4.4.3 Work two holidays per year.

4.5 Per Diem Two Clinical – 17.5 % in addition to base rate

4.5.1 At least 2 years' experience in their discipline

4.5.2 Able to float to two or more units.

4.5.3 Work a minimum of 2 shifts per pay period.

4.5.4 Work 2 weekend shifts in 2 pay periods.

4.5.5 Work two holidays per year.

5.0 Procedure:

5.1 All available Per Diem positions must be posted online

5.1.1 Exception: During periods of staffing shortage, directors may offer per diem positions to eligible staff members who are otherwise unable to work regular, full-time positions.

5.2 Fulltime or Part time employees who change their status to Per Diem, will not be allowed to revert their status back to a full or part time for a period of 90 days.

5.3 If an employee changes from regular full or part time status to a per-diem status, the employee shall be treated as terminated as of the date of such change for purposes of reconciling his benefit status ie. PTO payout, medical, dental and vision and COBRA eligibility. Such employee shall be paid those vested benefits, if any, that are payable on termination of full or part time employment status.

5.4 All Per Diem Employees must sign and return the Per Diem Agreement

5.5 Per Diem employees who do not work the number and type of shifts required may be adjusted down and their differentials adjusted accordingly to be paid at their base rate of pay.

5.6 Per Diem Employees who are not scheduled and who do not work for 90 days will be terminated as of the 90th day after their last shift worked.

6.0 References: Not applicable

7.0 Attachment List:

7.1 Attachment A - Per Diem Agreement

8.0 Summary of Revisions:

8.1 Per Diem and requirements adjusted in 1.2 and 4.2.2

8.2 Added 4.4, 4.5, 5.2, 5.3



PER DIEM AGREEMENT

I have reviewed the Per Diem Policy HRD-00040 and understand my scheduling availability and obligations as outlined in the policy.

Please check one below:

_____ Per Diem One: No differential

- Work and/or scheduled a minimum of three shifts in 60 days

_____ Per Diem Two: 10% in addition to base rate

- Work and/or scheduled a minimum of four shifts in 60 days
- Have at least 2 years' experience

_____ (Nursing Only) Per Diem Three: 15% in addition to base rate

- At least 2 years' experience
- Able to float to two or more units* (_____ and _____)
- Work a minimum of 48 hours in four weeks
- Work 24 hours on weekend shift in four weeks
- Work two holidays per year

_____ (Nursing Only) Per Diem Four – 20% in addition to base rate

- At least 2 years' experience
- Able to float to three or more units* (_____, _____, and _____)
- Work a minimum of 72 hours in three weeks
- Work 24 hours on weekend shift in four weeks
- Must work 3 holidays per year, one of which must be a major holiday

Signature of Employee

Date

Signature of Department Director

Date

***Must have required certifications to work designated departments**

Copy of Policy to Employee

REPORT DATE	MONTHLY STATUS REPORT	PREPARED BY
Date: March 20 th , 2024	PMHD Human Resources Report	Charity Dale, Chief Human Resources Officer

LABOR SUMMARY	
NEW HIRE	24
TERMINATIONS	VOLUNTARY- 9 INVOLUNTARY- 2
HOSPITAL AND CLINIC TOTAL HEADCOUNT	894
PIONEERS SKILLED NURSING TOTAL HEAD COUNT	128
PIONEERS MEMORIAL HEALTHCARE DISTRICT TOTAL HEADCOUNT	1022

NEW HIRE		TERMINATIONS	
DEPT	#	DEPT	# VOL/INV
NURSING	11	NURSING	8 - VOLUNTARY
CLINICAL PROFESSIONAL	0	CLINICAL PROFESSIONAL	0
ALLIED HEALTH	3	ALLIED HEALTH	2
PT. SERVICES	1-NO SHOW 1-RESCINED	PT. SERVICES	1-VOLUNTARY
SUPPORT SERVICES	2-(ONE NO SHOW)	SUPPORT SERVICES	2- INVOLUNTARY
CLINICS	1	CLINICS	2 VOLUNTARY
SKILLED NURSING	3	SKILLED NURSING	6 VOLUNTARY

2024 PMHD HR PROJECTS

PROJECT	PERCENT COMPLETE	NOTES
ADP WORKFORCE NOW IMPLEMENTATION	90%	We are set to go live on 4/1/2024.
ADP BENEFIT CARRIER FEED BUILDOUT	60%	We have all the foundation work ready for the go live feed on 4/1/2024
BENEFIT RENEWAL PROCESS	50%	Senior leaders are working with Gallagher on this year's renewal.
REVAMP OF NEW HIRE ORIENTATION	75%	With the addition of the training and development manager, we will be revamping our new hire orientation to be a 4-day process. Day 1 and 2 will be offered to all PMHD employees, day 3 and 4 will encompass the clinical new hire orientation.
FULL AUDIT OF SKILLED NURSING FACILITY	50%	We are doing a full HR audit to ensure all employees files are complaint and survey ready
DNV SURVEY PREPAREDNESS	50%	We are working through the last DNV survey findings. We are addressing each item to ensure proper documentation is placed in each clinical employee's file.
PI PROJECT- REVIEWING ALL HR POLICIES	40%	Our HR PI project consists of reviewing all HR policies. Our goal is to review 10 policies per month until all policies have been reviewed.

FEBRUARY BENEFIT PARTICIPANTS

PLAN	# ACTIVE PARTICIPANTS
457B	530
401A	757

MEDICAL	643
DENTAL	274
VISION	278
STD	197
LTD	820
LIFE	820
CRITICAL ILLNESS	334

FEBRUARY LEAVE OF ABSENCE

LEAVE	# EMPLOYEES
FMLA/ CFRA	22
INTERMITTENT FMLA	14
PERSONAL LEAVE	7
BONDING	8
WORKMENS COMP	8
MILITARY LEAVE	1
COVID	1
Covid/ W/C	3
SICK LEAVE LESS THAN 2 WEEKS	10

FEBRUARY VOLUNTEERS/ STUDENTS

PROGRAM	# STUDENTS/ VOLUNTEERS
CRNA	2
PHYSICIAN ASSISTANT	2
CNA – CERTIFIED NURSES AIDE	20
RN- REGISTERED NURSE STUDENT	103
VOLUNTEERS	1 pending clearance
TOTAL VOLUNTEERS/ STUDENTS	53

FEBRUARY RECRUITMENT ACTIVITIES

DEPARTMENT	# OF OPEN POSITIONS
TRAVLERS	L&D 8- 7 DAYSHIFT- MS -3 2 DAYSHFIT 1 NIGHT'S TOTAL 11
NURSING	29
CLINICAL NON -NURSING	18
CLINICAL PROFESSIONAL	1
ALLIED HEALTH	3
PT. SERVICES	6
SUPPORT SERVICES	0
CLINICS	5

SKILLED NURSING FACILITY

10

FEBRUARY POLICIES FOR REVIEW

POLICY NAME	POLICY #	ACTION	STATUS
CLASSIFICATION OF EMPLOYEES	HRD-00077	SENT FOR APPROVAL	
DRESS AND APPEARANCE GUIDELINES	HRD-00005	UNDER REVIEW	
EMPLOYMENT OF RELATIVES	HRD-00070	UNDER REVIEW	
EMPLOYMENT VERIFICATION	HRD-00069	NO REVISION NEEDED	COMPLETED
FAMILY AND MEDICAL LEAVE FMLA/CFRA	HRD-00016	REVISED	COMPLETED
HARASSMENT, DISCRIMINATION AND RETALIATION PREVENTION	HRD-00018	NO REVISIONS NEEDED	COMPLETED
HOLIDAY BONUS/SUPPLEMENTAL PAY	ADM-00200	REVISED	COMPLETED
JOB POSTINGS / HIRING EMPLOYMENT	HRD-00065	NO REVISION NEEDED	COMPLETED
REPORTING TIME PAY	HRD-00046	UNDER REVIEW	
RN SEASONAL LEAVE PROGRAM	HRD-00128	RETIRED	COMPLETED
STANDARDS OF CONDUCT	HRD-00021	UNDER REVIEW	

2024 PIONEERS ACTIVITIES COMMITTEE

EVENT	MONTH OF EVENT
Employee Recognition Banquet	7/2024
50/50 raffle – Daycare outside toys fundraiser	4/2024
Monthly employee recognition program	5/2024

FEBRUARY EMPLOYEE HEALTH

We had 35 employee COVID illnesses in January (19 in December, 25 in November, 24 in October). 25 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 70 active ee's; reminder letters sent to ee's in December. Reminder discusses at Safety Committee in February. Flu vaccine continues to be offered and encouraged for all healthcare workers. 71% of employees have participated in our flu program (59% of our employees have received flu vaccination; 11.5% have declined flu vaccine; 29.5% have not participated). Reminder emails were sent out during January.

Workers' Compensation Summary

19 employee injuries were reported in January. 5 injuries from acute care, 14 injuries from SNF. Twelve COVID Illness, three sharp injuries, one wrist sprain, one foot sprain, one shoulder sprain, one slip and fall. 15 of the injuries resulted in work comp claims to BETA; three injuries received first aid care; one injury required no medical care/reported for tracking purposes.

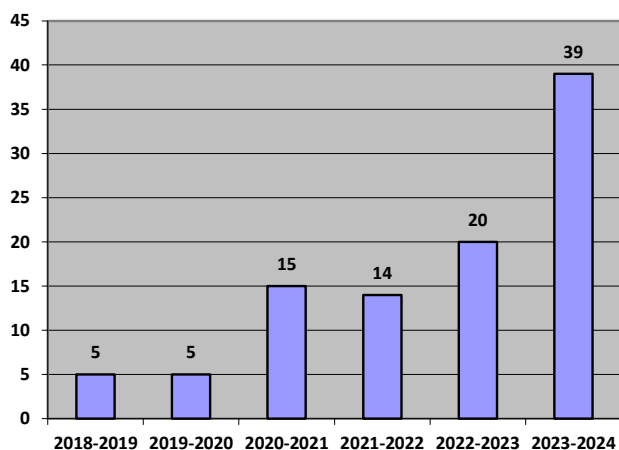


Workers' Compensation Scorecard

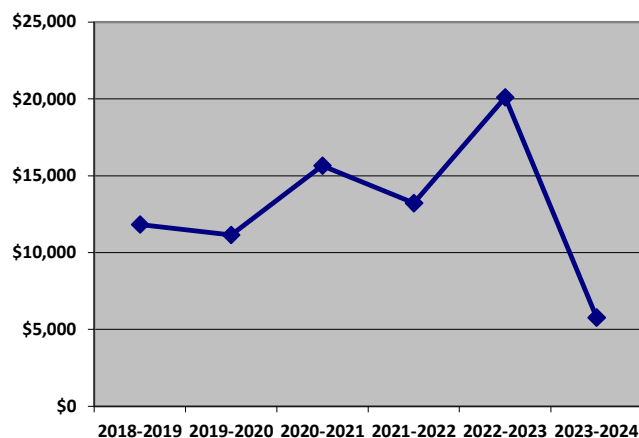
February 2024

Pioneers Memorial Healthcare District

Open Claims by Fiscal Year



Avg Cost Per Claim



Claim Activity by Month

Current Fiscal Year

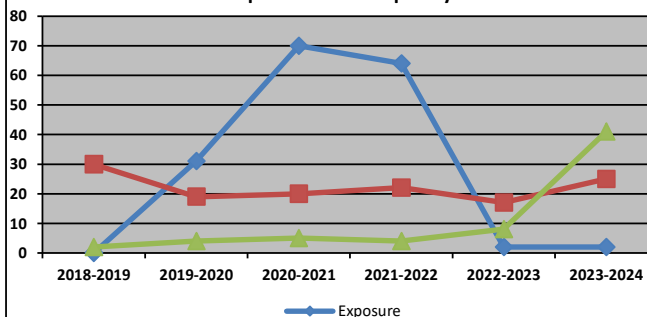
Month	2023-2024		Last 5 Years
	Count	Closed	
Jul	15	9	3
Aug	7	6	6
Sep	12	12	5
Oct	13	5	10
Nov	13	7	11
Dec	13	7	8
Jan	17	7	8
Feb	3	1	11
Mar	-	-	-
Apr	-	-	-
May	-	-	-
Jun	-	-	-
Total 2023-2024	93	54	62

Cause of Injury by Claim Type

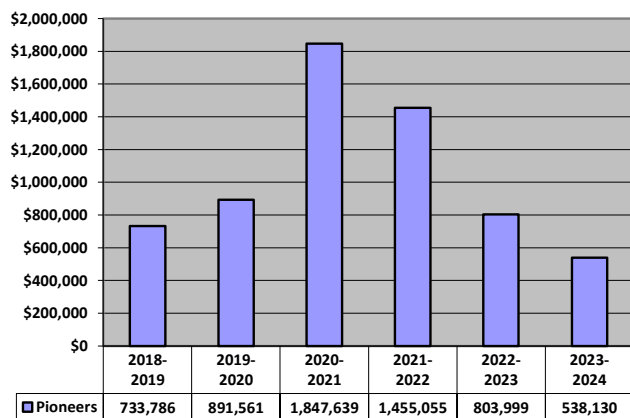
Dating Back to Fiscal Year 2018-2019

	Indem	Medical
Strain or Injury By	23.2%	36.3%
Fall, Slip or Trip Injury	8.7%	22.6%
Strain or Injury By	23.2%	36.3%
Struck or Injured By	2.4%	5.6%
Exposure	44.6%	0.0%
All Other	-2.1%	-0.8%

Top 3 Causes - Frequency



Incurred Losses by Year



Ex Mod History

